

UNI  
BASEL

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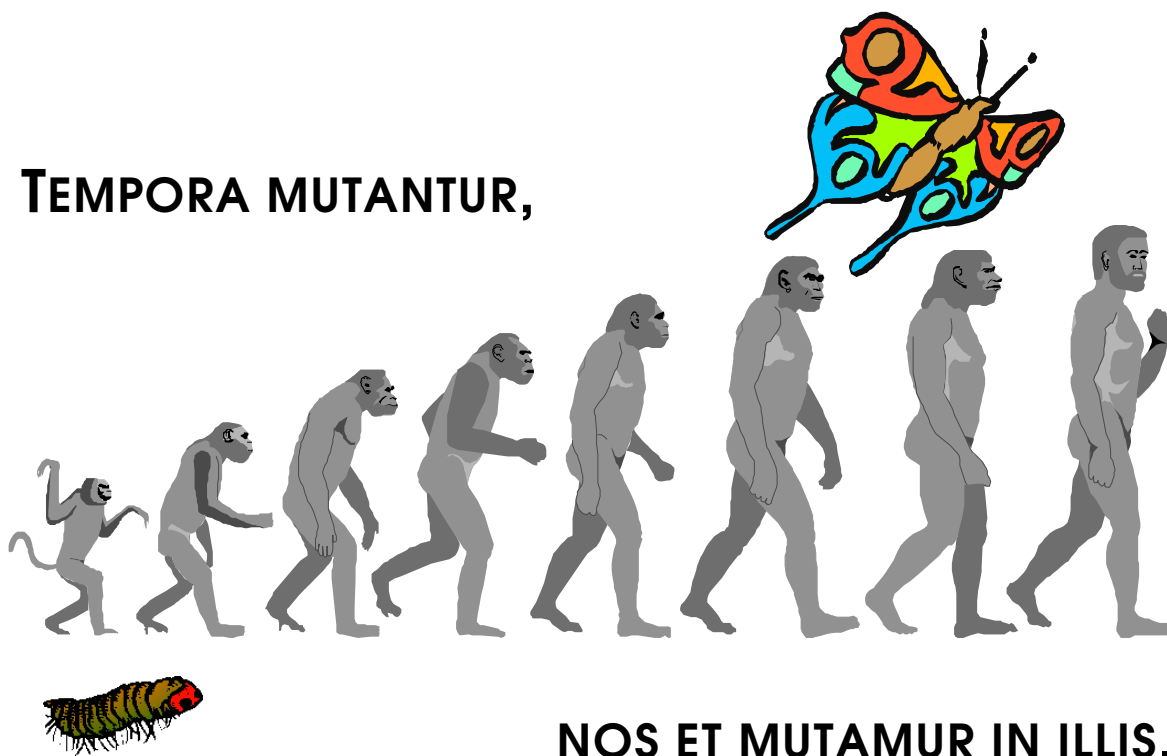
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## INSTITUTE OF PHARMACEUTICAL TECHNOLOGY UNIVERSITY OF BASEL

INSTITUTE FOR INNOVATION IN INDUSTRIAL PHARMACY, IFIIP  
CENTER FOR INNOVATION IN COMPUTER AIDED PHARMACEUTICS, CINCAP LLC

**TEMPORA MUTANTUR,**



**NOS ET MUTAMUR IN ILLIS.**

INSTITUTE OF PHARMA TECHNOLOGY,  
SCHOOL OF LIFE SCIENCES, UNIVERSITY OF APPLIED SCIENCE

**INSTITUTE OF PHARMACEUTICAL TECHNOLOGY  
UNIVERSITY OF BASEL**



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# PRESENTATION OF THE INSTITUTE

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## A. Organisation

The Institute of Pharmaceutical Technology (Head: H. Leuenberger) is part of the Department of Pharmaceutical Sciences of the University of Basel. The Department of Pharmaceutical Sciences of the University of Basel [Uni BS] has formed, together with the Institute of Pharmaceutics of the Federal Institute of Technology Zürich [ETHZ] the Center of Pharmaceutical Sciences of Uni BS and ETHZ. The first contract of this collaboration dates back to 1994 and was signed by Prof. Dr. H.R. Striebel, minister of education of the Basel government and Prof. Dr. J. Nüesch, president of the ETH Zürich. The cooperation was started by Prof. Dr. G. Folkers and Prof. Dr. H. Leuenberger. The concept of this partnership (see D.2.1) may be revised in future.

## B. Location/Space

Basel and its neighbourhood is the home of the world famous pharmaceutical companies Novartis Pharma AG, F. Hoffmann-La Roche AG and of pharmaceutical small and medium sized enterprises (SMEs) as well as of the equipment manufacturer Glatt. This pharma cluster, i.e. Pharma Hub in Basel provides an excellent environment for research and teaching in pharmaceutical sciences. Recently an increasing number of start-up and spin-off companies have been founded and a special platform “Bio Valley” was formed to stimulate the cooperation and foundation of companies in the area of biotechnology and pharmaceutical sciences.

The Institute of Pharmaceutical Technology is located on the second floor of the Pharmacenter of the University of Basel. Due to its research and teaching focus, the Institute of Pharmaceutical Technology requires sufficient lab space to accommodate large-size dosage form manufacturing and processing equipment. The necessary space was provided in the Pharmacenter and the external Industrial Pharmacy Laboratory (IPL) at the Mülhauserstrasse 49/51. A large part of the space is dedicated to the practical training of undergraduates (bachelor courses) and the master courses (which are in development).

## C. Mission

- Excellent Teaching and Research in Pharmaceutical Technology concentrating on the application of basic physical and physical-chemical principles to dosage form (or concept) design and performance evaluation affecting drug delivery.
- Contributing to the mechanistic understanding of drug formulation, processing and delivery phenomena.



- Providing students with the fundamental skills for following a career in academia, in industry or in related fields such as hospital and community pharmacy or government organizations, based on a Master of Science in pharmacy respectively MSc in Pharmaceutical Sciences (in development) or PhD degree in Pharmaceutical Sciences (for industry, academia, hospital) or a Federal Diploma as a Pharmacist (for hospital and community pharmacies). Already in 2003 the curriculum of a BSc in Pharmaceutical Sciences was adopted.
- Pharmacists have excellent job-opportunities in the pharmaceutical industry (see the web page of the Swiss Society of Industrial Pharmacists [www.gsia.ch](http://www.gsia.ch)), in hospital and community pharmacies.
- MAXIM of the Institute of Pharmaceutical Technology: “Science fascinates us as the key for Technologies changing the world” (freely adapted from Isaac Asimov).

## D. Teaching

### *D. 1. Undergraduate Teaching (Bachelor/Master students)*

For the preparation of the master theses (21 weeks) the following courses, including practical laboratory training work, are offered:

- Liquid-sterile Dosage Forms
- Semi-solid Dosage Forms
- Solid Dosage Forms
- The Seminar „Pharmaceutical Technology” complements the contents of the courses mentioned. In addition, the seminar is designed for the training of the presentation skills.

Within the following years, it is planned to update the courses taking into account new learning technologies and to have the theoretical courses available in German, English and Russian language. The Institute of Pharmaceutical Technology is a member of GPEN [Global Pharmaceutical Education Network; <http://gpen.pharmchem.ku.edu>].

### *D. 2. Graduate and Postgraduate Teaching*

#### D.2.1 Graduate study program in cooperation with the Center of Pharmaceutical Sciences, Basel – Zürich.

The PhD students can enrol for the graduate study program of the Pharmazentrum Basel-Zürich in order to obtain credit points necessary to complete the PhD-study.

The program consists of an introductory course with the topic for Drug Discovery and Development and seminars given by eminent speakers usually on Wednesday during the semesters in the area of Drug Discovery and Development ([www.pharmazentrum.ch](http://www.pharmazentrum.ch) → Graduate Study Program).

#### D.2.2 Co-operation with the TTC (Technology Training Center), Binzen

The Glatt Group has established a special Technology Training Center [TTC] at the Binzen Facility, Germany.

Binzen is located close to Lörrach and can be reached easily on highway from Basel in ca. 20 minutes. The Institute of Pharmaceutical Technology has a close co-operation with Klaus Eichler, head of the TTC.

The program of TTC is available at the following Web Site: <http://www.ttc-binzen.de>.

In case, that the courses are not overbooked a limited number of PhD students can participate at the individual courses. The participation at these courses is counted as part of postgraduate education in Pharmaceutical Technology.



### *D. 3. New Learning and Teaching Technologies*

#### *Co-operation with MUCTR, Moscow, Russia/Development of Curriculum*

Since 2001 the Institute of Pharmaceutical Technology (IPT), University of Basel and the Mendeleyev University of Chemical Technology of Russia (MUCTR) have established an institutional partnership, which is supported by the Swiss National Science Foundation (SNF) in the framework of the SCOPES (Scientific CoOperation Programme between Eastern Europe and Switzerland) project 7IP 062613.

The results of this collaboration are new teaching technologies, introduced at MUCTR and IPT. They are the multimedia lectures in pharmaceutical technology, which are held now in parallel at Basel University and MUCTR. The educational web portal "Pharmacy online" was awarded with a medal at the 4<sup>th</sup> Moscow International Salon of Innovations. These multimedia lectures are extremely popular and helpful to the students at MUCTR, because they can compensate to a certain extent the lack of equipment in the practical courses. However, multimedia lectures can never replace hands on training and therefore the continuation of the collaboration is ongoing. In this respect SNF decided in 2005 to give a continuous support for this cooperation through the grant IB 74 BO - 110911 "New concepts in training industrial pharmacists and pharmaceutical engineers to be developed and implemented at the Russian-Swiss scientific and educational centre in MUCTR". This cooperation has lead to the formation of the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies (RSSC, see [www.rs-pharmcenter.ru](http://www.rs-pharmcenter.ru)). Dr. Charles Kleiber, State Secretary for Education and Research of the Swiss Federation, declared this joint lab - in a meeting at Bavois, April 5, 2006 - as a model to be copied. It is planned that this Russian-Swiss Center will receive lab and office space on the first floor of a new research building (under construction) in Tushino, the high-tech park of MUCTR in Moscow (see: [www.rs-pharmcenter.ru](http://www.rs-pharmcenter.ru) )



## E. Research

### E. 1. Introductory remarks

Our research in pharmaceutical technology concerns the design and the preparation of dosage forms for a safe transport of the active substance (drug-load) to its site of action, i.e., the precise amount of drug should be delivered at the right time at the right site in order to perform its optimal therapeutic effect (with minimal side effects)! The design, the development and the manufacture of dosage forms are often declared in industry as the core activity or core business of industrial pharmacists since today most of them work in this area. Due to its complexity, the design of drug formulations is so far mainly based on empirical knowledge often simply using the “trial and error” approach. Thus, there is a need for action. Solid dosage forms represent the majority of prescribed medications, presently and most likely also in the future. Solid dosage formulations are however based on the technology of powders which is still not in a state of maturity. Research in the field of dosage form design, being products with a high added value, should therefore be rewarding.

### E. 2. Research Focus/Objectives

Our ambitious objective is to develop a **rigorous scientific framework for the design of formulations** and for drug processing using solid dosage forms as typical model formulations. The ultimate goal is not only to have a mechanistic understanding of formulations and processes but also to develop first principles. These topics fit ideally the goals of FDA for a drug quality system for the 21<sup>st</sup> century and FDA's PAT initiative ([www.fda.gov/cder/OPS/PAT.htm](http://www.fda.gov/cder/OPS/PAT.htm)).

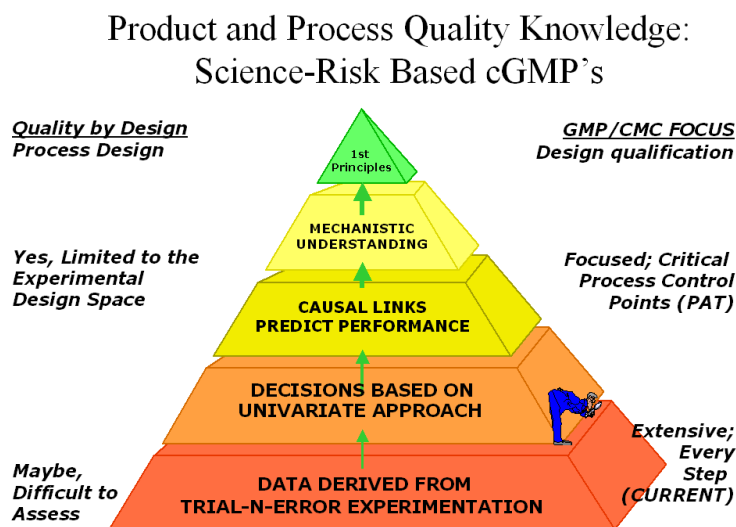


Figure 1 / E. 2 - Science Pyramid  
(Courtesy A. Hussain, former deputy head CDER/FDA )

This focus leads to an expertise in powder technology, which is a prerequisite for a safe scale-up and for the design of novel drug delivery systems such as particles to be inhaled, i.e. for pulmonary administration. For this reason it is important to explore innovative process technologies taking into account the **opportunities of nanoscience** and nanotechnology in order to solve present problems of novel drugs such as poor water solubility and the parenteral administration of proteins. Due to the high density of pharmaceutical expertise in Basel a complementary focus in research resides in the close **cooperation with the pharmaceutical industry** including the Glatt Company as manufacturer for process equipment for the pharmaceutical industry. The goals of these activities are to create win-win situations and to compensate as much as possible the lack of university resources for the Department of Pharmaceutical Sciences at the University of Basel.

For dosage form design guaranteeing optimal drug delivery characteristics, drug specific properties such as solubility and biomembrane permeability as well as interaction of the dosage form at the site of application must be taken into account. This is a further research focus of the Institute of Pharmaceutical Technology under the guidance of Prof. Dr. Georgios Imanidis, Deputy Head of the Institute, with the objective to



develop **models for a mechanistic understanding of drug transport through biological membranes**, notably human epidermis, intestinal epithelium simulated by the Caco-2 cell culture system and artificial phospholipid membranes, and discover **delivery system-based methods to influence it**.

### E. 3. Research Areas

#### E.3.1 Main Areas

##### **Research in Powder Technology**

- Dry and Moist Agglomeration of Powder, i.e. Granulation, Tableting
- Control and Scale-up of the Moist Agglomeration Process
- Computer assisted Design of Solid Dosage Forms
- Preformulation and Formulation Research

##### **New Process Technologies**

- Vacuum Fluidised Bed System
- Spray Freeze Drying at Atmospheric Pressure
- Scale-up in the 4<sup>th</sup> Dimension (Moist Agglomeration and Drying Process)
- Supercritical CO<sub>2</sub> and Liposomes
- High Temperature Short Time Sterilization

##### **Basic Research Activities (SNF, Industry)**

- Application of Percolation Theory and Fractal Geometry
- Formulation Research: Robustness and Percolation Thresholds (Critical Concentrations)
- Multicomponent Formulations: Fractals and Order in a Chaotic System
- Solubility, Structure of Water, Hydrophilic Solutions

##### **Drug Absorption; (Prof. Dr. G. Imanidis)**

- Interface Dosage Form/Body of Patient
- Drug Transport: Intestine/Systemic Circulation
- Transmucosal, Transepithelial Transport
- Problem of Bioavailability of topical dosage forms
- Problem of Drugs with a Poor Water Solubility

Specifically, research related to Drug Absorption is subdivided into two focus areas:

1. Dermal (topical) and transdermal (systemic) delivery of drugs including low molecular weight organics and peptide analogues employing formulation design and iontophoresis as means to modulate and enhance delivery rate.  
Fundamental *in vitro* studies of the effect of phase structure in multi-phasic systems and of parameters involved in iontophoresis (pH micro-environment, electroosmotic flow, fraction of aqueous channel pathway) are undertaken, modelling processes based on physicochemical principles to allow quantitative assessment of the influencing factors. Simultaneous transport and metabolism in the skin is considered, drug concentration within cutaneous tissue is estimated and pharmacological concentration/response relationships established *in vivo* using site of action concentration as a measure of skin bioavailability.
2. Intestinal drug absorption using the Caco-2 cell line and phospholipid vesicles as model to simulate the absorption epithelium. A mechanistic approach is taken to identify the routes that are relevant for



transepithelial transport of drugs and to establish possible relationships between the fluidity of the plasma membrane of the cells and the phospholipid bilayer of the vesicles and the permeation rate. Steady state and real time fluorescence depolarisation measurements are used to obtain a measure of membrane fluidity and the effect of adjuvants such as surfactants and lipids contained in drug formulations on the membrane is evaluated. The interrelation between membrane properties and the function of efflux mechanisms such as those related to P-glycoprotein is studied and cellular pharmacokinetics considering transport and metabolism established.

#### E. 4. Research Policy

The institute of pharmaceutical technology is committed to follow an open minded strategy by establishing a network of partners which include similar research labs in academia and in industry (see G. Research and Co-operation Network). This means that basic and applied research is defined along the concept of Prof. Leopold Ruzicka (ETHZ, Nobel Laureate 1939) that there is no difference between basic and applied research, if in basic research the appropriate molecule, i.e. a model substance or system of practical value is chosen. In Figure 2 the still most popular and wide-spread model is described, which can be characterized as a “closed-loop” system strictly focusing on basic research. Figure 3 describes an “open loop” model, a system which is favoured by the head of the institute of pharmaceutical technology.

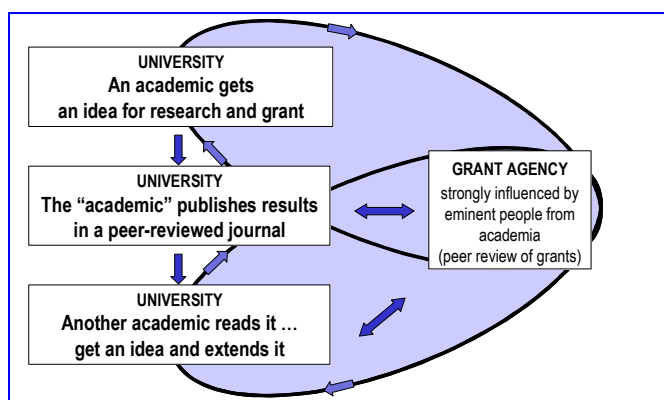


Figure 2 / E. 4 - A “closed loop” model of academic research

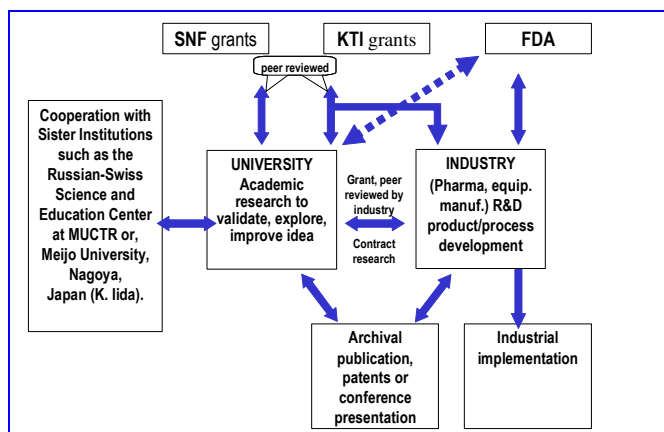


Figure 3 / E. 4 - An “open loop” model of cooperative research and interactions

The research policy of the Institute of pharmaceutical Technology can be summarized as follows:

- Problem oriented, derived from needs, (Applied and Basic Research)
- Themes, Projects are interrelated. Identification of interesting Niche Topics
- Optimisation of Return on Investment
- Close Cooperation with the Industry (Pharma, Equipment Manufacturer)
- Focus on inter- and transdisciplinary research to stimulate innovation
- Focus on a lateral approach in order to facilitate and stimulate the discovery process
- Basic research using as much as possible model substances, which are relevant for application for the benefit of society, which closes the gap between pure basic and applied research.



## E. 5. Important Research Papers

### E.5.1 Application of Percolation Theory and Fractal Geometry

- Percolation Theory, Fractal Geometry and Dosage Form Design, H.Leuenberger, L.Holman, M.Usteri and S.Winzap, *Pharm.Acta Helvetiae* **64**:34-39 (1989).
- The application of percolation theory in powder technology (Invited review), Hans Leuenberger, *Advanced Powder Technology* **10**:323-353 (1999)

### E.5.2 New Process Technologies

- Granulation and Drying in Vacuum Fluidised Bed Systems, B.Luy, B.Hirschfeld and H.Leuenberger, *Drugs made in Germany* **32**:3-8 (1989).
- Atmospheric Spray Freeze Drying: a suitable alternative in freeze drying technology, M.Mumenthaler and H.Leuenberger, *Int.Journal of Pharm.* **72**:97-110 (1991)
- Scale-up in the field of Granulation and Drying. Chapter 6. Bookchapter, in english. Hans Leuenberger, *Drugs and the Pharmaceutical Sciences*, Volume 118, ISSN 0360-2583. Pharmaceutical Process Scale-Up 118 2001, 151-170. ISBN 0-8247-0625-0. Second Edition 2005. Editor Levin Michael.
- New Trends in the Production of Pharmaceutical Granules: Batch versus Continuous Processing. Publication, in english. Hans Leuenberger, *Eur.J.Pharm.Biopharm.* 52 (3), 2001, 289-296. ISSN 0939-6411.
- New Trends in the Production of Pharmaceutical Granules: The classical batch concept and the problem of scale-up. Publication, in english. Hans Leuenberger, *Eur.J.Pharm.Biopharm.* 52 (3), 2001, 279-288. ISSN 0939-6411.
- Thermal Sterilization of Heat Sensitive Products using High-Temperature Short-Time Sterilization. Publication, in english. Angelika Mann, Markus Kiefer, Hans Leuenberger, *J.Pharm.Sci.* 90 (3), 2001, 275-287. ISSN 0022-3549.
- Spray Freeze Drying - The Process of Choice for low water soluble Drugs? Publication, in english. Leuenberger Hans, *J.Nanop.Res.* 4 (1.2), 2002, 111-119. ISSN 1388-0764.

### E.5.3 Experimental Design; Surface Response Methodology Artificial Neural Networks; Expert Systems

- A Factorial Design for Compatibility Studies in Preformulation Work, H.Leuenberger and W.Becher, *Pharm.Acta Helv.* **50**:88-91 (1975).
- Mathematische Modellierung und Optimierung pharmazeutisch-technologischer Qualitätsmerkmale fester Arzneiformen, H.Leuenberger, P.Guitard und H.Sucker, *Pharmazie in unserer Zeit* **5**:65-76 (1976).
- Basic Concepts of Artificial Neural Networks (ANN) Modelling in the Application to Pharmaceutical Development, J.Bourquin, H.Schmidlin, P.vanHoogevest and H.Leuenberger, *Pharm.Development and Technology* **2**:95-109 (1997).
- Advantages of Artificial Neural Networks (ANNs) as alternative modeling technique for data sets showing non-linear relationships using data from a galenical study on a solid dosage form. Publication, in english. Jacques Bourquin, Heinz Schmidli, Peter van Hoogevest, Hans Leuenberger, *Eur.J.Pharm.Sci.* 7 (1), 1998, 5-16. ISSN 0928-0987.
- Comparison of artificial neural networks (ANN) with classical modeling techniques using different experimental designs and data from a galenical study on a solid dosage form. Publication, in english. Jacques Bourquin, Heinz Schmidli, Peter van Hoogevest, Hans Leuenberger, *Eur.J.Pharm.Sci.* 6 (4), 1998, 287-301. ISSN 0928-0987



- Pitfalls of artificial neural networks (ANN) modeling technique for data sets containing outlier measurements using a study on mixture properties of a direct compressed dosage form. Patent Specification, in english. Jacques Bourquin, Heinz Schmidli, Peter van Hoogevest, Hans Leuenberger, *Eur.J.Pharm.Sci.* 7 (1), 1998, 17-28. ISSN 0928-0987.

#### E.5.4 Drug Delivery through Biological and Artificial Membranes

- G.Imanidis, K.C.Hartner and N.A.Mazer. Intestinal Permeation and Metabolism of a Model Peptide (Leuprolide) and Mechanisms of Permeation Enhancement by Non-Ionic Surfactants. *Int.J.Pharm.* **120**:41-50 (1995).
- G.Imanidis, C.Waldner, C.Mettler and H.Leuenberger. An Improved Diffusion Cell Design for Determining Drug Transport Parameters across Cultured Cell Monolayers. *J.Pharm.Sci.* **85**:1196-1203 (1996).
- G.Imanidis, S.Helbing-Strausak, R.Imboden and H.Leuenberger. Vehicle-dependent *In Situ* Modification of Membrane-controlled Drug Release. *J.Control.Release* **51**:23-34 (1998).
- R.Imboden and G.Imanidis. Effect of the Amphoteric Properties of Salbutamol on its Release Rate through a Polypropylene Control Membrane. *Eur.J.Pharm.Biopharm.* **47**:161-167 (1999).

### E. 6. Suggested Further Reading

#### E.6.1 Application of Percolation Theory and Fractal Geometry

- Fractal Dimension of Porous Solid Dosage Forms, M.Usteri, J.D.Bonny and H.Leuenberger *Pharm.Acta Helv.* **65**:Nr. 2 (1990): 55-61.
- Formation of a Tablet: A Site-Bond Percolation Phenomenon, H.Leuenberger and R.Leu *J.Pharm.Sci.* **81**:Nr. 10 (1992): 976-982.
- Matrix-Type Controlled Release Systems: I. Effect of Percolation on Drug Dissolution Kinetics, J.D.Bonny and H.Leuenberger *Pharm.Acta Helv.* **68**: (1993): 25-33.
- Percolation Effects in Matrix-Type Controlled Drug Release Systems, H.Leuenberger, J.D.Bonny, M.Kolb *Int.J.of Pharm.* **115** :(1995): 217-224.
- Use of Percolation Theory to Interpret Water Uptake, Disintegration Time and Intrinsic Dissolution Rate of Tablets Consisting of Binary Mixtures, R.Luginbühl and H.Leuenberger *Pharm.Acta Helv.* **69**: (1994): 127-134.
- Percolation Theory and Robust Formulations in Powder Technology, H. Leuenberger in Proceedings '96 China-Japan Symposium on Particuology edited by Yong Jin, Mooson Kwauk, Genji Jimbo and Yasuo Konseka, Tsinghua University Beijing May 24-25, 1996.



## E.6.2 Process Technology/Solid Dosage Form Design

- Theory of the Granulating Liquid Requirement in the Conventional Granulation Process, H.Leuenberger, H.P.Bier and H.Sucker *Pharm.Techn.Intern.* **3**: (1979): 60-67.
- Scale-up of Granulation Processes with - Reference to Process Monitoring, *Acta Pharm.Techn.* **2**: (1983): 274-280.
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## E.6.4 Drug Delivery through Biological and Artificial Membranes

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- G.Imanidis and R.Imboden. Utilizing Vehicle Imbibition by a Microporous Membrane and Vehicle Viscosity to Control Release Rate of Salbutamol, *Eur. J. Pharm. Biopharm.* **47**:283-287 (1999).
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## *E. 7. Publications: Institute of Pharmaceutical Technology 2001-2005*

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Atmospheric Spray Freeze Drying - The Process of Choice for low water soluble Drugs? Proceedings, in english. Hans Leuenberger, *Proc.Int.Sci.Sem.* 2001, 16-22. ISBN 5-7237-0302-1. Editors: Men-shutina Nathalia V., Goncharova S.V., Shishulin D.V., 2001 International Scientific Seminar; Moscow 10.09.01 - 11.09.01.

Evaluation of flow properties of dry powder inhalation of salbutamol sulfate with lactose carrier. Publication, in english. Kotaro Iida, Youhei Hayakawa, Hirokazu Okamoto, Kazumi Danjo, Hans Leuenberger, *Chem.Pharm.Bull.* 49 (10), 2001, 1326-1330. ISSN 0009-2363.

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Thermal Sterilization of Heat Sensitive Products using High-Temperature Short-Time Sterilization. Publication, in english. Angelika Mann, Markus Kiefer, Hans Leuenberger, *J.Pharm.Sci.* 90 (3), 2001, 275-287. ISSN 0022-3549.



## 2002

A novel approach to the characterization of polar liquids Part 2: Hydrophilic Solutions. Publication, in english. Stengele Andrea, Rey Stephanie, Leuenberger Hans, Int.J.Pharm. 241 (2), 2002, 231-240. ISSN 0378-5173.

Creation of multimedia education courses in the pharmaceutics area. Proceedings, in english. Shishulin D.V., Menshutina Nathalia V., Avramenko G.A., Leuenberger Hans, Gordeev L.S. Proc.CHISA 2002 on CD 2002. 15<sup>th</sup> International Congress of Chemical and Process Engineering; Prague 25.08.02 - 29.08.02.

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## 2003

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Effect of Surface Layering Time of Lactose Carrier Particles on Dry Powder Inhalation Properties of Salbutamol Sulfate. Publication, in english. Iida Kotaro, Hayakawa Youhei, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans, Chem.Pharm.Bull. 52 (3), 2004, 350-353. ISSN 0009-2363.

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Influence of Storage Humidity on the in Vitro Inhalation Properties of Salbutamol Sulfate Dry Powder with Surface Covered Lactose Carrier. Publication, in english. Iida Kotaro, Hayakawa Youhei, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans, Chem.Pharm.Bull. 52 (4), 2004, 444-446. ISSN 0009-2363.

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## 2005

Cross-linked powered/microfibrillated cellulose ii. Patent Specification. Kumar Vijay, Reus Marilu, Leuenberger Hans. U.S. Patent No. 2005287208 2005.

Detection of percolation phenomena in binary polar liquids by broadband dielectric spectroscopy. Publication, in english. Hernandez Perni Maria Engracia, Stengele Andrea, Leuenberger Hans. Int.J.Pharm. 291 (1.2), 2005, 197-209. ISSN 0378-5173.

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Influence of storage humidity on the in vitro inhalation properties of salbutamol sulfate dry powder with surface covered lactose carrier. Publication, **in japanese**. Iida Kotaro, Hayakawa Youhei, Todo Hiroaki, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans. Pharm.Technol.Jpn 21 (5), 2005, 743-748. ISSN 0910-4739.

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Pharmaceutical Process Scale-Up, **2<sup>nd</sup> ed.**, 2005, 151-170. Marcel Dekker Inc. New York. Ed. Levin Michael. ISBN 0-8247-0625-0.

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Towards a better understanding of the parameter  $E_i/E$  in the characterization of polar liquids. Publication, in english. Hernandez Perni Maria Engracia, Stengele Andrea, Leuenberger Hans. Int.J.Pharm. 291 (1.2), 2005, 189-195. ISSN 0378-5173.

### *E. 8. Contribution by External Docents (see also attachment)*

- Prof. Theodor Güntert, PhD, having important responsibilities in his job at Roche Basel is lecturing Biopharmaceutical and Pharmacokinetic topics and is supervising a tutorial with practical applications of Pharmacokinetic data.
- PD Daniëlle Giron, PhD, is expert and head of the Thermoanalytic laboratory at Novartis Pharma Ltd. Her contribution teaching thermoanalytical topics is highly appreciated. Her publications are listed in the attachment.
- PD Peter van Hoogevest, PhD, is an expert in the formulation and the manufacture of liposomes. He is COO of Phares Drug Development Ltd., Muttentz, a company specialised in liposomal technologies and applications. He is teaching liposomal related topics (including practical training) at the Institute of Pharmaceutical Technology.
- PD Stephan Marrer, PhD, from F. Hoffmann-La Roche AG, has accepted other responsibilities at F. Hoffmann-La Roche AG and handed over his teaching responsibilities to Dr. Rolf Altermatt and Dr. Rainer Schmidt. The significant contribution of Dr. Marrer in co-coaching PhD-Students is acknowledged.
- Dr. Rolf Altermatt from F. Hoffmann-La Roche AG, is successor of Stephan Marrer and takes care of teaching Quality Assurance topics and is coaching PhD students.
- Dr. Rainer Schmidt from F. Hoffmann-La Roche AG, takes care of teaching Quality Assurance topics and is coaching PhD students.
- Klaus Eichler is head of the Technology Training Center at Glatt in Binzen, BRD. He is an excellent organiser and moderator of Meetings, Workshops and Symposia world-wide. The Institute of Pharmaceutical Technology is proud of working with him for years.
- PD Michel Ulmschneider, PhD, is private docent at the Université de Haute Alsace, Mulhouse and is teaching chemometrics for advanced students in pharmaceutical sciences.
- Bernd Herzog, PhD, is head of several R+D application labs at Ciba Specialty Chemicals Inc., Grenzach-Wyhlen within the segment of home and personal care (main focus on sun screens for skin protection).



## F. Curriculum Vitae

### F. 1. G. Betz

#### Personal information:

Date of birth 27<sup>th</sup> of February 1971  
Place of birth Ravensburg/Germany

#### Education:

1990 Allgemeine Hochschulreife (Abitur) at Matthias Erzberger Schule, Biberach/Riss, Germany  
1990-1996 Pharmacy studies at Albert Ludwig University, Freiburg, Germany  
Practical year at Ciba AG, Wehr, Germany and Apotheke Stadtmitte, Stuttgart, Germany  
1996-2000 Ph.D. study under the supervision of PD. Dr. G. Imanidis and Prof. Dr. H. Leuenberger at Institute of Pharmaceutical Technology, University of Basel, Switzerland with the title:  
“Heparin Penetration into and Permeation through Human Skin from Aqueous and Liposomal Formulations In vitro and Interactions of Phospholipids with Skin.”

#### Professional activities:

1996-2000 Lectureship in practical university courses of the liquid sterile dosage forms and liposomal formulations.  
Lectureship and workshop in oral scientific presentation technique and body language.  
2001-2002 Postdoctoral-fellow and head teaching assistant under Prof. Dr. H. Leuenberger at Institute of Pharmaceutical Technology, University of Basel, Switzerland.  
Since 2002 Head of the Industrial Pharmacy Lab and head teaching assistant at Institute of Pharmaceutical Technology, University of Basel, Switzerland.  
Since 2003 University Teaching Position in Pharmaceutical Technology, University of Basel.  
2004 NETS Entrepreneurship Program:  
Create Switzerland, Lausanne  
Babson College, Wellesley, Massachusetts

#### Awards

2004 NETS Award for young scientists sponsored by Gebert Rűf Stiftung Basel, Switzerland.  
NETS Special Award sponsored by Gebert Rűf Stiftung Basel, Switzerland.



## F. 2. G. Imanidis

Georgios Imanidis, June 8, in Serres, Greece

born 1958

### EDUCATION

High school (gymnasium) education with emphasis on sciences in Serres, Greece	1973 – 1976
University admission examination	1976 June
Pharmacy studies at the Aristotelion University of Thessaloniki, Thessaloniki, Greece	1976 – 1980
Graduation with the Pharmacy degree	1980 Nov.
Post-graduate studies in Pharmaceutical Technology and Industrial Pharmacy at the „Pharmazeutisches Institut“ of the University of Basel, Basel, Switzerland	1980 – 1982
Advanced diploma in Pharmaceutical Technology,	1982 Dec.
Ph.D. thesis in Pharmaceutical Technology under the supervision of Prof. H. Leuenberger at the „Pharmazeutisches Institut“ of the University of Basel, Basel, Switzerland	1983 – 1986
Doctor of Philosophy degree	1986 Feb.

### PROFESSIONAL APPOINTMENTS

Part-time (50%) teaching assistant in Pharmaceutical Technology at the „Pharmazeutisches Institut“ of the University of Basel, Basel, Switzerland	1983 – 1986
Post-doctoral fellow in Drug Delivery Research under Prof. W.I. Higuchi in the Department of Pharmaceutics, University of Utah, Salt Lake City, UT, U.S.A.	1986 – 1988
Senior research scientist in the Department for Drug Absorption Studies, TheraTech, Inc., Salt Lake City, UT, U.S.A.	1988 – 1990
Adjunct staff scientist in the Department of Pharmaceutics, University of Utah, Salt Lake City, UT, U.S.A.	1988 – 1990
Recipient of a scholarship from the Roche Research Foundation to study drug absorption using cell cultures as an alternative to animal experiments at the „Pharmazeutisches Institut“ of the University of Basel, Switzerland	1991 – 1992
Scientific staff member, „habilitand“, and head teaching assistant at the „Pharmazeutisches Institut“ of the University of Basel, Department of Pharmaceutical Technology, Basel, Switzerland	1992 – 1999
Awarded the title of a docent „PD“ by the Faculty of Natural Sciences of the University of Basel through the process of „Habilitation“.	2000
Faculty member (full time) at the Institute of Pharmaceutical Technology, University of Basel, Switzerland, by virtue of the docent “PD” title awarded by the Faculty of Natural Sciences of the University of Basel through the process of “Habilitation”.	since 2000
Prof. (tit.) awarded by the Faculty of Natural Sciences of the University of Basel (22.11.2005), confirmed by the University Council in January 2006.	2005 Nov.
Appointment as Professor for Pharma Technology at the School of Life Sciences at the University of Applied Sciences Northwestern Switzerland.	May 2006



### F. 3. H. Leuenberger

#### EDUCATION

1962	Matura Type B (latin, english, maths) Realgymnasium Basel
1971	PhD-Thesis in Nuclear Physics (University of Basel)
1967	Diploma in Experimental Physics (University of Basel)

#### INDUSTRIAL CAREER

11.1.2007	Foundation of the Center for innovation in computer aided pharmaceuticals, CINCAP llc, registered c/o Ifiip llc together with Dr. Maxim Puchkov; see <a href="http://www.cincap.ch">www.cincap.ch</a> , office at the Birsigstr.79, CH-4054 Basel.
1.11.2006	Prof. Dr. Hans Leuenberger, Foundation of the Institute for innovation in industrial pharmacy, Ifiip llc, registered in CH-4148, Pfeffingen, Switzerland; see <a href="http://www.ifiip.ch">www.ifiip.ch</a> , office at the Birsigstr. 79, CH-4054 Basel.
1973-1982	Research Group Leader, Pharmaceutical R+D, Sandoz Ltd., Basel
1971-1973	Head of R+D Laboratory (Preformulation work) Analytical R+D Department, Sandoz Ltd., Basel

#### SABBATICALS AND EXPERIENCES ABROAD

1980	Head Pharma R+D, Sandoz España, Barcelona ad interim (Spain)
1979	University of Michigan, Ann Arbor (Prof. Dr. W. I. Higuchi, Prof. Dr. N. F. Ho, Dr. E. W. Hiestand), U.S.A.
1973	University of Hamburg (Prof. Dr. H. Sucker) Germany

#### CAREER IN ACADEMIA

Since 1.11.2006	Prof. Leuenberger is coaching 20 PhD students at the University of Basel, who have not yet completed their PhD studies, holding a lectureship at the Faculty of Natural Sciences of the University of Basel, with the topic “Pharm. Technology” for the postgraduate PhD seminar in Pharm. Technology and for coaching PhD students.
1.11.2006	Hans Leuenberger, Prof. emeritus in Pharmaceutical Technology, University of Basel. Prof. Leuenberger has coached between 1982 and 2006 133 PhD Students, who work today mainly in the pharmaceutical industry. He also co-coached PhD students from other Universities such as University of Seville; Mendeleyev University of Chemical Technology of Russia; Mahidol University, Bangkok etc.
16.7.2006	Foundation of Ifiip llc, Institute for innovation in industrial pharmacy, P.O. Box, CH-4011 Basel, Tel. +41 61 753 9068 Fax +41 61 753 9069, <a href="http://www.ifiip.ch">www.ifiip.ch</a> Cell +41 76 381 68 93 Prof. Dr. Hans Leuenberger, Head Institute for innovation in industrial pharmacy and CEO Ifiip llc, Kreuzackerweg 12, CH-4148, Pfeffingen, Switzerland
1982 - 2006	Head Institute of Pharmaceutical Technology
1995 - 2004	Head Department of Pharmaceutical Sciences



1994 - 95	Dean of the Faculty of Natural Science at the University of Basel, Founder of the Faculty Committee of Department Heads
1988-1993	Member of the Export Group 12 (Pharmaceutical Technology) of the European Pharmaceutical Commission, Strasbourg, France
Since 1982	Elected as Full-Time Ordinary Professor of Pharmaceutical Technology and Head of the Institute of Pharmacy at the University of Basel, Totengässlein 3, CH-4051 Basel (Historical Site close to the Museum, location till 2000)
1982-2000	Planning of a new building for the Institute of Pharmacy (Pharmacenter of the University of Basel, Klingelbergstr.50)
Since 1982/83	Referee for different journals and member of editorial boards such as J. Pharm. Sci. e.g. in 1990/92
1980 - 1982	Part Time Lecturer at the University of Basel as Private Docent (PD) in Pharmaceutical Technology
Publications: Patents:	more than 240 more than ten

#### SERVICES

Since 2007	President of the Swiss Academy of Pharmaceutical Sciences c/o Swiss Society of Pharmaceutical Sciences (SGPhW)
2006	Member of the Sci. Advisory Board for the <b>Engin. Research Center</b> for Structured Organic Composites (ERC-SOC). supported by US National Science Foundation, Arlington, USA. <b>Rutgers</b> ; Rutgers, State University of New Jersey. <b>NJIT</b> ; New Jersey Institute of Technology. <b>Purdue</b> ; Purdue University. <b>UPRM</b> ; University of Puerto Rico, Mayagüez.
2001	Member of Board of Directors of CAETS (International Council of Academies of Engineering and Technological Sciences)
Since 2001	President Swiss Society of Pharm. Sciences (SGPhW)
1999 - 2001	Member of the Scientific Council of CASS (Conseil des Académies Scientifiques Suisses)
1993 - 2001	Vice President of the Swiss Academy of Engineering Science
1993 - 1999	Member of the Board of CASS (Conseil des Académies Scientifiques Suisses) as Vice President of SATW
1993-1997	Member of peer review committees ETHZ (1993), University of Groningen and Utrecht (1997)
1992-96	President of the Scientific Council [SC] of the Swiss Academy of Engineering Science [SATW] and founder of the Lateral Think Tank of the SC
1987	Member of the Swiss Academy of Engineering Sciences (SATW)



#### F. 4. Research Awards, Medals, Nominations (Membership Awards)

H. Leuenberger, on behalf of the Institute of Pharmaceutical Technology:

2007	Nomination as Doctor of Philosophy (PhD) honoris causa in pharmaceutics by Mahidol University, Bangkok, Thailand
Since 2007	Honorary Member of the Society of Pharmacists of the Canton of Basel-City (BAV, Baselstädtischer Apothekerverband)
Since 2007	Honorary President of the Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos, CISDEM, University of Seville, Spain
2006	At the 50 years celebration ceremony of SPTJ on November 8, 2006 the SPTJ presented him the “50 <sup>th</sup> Anniversary Award of the Society of Powder Technology of Japan” (SPTJ) for his distinguished achievements and outstanding contributions to promote the international cooperation in powder technology.
2006	In recognition of his achievements in Pharmaceutical Technology the “European Pharmacopoeia – Council of Europe Medal”
Since 2005	Honorary Director of the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies at the Mendeleyev University of Chemical Technology of Russia [MUCTR, Moscow ( <a href="http://www.muctr.ru">www.muctr.ru</a> )]
2005	The International Symposium on Agglomeration (Bangkok, Thailand, March 16-18) Certificate of Agglomeration Award in Recognition of the Outstanding Contribution to the Development Of Agglomeration Sciences
2004	Certificate of Appreciation for Outstanding Service issued by the International Council of Academics of Engineering and Technological Sciences Inc., Washington DC ( <a href="http://www.caets.org">www.caets.org</a> )
Since 2001	Member of the Scientific Advisory Board of the Grand École des Mines, Albi, France ( <a href="http://www.enstimac.fr">www.enstimac.fr</a> )
2001	Award of Particulate Preparations and Design of the Society of Powder Technology of Japan, Kyoto, Japan
Since 2001	Honorary member of the Swiss Academy of Engineering Sciences [SATW]
2000	IPS Medal 2000 [Industrial Pharmacy Section] of FIP [Fédération Internationale Pharmaceutique]
Since 1998	Corresponding Member of the Royal Academy of Pharmacy of Spain
Since 1998	Foreign Member of the Russian Academy of Engineering Sciences
1997	Jörg Bider Medal of the Swiss Society of Pharmacists [SAV]
1994	Innovation Award for New Process Technologies of the Governments Basel-City and Basel-Country
Since 1994	Honorary Member of the Swiss Society of Industrial Pharmacists [GSIA]
1993	AAPS Research Award in Pharmaceutical Technologies
1993	As Member of Expert Group 12 between 1988-93: the “European Pharmacopoeia – Council of Europe Medal”
Since 1990	Fellow of the American Association of Pharmaceutical Scientists [AAPS]
1989	University of Helsinki Medal



## G. Research and Co-operation Network

### G. 1. Academia

China Pharmaceutical University, Nanjing, P.R. China\*

Federal Institute of Technology [ETH] Zürich\*

École des Mines, Albi, France\*

Gifu Pharmaceutical University, Gifu Japan\*

Institute of Hospital Pharmacy, Basel

Institute of Informatics, University of Basel

Mahidol University, Bangkok, Thailand\*

Mendeleyev University of Chemical Technology of Russia [MUCTR], Moscow\*

Spitalapotheke, Kantonsspital Aarau

University of Kansas, Lawrence, Kansas, USA\*

University of Seville, Seville, Spain\*

University of Iowa, College of Pharmacy, Iowa City, USA

### G. 2. Industrial Partners

ADD, Advanced Drug Delivery Technologies, Reinach

Asulab AG, Neuchâtel

Bachem AG, Bubendorf

Capsugel Ltd., Arlesheim

Ciba Specialty Chemicals, - Grenzach D

Drossapharm AG, Arlesheim

Glatt AG, Pratteln

Glatt GmbH, Binzen, BRD

Glatt, System Techniques, Dresden, BRD

Mepha AG, Aesch

Novartis Animal Health Ltd, Basel

Novartis Pharma Ltd., Basel

Pentapharm AG, Aesch

Pfizer GmbH, Arzneimittelwerk Gödecke, Freiburg i.Br.

Phares Ltd., MuttENZ

Pharmatrans Sanaq AG, Basel

Roche Ltd., Basel

Roche Ltd., Grenzach, BRD

Skye Pharma, MuttENZ

Spirig AG, Egerkingen

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\* Based on formal agreements, activity depending on projects, time and resources, see typical model agreement: see e.g. first document of the list of documents concerning the cooperation with MUCTR.



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## PROGRESS REPORT 2006 AND OUTLOOK

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### H. Progress Report 2006

#### *H. 1. Special Events 2006*

##### H.1.1 Prof. Dr. Georgios Imanidis

Prof. Dr. Georgios Imanidis (Titular Professor at the University of Basel) was elected as head of the competence center Pharma Technology at the University of Applied Sciences Northwestern Switzerland (UAS), School of Life Sciences, MuttENZ, having a double professorship (University of Basel, UAS).

#### *H. 2. International relations of the Institute of Pharmaceutical Technology*

The author of this report was recently informed that the University of Basel is creating the position for a director of international affairs. This is an excellent idea and will help to keep alive the legacy of the existing network described below.

##### H.2.1 Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies at the Mendeleyev University of Chemical Technology of Russia (MUCTR), Moscow



Figure 4 / H.2.1- Construction of the building, Status: December 2006

The above mentioned center is the result of the cooperation between the IPT and the Cybernetic Department of MUCTR, which has been supported by the Swiss National Science Foundation (SNF) in the framework of the SCOPES (Scientific CoOperation Programme between Eastern Europe and Switzerland) project 7IP 062613. MUCTR has decided that the center will form a structural unit of MUCTR. The idea of the center and its activities are further supported by the SNF (SCOPES grant IB 74 BO - 110911). MUCTR is offering space on the first floor of the planned new building (see photos of the building in construction). This research building is located in the north of Moscow (Tushino, High Tech Park).





Figure 5 / H.2.1 Construction of the building, Status: April 2007

### **Seminar in Basel, April 2006**

Conclusion of the Executive Summary; Visit of a Delegation from Russia April 25 to May 1, 2006 and Seminar on April 26, in the Hotel Merian, Basel

The coordinator of the SCOPES project and head of the organizing committee, Prof.Dr. Hans Leuenberger, wants to thank, also in the name of all participants, all speakers and sponsors of this event. The presentations at the seminar on April 26, 2006 and the presentations during the visits of the different companies were highly appreciated by all participants.



Figure 6 / Seminar in Basel, April 2006, Café Spitz Basel



The main goal of the event was to inform the Swiss side about the progress of the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies at MUCTR in Moscow: This goal was achieved. The participants from industry are ready to think about possibilities how to strengthen the joint Russia Swiss Laboratory at MUCTR in Moscow by giving donations or facilitating the purchase of equipment. In addition, a document was signed to send a Postdoc, i.e. a former PhD student, who has done PhD studies in Basel (and in Bangkok, Thailand) to MUCTR to strengthen the Russian Swiss Center and to push forward the SCOPES project IB 74 BO - 110911.

The coordinator of the SCOPES project IB 74 BO - 110911 was invited by Dr. Charles Kleiber, the Head of the Swiss State Secretariat for Education and Research to a roundtable conference at Bavois, VD, to promote the scientific relations between Switzerland and Russia. At this event on April 5, 2006, Dr. Kleiber esteemed the concept of this joint Russian Swiss laboratory. This center owns laboratory and office space provided by MUCTR free of charge. In fact, the center is a structural unit of this university and will be located in the new building in the High-Tech Park of MUCTR in Tushino. At this event in Bavois the idea to establish a «Swiss House» in Russia (similar) to the existing «Swiss Houses» in the U.S. (Boston, San Francisco) was discussed as well. In the mean time, the coordinator of this SCOPES project received signals from the rector of MUCTR Prof. Dr. Vladimir A. Kolesnikov, that he would be happy to host the planned Swiss House at MUCTR in Moscow.

#### **International Seminar: “Innovative Technologies and Equipment for Pharmaceutical Industry” MUCTR December 2006, Moscow**

The third international event of the center in Russia was the above mentioned seminar which took place from 4 to 6 December 2006, at the MUCTR in Moscow.

The seminar was opened by Erwin H. Hofer, ambassador of Switzerland in the Russian Federation. The presentations (in English and Russian respectively) were translated simultaneously and the invitation with the program was written in English and Russian (see page 35 - the English version). In the evening of December 5, 2006, Dr. Erwin H. Hofer gave a reception at the Swiss Embassy, inviting all participants of the seminar. The rector of MUCTR repeated his offer to provide, if desired also space for a future Swiss Science House in Moscow.

#### **List of documents concerning the cooperation with MUCTR**

1. Contract: General Cooperation Agreement, between University Basel and MUCTR, November 1999, signed by Prof. Dr. Ulrich Gäbler et al.
2. Contract: General Cooperation Agreement, between Uni Basel and MUCTR, summer 2002, signed by Prof. Dr. Ulrich Gäbler et al.
3. SNF-SCOPES, Scientific Co-operation Agreement Oct. 2005/June 2006
4. Program of the International seminar, Dec 2006, Moscow



**GENERAL COOPERATION AGREEMENT**

**BETWEEN**

University of Basel,  
Institute of Pharmaceutical Technology

**AND**

D.I. Mendeleev University of Chemical  
Technology of Russia

**WHEREAS** University of Basel, Institute of Pharmaceutical Technology and D.I. Mendeleev University of Chemical Technology of Russia, Cybernetic Department, wish to collaborate through different teaching and research programs in order to improve the qualifications of the teaching staff and students of both establishments;

**WHEREAS** both establishments wish to develop, through this collaboration, their teaching and research resources in their fields of competence;

**WHEREAS** both universities have a genuine interest in the promotion of such international collaboration on the basis of equality and mutual assistance;

University of Basel, Institute of Pharmaceutical Technology, on the one hand, and D.I. Mendeleev University of Chemical Technology of Russia, Cybernetic Department, on the other, agree to the following :

*Article 1 . FIELDS OF COOPERATION*

The cooperation agreement includes all university level disciplines for which teaching and research activities thrive in both universities.

*Article 2 - MODES OF COOPERATION*

2.1 A separate agreement shall be required for each cooperative program. The following activities are considered:

- exchanges of professors and researchers;
- exchanges of students;
- joint research activities;
- joint organization of missions and seminars;
- exchanges of pedagogical, research and scientific documents;
- joint training programs;
- joint research of funding.

2.2 Each agreement shall specify all the contributions of the parties, its financial sources, the scope of the program, its duration and the conditions of its renewal.

2.3. It is also acceptable that the proposed project can be financially supported by a third party such as a private foundation, a company, a national or international foundation.

2.4 Each establishment will identify a person responsible for the program implantation within the framework of this agreement.

2.5 Each specific agreement shall be approved by the appropriate authorities of each establishment.



### ***Article 3 - DURATION AND SCOPE OF THE AGREEMENT***

The duration of this agreement is two (2) years from the time of its signing. It is subject to renewal by mutual consent of the parties.

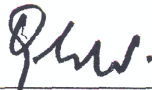
Either party may terminate this agreement by giving six (6) months written notice.

The present agreement will take effect upon its written approval by both parties.

**For D.I. Mendeleev University  
of Chemical Technology of Russia**

**For University of Basel**



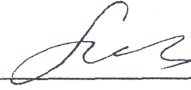
  
\_\_\_\_\_  
RECTOR  
Ulrich Gäbler



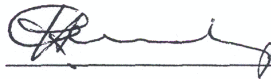
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Date 20.11.99

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Date 23/11/99

**Head of the Cybernetic Department  
of Chemical Technological processes**

  
\_\_\_\_\_  
Prof. L.S. Gordeev

**Head of the Institute of  
Pharmaceutical Technology**

  
\_\_\_\_\_  
Prof. H. Leuenberger



## **GENERAL COOPERATION AGREEMENT**

### **BETWEEN**

University of Basel,  
Institute of Pharmaceutical Technology

### **AND**

D.I. Mendeleev University of Chemical  
Technology of Russia

**WHEREAS** University of Basel, Institute of Pharmaceutical Technology and D.I. Mendeleev University of Chemical Technology of Russia, Cybernetic Department, wish to collaborate through different teaching and research programs in order to improve the qualifications of the teaching staff and students of both establishments;

**WHEREAS** both establishments wish to develop, through this collaboration, their teaching and research resources in their fields of competence;

**WHEREAS** both universities have a genuine interest in the promotion of such international collaboration on the basis of equality and mutual assistance;

University of Basel, Institute of Pharmaceutical Technology, on the one hand, and D.I. Mendeleev University of Chemical Technology of Russia, Cybernetic Department, on the other, agree to the following :

### **Article 1 . FIELDS OF COOPERATION**

The cooperation agreement includes all university level disciplines for which teaching and research activities thrive in both universities.

### **Article 2 - MODES OF COOPERATION**

2.1 A separate agreement shall be required for each cooperative program. The following activities are considered:

- exchanges of professors and researchers;
- exchanges of students;
- joint research activities;
- joint organization of missions and seminars;
- exchanges of pedagogical, research and scientific documents;
- joint training programs;
- joint research of funding.

2.2 Each agreement shall specify all the contributions of the parties, its financial sources, the scope of the program, its duration and the conditions of its renewal.

2.3. It is also acceptable that the proposed project can be financially supported by a third party such as a private foundation, a company, a national or international foundation.



- 2.4 Each establishment will identify a person responsible for the program implantation within the framework of this agreement.
- 2.5 Each specific agreement shall be approved by the appropriate authorities of each establishment.

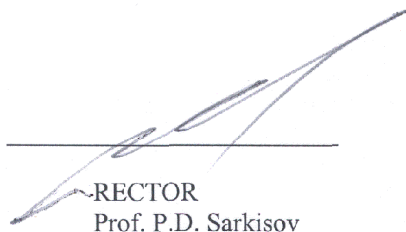
**Article 3 - DURATION AND SCOPE OF THE AGREEMENT**

The duration of this agreement is three (3) years from the time of its signing. It is subject to renewal by mutual consent of the parties.

Either party may terminate this agreement by giving six (6) months written notice.

The present agreement will take effect upon its written approval by both parties.

**For D.I. Mendeleev University  
of Chemical Technology of Russia**



\_\_\_\_\_  
RECTOR  
Prof. P.D. Sarkisov

28.06.2002  
Date

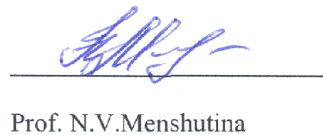
**For University of Basel**



\_\_\_\_\_  
RECTOR  
Ulrich Gaebler

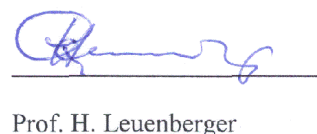
28.08.2002  
Date

**Responsible for cooperation  
Professor of the Cybernetic Department  
of Chemical Technological processes**



\_\_\_\_\_  
Prof. N.V. Menshutina

**Head of the Institute of  
Pharmaceutical Technology**



\_\_\_\_\_  
Prof. H. Leuenberger



**SCOPES 2005 – 2008**  
**Scientific Co-operation between Eastern Europe and Switzerland**

**Co-operation Agreement**

**No. IB74B0-110911**

between

the **Swiss National Science Foundation**, having its registered offices at Wildhainweg 3, 3001 Berne, Switzerland, duly represented by its Director, Daniel Höchli, and its Head of International Relations, Dr. Jürg Pfister

(hereafter referred to as "**the SNSF**")

and

the **Institute of Pharmaceutical Technology, University of Basel**, Klingelbergstrasse 50, 4056 Basel, Switzerland, duly represented by Prof. Hans Leuenberger, Head of Institute

(hereafter referred to as "**Contractor No. 1**")

and

the **Industrial Pharmacy Lab, Institute of Pharmaceutical Technology, University of Basel**, Mülhauserstrasse 51, 4056 Basel, Switzerland, duly represented by Prof. Hans Leuenberger, Head of Institute

(hereafter referred to as "**Contractor No. 2**")

and

the **Faculty of Cybernetics of Chemical Technology, Mendelev University of Chemical Technology of Russia**, Miusskaya sq. 9, 125047 Moscow, Russia, duly represented by Academician Pavel D. Sarkisov, Rector

(hereafter referred to as "**Contractor No. 3**")

and

the **Faculty of Organic Chemistry, Technology and Pharmacy, Mendelev University of Chemical Technology of Russia**, Miusskaya sq. 9, 125047 Moscow, Russia, duly represented by Academician Pavel D. Sarkisov, Rector

(hereafter referred to as "**Contractor No. 4**")

(Contractors No. 1, 2, 3 and 4 collectively referred to as "**the Contractors**")

and

**Professor Hans Leuenberger**, Institute of Pharmaceutical Technology, University of Basel, Klingelbergstrasse 50, 4056 Basel, Switzerland

(hereafter referred to as "**Co-ordinator**")

(collectively referred to as "**the Parties**")

Doc. ref.: IP Co-operation Agreement September 2005



**Article 21 Annexes**

The following annexes shall form integral part to this Co-operation Agreement:

- Annexe I: Global Concept
- Annexe II: Budget
- Annexe III: Power of Attorney of the concerned Contractors with original signatures

This Co-operation Agreement is made in English in six (6) original copies duly signed for and on behalf of the Parties, each party receiving an original copy.

**On behalf of the Swiss National Science Foundation:**

Berne, 28/6/ 2006

Berne, 28.6. 2006

D. Höchli  
(Daniel Höchli)

(Dr. Jürg Pfister)

**The Co-ordinator and on behalf of the Contractor(s) no. 1, 2, 3 and 4 (cf. Annexe II):**

Basel, 3. Oct. 2005

(Prof. Hans Leuenberger)

**On behalf of the Institute of Pharmaceutical Technology, University of Basel, Basel, Switzerland**

Basel, 3. Oct. 2005

(Prof. Hans Leuenberger)



Program of the International seminar, Dec 2006, Moscow

***Dear Ladies and Gentlemen!***

**Russian-Swiss Science and Education Center for Transfer of Biopharmaceutical  
Technologies  
at D.I. Mendeleev University of Chemical Technology of Russia**

with the support of

**the Embassy of Switzerland in Moscow**

invite Managers and Representatives of the Russian and international pharmaceutical  
Industries to take part in the International Seminar

**«INNOVATIVE TECHNOLOGIES AND EQUIPMENT FOR PHARMACEUTICAL  
INDUSTRY»**

This event will take place from 5 to 6 December 2006  
at D.I. Mendeleev University of Chemical Technology of Russia in the  
Conference Hall located at Miusskaya Square 9, Moscow.

**The Organizing Committee for the International Seminar:**

**Chairman:** V.A. Kolesnikov - Rector of D.I. Mendeleev University of Chemical Technology  
of Russia

**Co-Chairman: Prof. H. Leuenberger** – President of Swiss Society of Pharmaceutical  
Sciences, Head of Institute of Pharmaceutical Technology, Pharmacenter of Basel University,  
Honorary Director of Russian-Swiss Center of Pharmaceutical Technologies Transfer

**Co-Chairman: Prof. N. Menshutina** - Director of Russian-Swiss Center of Pharmaceutical  
Technologies Transfer

**Secretary: Dr. E. Guseva** – Vice-Director of Russian-Swiss Center of Pharmaceutical  
Technologies Transfer

During the Seminar the trends and perspectives of development of pharmaceutical products  
and process in the world will be covered. The leading companies of Switzerland, Germany  
and other European countries manufacturing equipment and developing technologies for  
pharmaceutical industry will present their novel developments (Novartis, Roche  
Pharmaceuticals, Mepha, Scan, Glatt, etc.). The topics will cover a wide spectrum of  
pharmaceutical manufacture including designing of pharmaceutical productions on GMP,  
standardization, isolation technologies and organization of clean rooms, quality control of  
pharmaceutical preparations and etc. The participation in the seminar is confirmed by the  
Certificate.



## Семинар для фармпредприятий в РХТУ им. Д.И.Менделеева

5-6 декабря 2006 г. Российско-швейцарский учебно-научный центр трансфера фармацевтических и биотехнологий провел III международный семинар «Инновационные технологии и оборудование для фармацевтических предприятий». **В.КОЛЕСНИКОВ**, ректор РХТУ им. Д.И.Менделеева и **Эрвин ХОФЕР**, чрезвычайный и полномочный посол Швейцарской Конфедерации в РФ обратились с приветственным словом к участникам семинара. В работе семинара приняли участие российские фармпроизводители, а также российские и зарубежные представители науки и бизнеса.



Слева посол Швейцарской Конфедерации в РФ Эрвин Хофер, ректор РХТУ В.А.Колесников



Посол Швейцарской Конфедерации в РФ Эрвин Хофер



Ганс Леуенбергер, директор Института инноваций в фармпромышленности Швейцарии



Н.В.Меньшутина, директор Российско-швейцарского учебно-научного центра трансфера фармацевтических и биотехнологий



А.М.Егоров, академик РАМН, химфакультет МГУ им. М.В.Ломоносова



Рольф Альтерматт, глава отдела контроля качества «Хоффманн ля Рош»

Подобный международный семинар, проводимый по инициативе Российско-швейцарского учебно-научного центра, проходит в РХТУ им. Д.И. Менделеева во второй раз, и наш журнал традиционно принимает в нем участие. О значимости мероприятия свидетельствует тот факт, что на его открытии неизменно присутствует посол Швейцарии в РФ **Эрвин Хофер**. В этот раз благодаря инициативе директора Российско-швейцарского центра, профессора **Н.В.Меньшутин** и директора швейцарского Института инноваций в фармацевтической промышленности **Ганса Леуенбергера** удалось пригласить в Москву высокопрофессиональных зарубежных специалистов, сообщивших присутствующим российским фармпроизводителям о последних ноу-хау в мировой фармацевтической промышленности. С одной стороны, на семинаре выступили представители известных фармтехнических компаний, таких как Huetlin GmbH, SKAN AG, Christ Water Technology, Bausch+Stroebel, поставляющие современное оборудование и технологии на российские заводы, с другой стороны, специалисты известных зарубежных фармфирм, таких как Hoffmann La Roche, Novartis, Bosnalijek рассказали о своем опыте работы на современном оборудовании, преимуществах и проблемах, возникающих при внедрении и апробации новых машин. Подобный опыт несомненно оказался очень полезен присутствующим российским технологам, инженерам, специалистам по качеству и валидации. Так, с особым вниманием был выслушан доклад **Ерика Штурзенегера**, директора вспомогательного производства Novartis о преимуществах и ограничениях использования изоляционной техники в фармпромышленности. Доклад так интересен, что мы решили опубликовать его в нашем сегодняшнем выпуске. Тему барьерных изоляционных технологий





Слева Н.В.Чингаева, главный технолог ЗАО СЕВЕРНАЯ ЗВЕЗДА и С.Р.Мовсесов, руководитель отдела фармацевтического оборудования ООО «БВТ-Сервис»



Слева О.П.Пантелеева «Inpojet» и С.В.Емшанова, руководитель ЦНИР ОАО «Акрихин»



В.М.Смыченко, начальник производства, ООО «Росбио»

продолжил в своем выступлении и **Поль Рюффё**, вице-президент швейцарской компании SKAN AG, много лет работающий по проблемам изоляторов, который сделал детальное сравнение использования изоляторов и чистых комнат в фармацевтическом производстве. Поль Рюффё уже неоднократно приезжает в Москву, принимал участие во всех 3 семинарах в РХТУ им. Д.И.Менделеева.

## Прием в Посольстве Швейцарской Конфедерации в РФ

Вечером 5 декабря 2006 г. в посольстве Швейцарской конфедерации в РФ в Москве, в переулке Огородной слободы, состоялся торжественный прием по случаю проведения российско-швейцарского семинара, на котором нам удалось вручить наш журнал «Фармацевтические технологии и упаковка» послу Швейцарской Конфедерации РФ Эрвину Хоферу.



Слева направо: Ганс Леуенбергер, директор института инноваций в фармпромышленности Швейцарии, Н.В.Меньшутин, директор Российско-швейцарского учебно-научного центра фармацевтических и биотехнологий, посол Швейцарской Конфедерации в РФ Эрвин Хофер и М.А.Кушнарева, главный редактор журнала «Фармацевтические технологии и упаковка».

Фото М.Г.Гордиенко

Несомненно запомнится слушателям и сообщение **Г.Леуенбергера**, профессора Базельского Института фармацевтических технологий о применении теории перколяции в процессах смешения и влажной агломерации, а также выступление **Маркуса Кноля**, главы фармацевтического отдела немецкой компании Huetlin GmbH, который поделился последними ноу-хау, заложенными в принцип действия аппаратов псевдооживленного слоя.

Активная маркетинговая стратегия швейцарской компании «Крист» нашла подтверждение в выступлении **С.Мовсесова**, руководителя отдела фармацевтического оборудования ООО «БВТ-Сервис». Он сообщил о новых европейских нормативных требованиях для подготовки воды для фармацевтических целей и о возможностях установок «Крист», которые предлагаются для российских заводов.

Запомнится участникам семинара и доклад **А.Росола**, директора российского представительства известной немецкой компании BAUSCH+ STROEBEL о новых технических решениях в оборудовании для обработки одноразовых шприцев в гнездовых кассетах, в частности, о работе современной машины наполнения и укупорки шприцев, производительностью до 11300 шприцев/час, в которой транспорт кассет осуществляется с помощью круглых ремней в GMP исполнении.

Также на конференции звучали выступления **А.Егорова**, академика РАМН, зав. лабораторией инженерной энзимологии химического факультета МГУ, **А.Карякина**, заведующего центральной лабораторией государственного контроля и изучения качества препаратов крови, кровезаменителей и средств парентерального питания Гематологического научного центра РАМН, **А.Афонина**, зам. руководителя отдела технологий и материалов Degussa, **И.Родиной**, ведущего специалиста отдела предклинических исследований ОАО «Завод экологической техники и экопитания «ДИОД».

Приехавшие на семинар российские технологии также с интересом прослушали сообщения зарубежных специалистов – **Р.Альтерматта**, главы отдела контроля качества, Hoffmann-La Roche Ltd ROCHE (Switzerland), **М.Пашич**, ассистента компании Bosnalijek d.d. (Босния), **Х.Конарковски**, директора по развитию бизнеса ИИХР, **С.Лоулоуди-Спанос**, консультанта по бизнесу MES и LIMS американской компании AspenTech.

**На конференции работал корреспондент нашего журнала. Фото М.Гордиенко, Л.Крячко**



## H.2.2 Ideas for similar partner institutions

The dynamic activities at the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies has lead to follow-up ideas for similar centers. This development has been promoted by the fact, that Dr. Charles Kleiber, State Secretary, Swiss Federation, mentioned at a meeting in Bavois, April 5, 2006, the Russian-Swiss Science and Education Center at MUCTR as a model to be copied.

Thus the foundation of the Russian-Swiss Science and Education Center for Pharmaceutical and Biological Technologies has lead to follow-up ideas to create similar institutions in the following countries:

**in France** ("Institut Franco-Suisse des Sciences et Procédés Pharmaceutiques" at the new technical university École des Mines, Albi-Carmaux, EMAC) and

**in Spain** ("Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos" at the University of Seville).

Similar ideas are in discussion in China, Japan and Thailand.

Such institutions could complement the existing Swiss Houses, strengthening the presence of Switzerland in the area of Science abroad, promoted by the secretary of state of Research and Education and to a certain extent the Swiss Hubs to promoting economical and technology transfer relations between Switzerland and abroad.

## H.2.3 Documents of emerging similar partner institutions

### Cooperation with the Grand École des Mines Albi-Carmaux

Institute Franco Suisse at EMAC

Agreement for a facilitated access to the curriculum of a Pharmaceutical Engineer at EMAC for students who have completed a study in Pharm. sciences at the University of Basel (for students with a diploma and equivalent MSC diploma).



ÉCOLE DES MINES D'ALBI  
C A R M A U X

*Mémoire de coopération  
et lettre d'intention  
En vue de la création d'un*

**Institut Franco-Suisse  
des Sciences et Procédés Pharmaceutiques**



***Préambule :** Cette action s'inscrit dans le cadre de la mondialisation des échanges culturels et scientifiques. Elle a pour but de renforcer les liens d'amitié établis entre deux pays souverains que sont la Suisse et la France, forts tous deux de leurs traditions séculaires comme de leurs industries de haute technologie. L'axe ainsi renforcé entre les deux pays pourra dans un deuxième temps servir de base à une coopération Européenne et Internationale élargie, en réseau, dans les domaines concernés.*

**P**ar ce memorandum de coopération et lettre d'intention, échangés symboliquement entre les représentants de l'Ecole des Mines d'Albi, France, dans le cadre de sa mission de développement stratégique du Génie Pharmaceutique, et de Suisse, dont l'Institut de Technologie Pharmaceutique de l'Université de Bâle, nous entendons poursuivre les buts suivants :

#### **Article 1 : Domaines de coopération**

Ce memorandum est applicable, de manière non exhaustive, à toute discipline faisant l'objet d'enseignement ou de recherche dans les deux Institutions. Il vise principalement à travailler au progrès des sciences pharmaceutiques, particulièrement dans le domaine des poudres et procédés, attendu que 80% des formes pharmaceutiques sont des formes solides, mais également dans le domaine des bio et nanotechnologies, ou encore dans tout autre domaine connexe hautement innovant par les technologies mises en œuvres, pouvant bénéficier des complémentarités et synergies issues de ce rapprochement.

Il vise également notamment à promouvoir les « Albi International Rencontres in Pharmaceutical Engineering » (AIRPE), ainsi que la double formation de Pharmaciens-Ingénieurs de l'Ecole des Mines d'Albi.

Plus généralement, il vise à mettre en synergie les acteurs du projet et à les faire participer activement à l'espace européen et international de l'éducation, de la connaissance, de la recherche et du transfert de technologie.

#### **Article 2 : Modes de coopération**

##### **2.1. Projet :**

Il est décidé de l'établissement d'un **Institut Franco-Suisse des Sciences et Procédés Pharmaceutiques (IFSSPP)**. Cet Institut a pour objet de développer les relations de l'Ecole des Mines d'Albi dans le domaine du génie pharmaceutique en la rapprochant de partenaires Suisses, académiques, Universités ou autres Institutions ou laboratoires de statut public ou privé, et industriels du médicament ou d'industries connexes.



Chaque action de coopération sera considérée comme un projet spécifique et pourra faire l'objet d'un avenant spécifique au présent Mémoire, définissant le projet et prenant en compte notamment la durée de la coopération et les apports financiers de/et à chaque institution. Parmi ces projets possibles, on peut citer de manière non exhaustive :

- Dans la domaine de la formation :
  - Organisation conjointe de programmes de formation
  - Développement de la formation de Pharmaciens-Ingénieurs
  - Echange de Professeurs et de chercheurs
  - Echanges d'étudiants
  - Edition ou échange de documents pédagogiques
  - Utilisation de nouvelles technologies de formation
- Dans le domaine de la recherche :
  - Activités de recherche conjointes
  - Edition, publication ou échange de documents scientifiques
- Dans le domaine de la diffusion des connaissances et de la communication :
  - Organisation de missions, de colloques ou de séminaires
  - Développement des « Albi International Rencontres in Pharmaceutical Engineering »
  - Editions et publications conjointes
  - Utilisation des nouvelles technologies de l'information et de la communication
- Dans le domaine de transfert de technologie :
  - Transfert de technologie et création de start-ups

## **2-2 : Localisation**

Les parties conviennent d'un commun accord que le siège de l'Institut Franco-Suisse des Sciences et Procédés Pharmaceutiques sera localisé à **l'Ecole des Mines d'Albi-Carmaux**. Ceci permettra à l'Institut d'oeuvrer en synergie avec le Laboratoire de Génie des Procédés des Solides Divisés (UMR CNRS 2392).

## **2-3 : Soutien à projet**

Chaque projet conjoint pourra recevoir l'aide d'un tiers, constitué, de manière non limitative, d'une fondation privée, d'une société industrielle ou commerciale, d'une fondation locale ou régionale, nationale, fédérale, européenne ou internationale par exemple. Chaque projet pourra faire l'objet de recherche conjointe de financement par les parties.

Pourront être sollicités, en tant que de besoin, tous types d'organismes ou de programmes. A titre d'exemple, on peut citer l'Agence Nationale pour la Recherche, le CNRS, l'INSERM (France), le Fonds National Suisse, la Commission Technologie et Innovation (Suisse), ou encore les différents programmes Européens comme Socrates, Leonardo da Vinci, e-learning, Tempus, Erasmus Mundus, Marie Curie, ERA-link, Eureka, RTN, COST, ou les différents PCRD.



## 2-4 : Responsables du projet

D'un commun accord, les parties conviennent qu'Hans Leuenberger est choisi comme consultant pour la création de l'Institut.

Ce projet est mené dans le cadre de la mission de développement stratégique du Génie Pharmaceutique de l'Ecole des Mines d'Albi, animée par Michel Baron.

Les parties conviennent d'un commun accord de le choisir en tant que Directeur de l'Institut.

### Article 3 : Confidentialité

Les informations échangées entre les membres de chaque Institution ou partenaire resteront la propriété intellectuelle de l'Institution ou du partenaire d'origine, et seront protégées par chaque Institution ou partenaire, sauf accord expresse en vue de publication, de valorisation ou d'exploitation industrielle. Dans le cas d'invention conjointe, les Institutions ou partenaires se concerteront afin de déterminer quel type de publication ou d'exploitation il conviendrait de mettre en oeuvre.

### Article 4 : Durée de validité

Le présent memorandum est établi pour une durée d'un an et reconduit tacitement chaque année, sauf dénonciation expresse par l'une ou l'autre des parties.

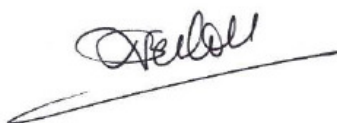
*Ce document a été établi en Français en 4 exemplaires tous originaux et authentiques.*

Albi, le 2 Novembre 2005

**Hans Leuenberger**  
Professeur et Directeur  
Institut de Technologie  
Pharmaceutique  
Université de Bâle  
Membre du Conseil Scientifique  
de l'EMAC  
Président, Swiss Association of  
Pharmaceutical Scientists



**Bruno Verlon**  
Directeur  
Ecole des Mines d'Albi-Carmaux



**Michel Baron**  
Professeur  
L.G.P.S.D. – UMR 2392  
Ecole des Mines d'Albi-Carmaux  
Responsable de la mission de  
développement stratégique  
du Génie Pharmaceutique  
de l'EMAC





## **CONVENTION DE PARTENARIAT**

### **ENTRE**

**L'Ecole Nationale Supérieure des Techniques Industrielles et des Mines d'Albi-Carmaux,**  
Campus Jarlard - 81013 Albi CT Cedex 09

représentée par son Directeur, Monsieur Bruno VERLON,  
ci-après désignée Ecole des Mines d'Albi,

**d'une part,**

### **ET**

**L'Université de Bâle, Département des Sciences Pharmaceutiques, Pharmacenter,**  
Klingelbergstrasse 50,  
4056 Basel - Suisse

représenté par le Vice-Recteur de la recherche, le Prof. Gian-Reto PLATTNER de l'Université  
et par le Prof. Hans LEUENBERGER, Directeur du Département des Sciences Pharmaceutiques  
ci-après désigné Pharmacenter,

**d'autre part,**

### **Préambule :**

La présente convention précise les conditions pour la mise en place d'un partenariat entre l'Ecole des Mines d'Albi et le Pharmacenter, en vue de l'attribution du diplôme d'Ingénieur à certains étudiants.

### **Article 1 : Modalités d'admission à l'Ecole des Mines d'Albi.**

Les étudiants du Pharmacenter doivent, pour pouvoir être recrutés à l'Ecole des Mines d'Albi,

avoir obtenu leur diplôme de pharmacien à l'Université de Basel (diplôme d'Université ou diplôme fédéral, ou diplôme équivalent : Bachelor/Master incluant thèse de Master avec unités de valeur de la filière industrie)

avoir déposé un dossier de candidature d'admission sur titres en 3<sup>e</sup> année auprès de l'Ecole des Mines d'Albi dans les délais fixés par cette dernière,

suivre une formation spécifique dans leur Université en mathématique et physique

subir les épreuves d'admission sur titres en 3<sup>e</sup> année (anglais et entretien avec jury)

Les élèves admis devront, à la rentrée, suivre des cours de mathématiques et de sciences physiques qui seront organisés par l'Ecole des Mines d'Albi selon des modalités à finaliser



**Article 2 : Enseignements suivis à l'Ecole des Mines d'Albi.**

Les étudiants du Pharmacenter, admis en 3<sup>ème</sup> année de l'Ecole des Mines d'Albi, sont soumis au règlement en vigueur à l'Ecole tant pour leurs enseignements à l'Ecole que pour les stages.

Conformément au statut de l'Ecole, ils sont d'abord recrutés sur un statut de stagiaire pendant un an et sont titularisés en fin de 3<sup>e</sup> année (la 1<sup>ère</sup> année pour eux), au vu de leurs résultats.

**Article 3 : Droits divers**

L'élève devra s'inscrire à l'Ecole des Mines d'Albi et devra s'acquitter des droits de scolarité pendant sa première et sa 2<sup>ème</sup> année à l'Ecole des Mines d'Albi.

**Article 4 : Fin d'études et équivalences**

Le sujet du stage de fin d'études de l'Ecole des Mines d'Albi qui a lieu en 4<sup>ème</sup> année (soit la 2<sup>ème</sup> année pour eux), sera validé par le Pharmacenter. Il pourra être effectué dans une entreprise industrielle ou bien dans un laboratoire académique, comme celui de l'UMR 2392 du CNRS, ou ceux du Pharmacenter. Le suivi pédagogique de ce stage sera assuré par l'Ecole des Mines d'Albi, en coordination avec le Pharmacenter.

Ils devront dans tous les cas justifier, sur la totalité de leur cursus, d'une expérience industrielle significative.

Les élèves qui auront satisfait à l'ensemble des exigences du cursus ingénieur à l'Ecole des Mines d'Albi, travail de fin d'études inclus, se verront attribuer le titre d'ingénieur diplômé de l'Ecole des Mines d'Albi.

**Article 5 : Durée de la convention**

La présente convention prend effet à la date de sa signature, et règle notamment les recrutements communs à la rentrée universitaire 2005.

Elle est signée pour deux ans, et tacitement reconduite sur une base bi-annuelle, sauf dénonciation par l'une ou l'autre des parties, avec un préavis minimum d'un an.

Fait à Basel, le 15 Octobre 2004

Le Vice-Recteur de la recherche  
du l'Université de Bâle



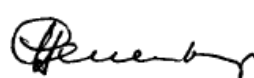
Prof. Gian-Reto PLATTNER

Le Directeur de l'Ecole  
des Mines d'Albi,



Bruno VERLON

Le Directeur du Département  
des Sciences Pharmaceutiques



Prof. Hans LEUENBERGER



ÉCOLE DES MINES D'ALBI  
C A R M A U X

**Double formation :  
Docteur en Pharmacie et Ingénieur**



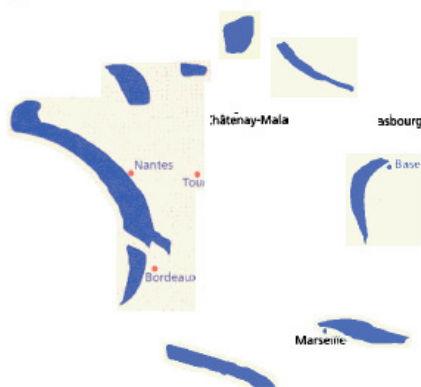
***Deux diplômes...  
une vision globale du médicament***



ÉCOLE DES MINES D'ALBI  
C A R M A U X



## Des partenaires académiques de haut niveau :



## Objectifs

Le programme d'enseignement a pour ambition de permettre au futur pharmacien ingénieur d'agir en qualité de manager pour la production ou le développement dans l'industrie pharmaceutique, et cosmétique, la chimie fine et la biotechnologie pharmaceutique, ainsi que de maîtriser les technologies actuelles et futures, et en particulier la réglementation.

## Recrutements et diplômes

Les étudiants sont recrutés sur titres après la 5<sup>e</sup> année de Faculté de Pharmacie, dans les Facultés de Pharmacie partenaires (le réseau des partenaires est à géométrie variable et extensible).

Au terme de la formation, les étudiants se voient décerner deux diplômes :

- le diplôme de Docteur en pharmacie de leur Université d'origine,
- le diplôme d'Ingénieur de l'Ecole des Mines d'Albi-Carmaux.

### Témoignage de partenaire universitaire :

« Le partenariat entre la Faculté de Pharmacie de Paris XI et l'Ecole des Mines d'Albi-Carmaux est naturel et exemplaire : notre Faculté est la plus importante en France pour la formation des pharmaciens industriels et l'Ecole des Mines d'Albi-Carmaux est, quant à elle, la première formation en France pour la formation d'ingénieurs pour l'industrie pharmaceutique. »

Pr Guy COUARRAZE  
Vice-Président Université Paris Sud

## AIRPE

Les « Albi International Rencontres  
in Pharmaceutical Engineering »

Créées à Albi, en 2001, à la demande de l'Industrie, ces journées internationales permettent aux industriels et universitaires du monde entier de se rencontrer et d'échanger leurs points de vue autour du Génie Pharmaceutique et de l'évolution du monde pharmaceutique. La troisième édition est en préparation.

## Recherche poudres à l'EMAC

L'Ecole des Mines d'Albi-Carmaux, c'est aussi l'école de l'innovation, avec 3 centres de recherche dont le Laboratoire de Génie des Procédés des Solides Divisés qui comprend 82 chercheurs permanents, doctorants et techniciens. Disposant d'un équipement de pointe, cette unité est associée au CNRS (UMR 2392). De nombreux travaux de recherche sous accord de secret y sont menés à la demande de l'industrie pharmaceutique.

## Structure de l'enseignement

L'enseignement est centré sur les sciences de l'ingénieur. L'année d'option permet d'approfondir le génie des procédés pharmaceutiques ou encore la bio-industrie, le génie industriel, l'éco-industrie et leurs environnements organisationnel et réglementaire.

Le cycle d'études a une durée de 2 ans et se conclut par un stage industriel d'au moins 6 mois. L'un des stages est réalisé à l'international.

### Le programme d'enseignement est le suivant :

#### • Première année

Les futurs ingénieurs abordent les sciences de l'ingénieur et affermissent leur savoir dans les domaines de la gestion, de l'économie et du management.

Cette année se termine par un stage assistant-ingénieur de 3 mois dans une industrie pharmaceutique. L'ensemble du programme représente un total de 800 h.

### Témoignage de partenaire industriel :

« L'industrie pharmaceutique vit une profonde mutation qui va s'accélérer dans les années à venir. Ses établissements industriels ont, par conséquent, un besoin accru de compétences nouvelles pour s'adapter à cet environnement changeant.

La double formation permet d'allier la connaissance approfondie du produit, de sa formulation et de son contrôle (que possèdent les pharmaciens) avec les techniques plus générales de l'ingénieur (méthodes d'atelier, approches technico-économiques, gestion de projet, ...).

En outre, il faut bien reconnaître que les écoles offrent aujourd'hui un réseau de partenariat international plus développé que celui des facultés, ce qui permet aux étudiants d'acquérir une connaissance indispensable d'autres environnements et d'autres cultures.

Nous ne pouvons qu'encourager ceux qui se lancent dans cette voie du double diplôme. C'est certes là un effort supplémentaire, mais, à coup sûr, générateur d'opportunités. »

Pierre GINESTET  
Pfizer PGM Amboise





#### Témoignage de partenaire universitaire :

« L'Ecole des Mines d'Albi-Carmaux dispose du plus grand centre européen en technologie des poudres. 80% des formes pharmaceutiques utilisent ces technologies en développement comme en production. L'intérêt de cette double compétence de pharmacien et d'ingénieur n'est pas à démontrer. »

Pr Dr Hans LEUENBERGER  
Directeur de l'Institut of Pharmaceutical Technology  
Université de Basel, Suisse  
Président, Swiss Association of Pharmaceutical Scientists

#### • Deuxième année :

##### « Une option d'approfondissement »

L'enseignement dispensé a pour ambition de permettre à un pharmacien ingénieur de maîtriser la technologie pharmaceutique dans le secteur de l'industrie pharmaceutique, de la bioingénierie, de l'éco-industrie dans les métiers de la production pharmaceutique, du supply chain management, ...

L'enseignement fournit également aux élèves de nombreux exemples d'applications dans des domaines particuliers où les défis scientifiques et technologiques restent nombreux. Il leur permet également d'être opérationnels dans le domaine de la recherche et du développement. Plusieurs choix d'options sont possibles : génie pharmaceutique, génie industriel, bio-industries, éco-industries, génie des systèmes d'information, ...

Des parcours fléchés panachant le génie industriel et le génie pharmaceutique sont également proposés.

L'ensemble du programme représente un total de 450h, auquel s'ajoute un travail de fin d'études de 6 mois minimum, co-encadré par l'Ecole des Mines d'Albi-Carmaux et la Faculté de pharmacie auprès de laquelle est inscrit l'étudiant.

#### Témoignage d'un pharmacien-ingénieur :

« Responsable des Opérations Pharmaceutiques dans un laboratoire pharmaceutique français (PME), j'encadre les activités de planning, production, maintenance et qualité. Au quotidien, la formation d'ingénieur complète idéalement celle de pharmacien par son approche plus pratique et plus technique. C'est une préparation concrète aux attentes de l'entreprise.

L'Ecole des Mines d'Albi-Carmaux est tout particulièrement adaptée et légitime pour proposer la double formation de pharmaciens-ingénieurs de par l'existence d'une unité poudres et procédés ainsi que par les options qu'elle propose, notamment en Génie Pharmaceutique et en Génie Industriel. »

Bertrand HIDAS  
un élève de l'EMAC



#### Témoignage de partenaire industriel :

« L'industrie pharmaceutique française qui développe des sites de classe mondiale a besoin de têtes bien faites. A cet égard, le double cursus Pharmacien-Ingénieur est une excellente préparation aux exigences du métier de producteur de médicament pour faire face, très vite et sur site, à ses responsabilités de manager gestionnaire. »

#### Evolution de la formation

Pour répondre à la demande des industriels et accompagner le Leem dans son action, l'Ecole des Mines d'Albi-Carmaux améliore en permanence le cycle Pharmacien Ingénieur :

- accroissement progressif, mais maîtrisé, du nombre d'étudiants afin de dispenser une vraie double formation sélective et de qualité,
- spécialisation affinée afin de répondre, de façon concrète, aux demandes spécifiques des entreprises partenaires ; des parcours fléchés sont proposés aux élèves en option,
- extension progressive à de nouvelles facultés de pharmacie partenaires, à leur demande.

#### Deux formations... pour quels métiers ?

- management en production haute technologie (procédés continus, ...),
- lancement et responsabilité de projets innovants,
- responsabilité en assurance qualité,
- audit international d'entreprises,
- invention et mise au point de dispositifs innovants, ...

Plus de la moitié des débouchés se situent dans le domaine de la production et de la qualité en pharmacie et cosmétique. La R & D représente un quart des débouchés. Les nouvelles options ouvertes conduisent à d'autres carrières (Bioengineering, Nutraceutique, Génie des systèmes d'information, Environnement et sécurité, ...).

#### Témoignage de partenaire industriel :

« La valeur ajoutée de cette formation est représentée incontestablement par sa « complémentarité » :

- côté diplôme pharmacien, ce sont de larges connaissances en termes de médicament, de santé publique, de réglementation, de législation, ...
- côté diplôme ingénieur, c'est la maîtrise des procédés, du management, de la productivité, ...

La polyvalence générée par ce double diplôme permet une intégration plus rapide et opérationnelle de son titulaire dans une équipe de management industriel.

En qualité d'industriels, nous avons, aujourd'hui, un besoin accru de managers à fort potentiel évolutif qui doivent être partie prenante dans l'évolution technologique de demain.

Ce double diplôme correspond, en tous points, à cette demande. »

Christian FABRE  
Directeur de l'Unité Poudres et Procédés - Groupe Pierre FABRE





## Formation Pharmacien et Ingénieur : une vision globale du médicament

« La France est le premier producteur européen de médicaments, au cœur d'une industrie pharmaceutique mondiale en profonde mutation. Nous avons l'ambition de former des Docteurs en Pharmacie Ingénieurs à l'aise dans la technique high tech de l'industrie pharmaceutique, qui maîtrisent tous les aspects du médicament depuis son élaboration et sa composition chimique ou biologique jusqu'à son procédé de fabrication, mais qui savent, également, travailler en équipe sur les projets, tout en respectant l'éthique de la profession ».



Michel Baron  
Responsable du Génie pharmaceutique à l'EMAC



## L'Ecole des Mines d'Albi-Carmaux (EMAC) :

### L'Ecole des Mines d'Albi-Carmaux

- ▶ Une école jeune (1992) et publique du Ministère de l'Economie, des Finances et de l'Industrie (MINEFI)
- ▶ Une école membre du Groupe des Ecoles des Mines (GEM) dont Paris créée en 1783
- ▶ Une école qui a reçu mission de prolonger la tradition de qualité scientifique des Ecoles des Mines dans le domaine du Génie des Procédés et, en particulier, du Génie Pharmaceutique
- ▶ Implantée sur le campus de Jarlard : 22 hectares
- ▶ 40 000 m<sup>2</sup> de bâtiments d'enseignement et de recherche



### Une école de formation d'ingénieurs

- ▶ 500 élèves ingénieurs en formation (4 années de formation confondues)
- ▶ 130 ingénieurs diplômés chaque année
- ▶ 1000<sup>e</sup> diplômé depuis 1992
- ▶ 8 options d'enseignement en 4<sup>e</sup> année
- ▶ 70 enseignants chercheurs
- ▶ 245 vacataires extérieurs issus des entreprises, universités, Grandes Ecoles partenaires
- ▶ 1 étudiant sur 2 est recruté avant la fin de ses études, souvent dans l'entreprise de son stage de fin d'études
- ▶ 88% des élèves ont trouvé un emploi 6 mois après l'obtention du diplôme
- ▶ 1/4 des ingénieurs (ou pharmaciens-ingénieurs) issus de l'EMAC travaillent aujourd'hui dans le secteur pharmaceutique ou cosmétique

### Un pôle de recherche au service de l'industrie

- ▶ 3 centres de recherche :
  - Génie des procédés des solides divisés (LGPSD)
  - Génie industriel (GI)
  - Outillage, matériaux et procédés (CROMeP)
- ▶ 100<sup>e</sup> doctorant diplômé depuis 1992
- ▶ 2 M€ de chiffre d'affaires par année civile générés par les contrats de recherche avec des entreprises dont 37 % hors de France
- ▶ 91 articles / revues et ouvrages scientifiques\*
- ▶ 99 conférences internationales avec actes\*
- ▶ 7 brevets\*
- ▶ 13 thèses\* (\* 2004)
- ▶ 7000 m<sup>2</sup> de laboratoires



ECOLE DES MINES D'ALBI  
C A R M A U X

### Un partenaire du développement économique et territorial

- ▶ Plus de 1000 entreprises partenaires
- ▶ 11 entreprises issues de l'incubateur de l'école
- ▶ 15 projets d'entreprises incubés
- ▶ 11 entreprises créées, 8 actives au 01/01/06 dont 7 installées dans le Tarn
- ▶ 25 emplois créés

Contact

#### Service Admissions

☎ : 05 63 49 32 60

☎ : 05 63 49 30 45

✉ : [admissions@enstimac.fr](mailto:admissions@enstimac.fr)

web : <http://www.enstimac.fr>

Rédaction : EMAC-Dorm-LGPSD-DE / Conception, mise en page : DNN communication  
 Directeur du Tarn, Groupe Pierre Fabre, GSK, EMC / Concepteur de l'école : Architecture et Studio  
 Crédits Photos : Profiteurs l'environnement

Campus Jarlard - 81013 ALBI CT Cedex 09 - Tél : 05 63 49 30 00 - Fax : 05 63 49 30 99





## UNIVERSIDAD DE SEVILLA

**AGREEMENT FOR ACADEMIC AND SCIENTIFIC COLLABORATION BETWEEN  
THE SWISS SOCIETY OF PHARMACEUTICAL SCIENCES (Schweizerische  
Gesellschaft der Pharmazeutischen Wissenschaften, SGPhW), THE INSTITUTE  
FOR INNOVATION IN INDUSTRIAL PHARMACY (Institut für Innovation in  
industrieller Pharmazie) AND THE UNIVERSITY OF SEVILLE**

Seville, December 4th, 2006

**This agreement is entered by and between:**

on one hand,

Prof. Dr. HANS LEUENBERGER, President of the Swiss Society of Pharmaceutical Sciences and, at the same time, Director of the Institute for Innovation in industrial pharmacy (Ifiip llc), having the address at P.O. Box, CH-4011 Basel (Switzerland).

AND :

on the other hand,

Excmo. Sr. D. MIGUEL FLORENCIO LORA, Magnificent Rector of the University of Seville.

The parts, in name and representation of their respective Institutions

**WITNESSETH:**

I.- That the signing institutions agree in their interest to facilitate the technology transfer between research centers involved in the design, characterization and optimization of pharmaceutical formulations in Switzerland and Iberoamerica, which would suppose an important impulse in the Area of the Pharmaceutical Technology, and to favour the growth of the Pharmaceutical Industry, specially in Developing countries, providing them with a higher capacity of innovation and competitiveness, contributing this way to the development of these regions.

II.- That are Institutions with juridical entity, which allows them to celebrate Agreements of this nature for the best fulfillment of their objectives.

III.- That the Centers, Departments and Research Groups of the Institutions that are cited below (and whose Letters of Intent are included in the Annexe I), have showed their support to the present Agreement and their desire to join the resultant Network of Pharmaceutical and Biopharmaceutical Technology Transfer.

A handwritten signature in cursive script, likely belonging to Hans Leuenberger.





## UNIVERSIDAD DE SEVILLA

### LIST OF INSTITUTIONS

Name	Institution	Country
Prof. Odorico Moraes	Universidade Federal do Ceará	Brasil
Profª. Gloria Holguín Martínez	Universidad de Antioquia	Colombia
Profª. Mayra González	Centro de Ingeniería e Investigaciones Químicas	Cuba
Prof. Antonio Iraizoz	Instituto de Farmacia y Alimentos. Universidad de la Habana	Cuba
Prof. Alberto Núñez Sellés	Centro de Química Farmacéutica. C. Habana	Cuba
Prof. Fausto Zaruma Torres	Universidad de Cuenca	Ecuador
Prof. René Antonio Rodríguez Soriano	Facultad de Química y Farmacia. Universidad de El Salvador	El Salvador
Prof. Isidoro Caraballo	Universidad de Sevilla	España
Prof. Ángel Concheiro	Universidad de Santiago de Compostela	España
Prof. Juan Manuel Irache	Universidad de Navarra	España
Prof. José Martínez Lanao	Universidad de Salamanca	España
Prof. Estuardo Serrano	Universidad San Carlos de Guatemala	Guatemala
Profª. Maria Jose Bernard	UNAM	México
Profª. Luz María Melgoza	UAM-Xochimilco	México
Dr. Gabriele Betz	Pharmazentrum. University of Basle	Suiza
Prof. Hans Leuenberger	Sociedad Suiza de Ciencias Farmacéuticas	Suiza
Profª. Comarlie Fernandez P.	Universidad de Los Andes	Venezuela

IV.- That the Secretariat of State of Switzerland for Education and Research (Staatsecretariat für Bildung und Forschung, SBF) is supporting a similar center in Moscow, the Russian Swiss Science and Education Center for the Transfer of Biopharmaceutical Technologies at the Mendeleyev University of Chemical Technology of Russia and has expressed his wish that more centers of this type should be created.





## UNIVERSIDAD DE SEVILLA

V.- Due to the previous considerations, the parts signatories show their interest to carry out Scientific and Academic interchanges that allow them to increase their academic relationship, establishing the suitable instruments for this purpose.

Taking all this into account they decide to carry out an Agreement of collaboration between the mentioned Institutions, in according to the following

### CLAUSES

**FIRST.-** The University of Seville, according to the legal regulations, will create the Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos.

**SECOND.-** The Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos, will have the following objectives:

1. Organization and development of transfer of technology and of processes in the field of the pharmaceutical and biopharmaceutical technology, at a national and international level. For this purpose:
  - a) There will be created a network for transfer of pharmaceutical and biopharmaceutical technology that will be managed by the Cátedra. Initially, they will belong to this network the centers, departments and research groups of the institutions related in the previous table, whose information is detailed in the Annexe 1.
  - b) Contracts or agreements for research and/or development will be performed with pharmaceutical companies and related industries.
2. Organization of specialized laboratories inside the University, to develop scientific studies.
3. Coordination of the students' formation by means of special courses, using the Infrastructure and equipment of the Network, following the technical requirements and the European standards.
4. Advanced Training of Specialists from the Industry.
5. Publication of the main Scientific Findings of the Iberoamerican and Swiss Research Organizations, to improve their commercial appeal to the International Market.
6. Depending on the specific research and development project the Network is encouraged to collaborate with sister institutions such as the Russian Swiss Science and Education Center for the Transfer of Biopharmaceutical Technologies in Moscow or the Institut Franco-Suisse des Sciences et Procédés Pharmaceutiques, Ecole des Mines d'Albi-Carmaux, Albi, France or other partner institutions.





## UNIVERSIDAD DE SEVILLA

**THIRD.-** The present Agreement may be modified or amended by mutual approval of the parts, by request of one of them. The modifications will be valid in the date of the approval by the Institutions.

**FOURTH.-** The Director of the Cátedra will be named by the Rector of the University of Seville in agreement with the President of the Swiss Society of Pharmaceutical Sciences (SGPhW) and the Director of the Institute for Innovation in Industrial Pharmacy (Iiip) in Basel.

**FIFTH.-** The present Agreement will be valid in the date of signature and will have a duration of three years, which will may be extended by equal periods automatically, unless one of the parties communicates the others through a written document and with three months of anticipation, the date of termination.

The representatives of three Institutions sign the present Agreement in the date and place ut supra.

**On behalf of UNIVERSIDAD DE SEVILLA**

**Magnificent Rector**

  
Miguel Florencio Lora

**On behalf of *Schweizerische Gesellschaft der Pharmazeutischen Wissenschaften (SGPhW)***  
**President**



Hans Leuenberger

**On behalf of *the Institute for Innovation in Industrial Pharmacy***  
**Director**



Hans Leuenberger



Figure 7 / Future Site of Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos at the University of Seville, Spain (in planning)



## Updated List of Institutions and Persons involved

Nombre / Name	Institución / Institution	País / Country
Prof. Odorico Moraes	Universidade Federal do Ceará	Brasil
Prof. Osvaldo Cavalcanti	Universidade de Maringá	Brasil
Prof. Alberto Núñez Sellés	Centro de Química Farmacéutica. C. Habana	Cuba
Prof. Antonio Iraizoz Colarte	Instituto de Farmacia y Alimentos. Universidad de la Habana	Cuba
Prof. Elisa Jorge Rodríguez	Universidad Central de Las Villas	Cuba
Prof. Mayra González	Centro de Ingeniería e Investigaciones Químicas	Cuba
Prof. Adriana Ruiz Correa	Universidad de Antioquia	Colombia
Prof. Fausto Zaruma Torres	Universidad de Cuenca	Ecuador
Prof. René Antonio Rodríguez Soriano	Facultad de Química y Farmacia. Universidad de El Salvador	El Salvador
Prof. Juan Manuel Irache	Universidad de Navarra	España
Prof. Ángel Concheiro Nine	Univ. de Santiago de Compostela	España
Prof. Isidoro Caraballo Director CISDEM	Universidad de Sevilla	España
Prof. José Martínez Lanao	Universidad de Salamanca	España
Prof. Estuardo Serrano	Univ. San Carlos de Guatemala	Guatemala
Prof. José Quiroz Oropeza	Universidad Autónoma de Puebla	México
Prof. Luz María Melgoza	UAM	México
Prof. Maria Jose Bernard	UNAM	México
Prof. Hans Leuenberger Presidente de Honor, Honorary President CISDEM	Sociedad Suiza de Ciencias Farmacéuticas Swiss Society of Pharmaceutical Sciences (SSPhS/SGPhW)	Suiza
Dr. Gabriele Betz	Universidad de Basilea	Suiza
Prof. Cormarie Fernández Pulido	Universidad de Los Andes	Venezuela



#### H.2.4 Farewell-Symposium on the occasion of the retirement of Prof. H. Leuenberger

##### Program

A Farewell-Symposium was arranged by Prof. Dr. G. Imanidis on October 19, 2006 (see announcement below).



The poster is enclosed in a thick yellow border. At the top, a blue oval contains the name 'Hans Leuenberger'. Below it, the words 'Farewell Symposium' are written in a large, black, stylized font. To the right, another blue oval contains the date 'October 19, 2006'. Further right is the logo of the University of Basel, consisting of a stylized star or snowflake shape with the text 'UNI BASEL' underneath. Below the text, there are two photographs: on the left, a portrait of Hans Leuenberger, a man with glasses and a dark suit; on the right, a photograph of a modern, multi-story building with many windows, identified as the Pharmacentre. Below the photographs, the text reads 'at the Pharmacentre'. Further down, it states 'on the occasion of the retirement of Professor Dr. Hans Leuenberger, Head of the Institute of Pharmaceutical Technology, University of Basel, 1982 - 2006.' At the bottom, the address 'Klingelbergstrasse 50, 4056 Basel' and 'Big Lecture Hall' are listed. A thick blue horizontal line is positioned below the address.

Hans Leuenberger

**Farewell Symposium**

October 19, 2006

UNI  
BASEL



at the  
Pharmacentre

on the occasion of the retirement of  
Professor Dr. Hans Leuenberger,  
Head of the Institute of Pharmaceutical Technology,  
University of Basel, 1982 - 2006.

Klingelbergstrasse 50, 4056 Basel  
Big Lecture Hall



## Morning Program

10.15-10.45	<b>Dr. Andreas Rummelt</b> CEO Sandoz AG	Kooperation Universität – Industrie Cooperation University - Industry
10.45-11.00	<b>PD Dr. Marcel Mesnil</b> Secretary-General SAV	Words of farewell
11.00-11.30	<b>Dr. Bernhard Luy</b> COO, Glatt AG/Glatt GmbH	Academia and Technical Applications: Hans Leuenberger as an interface to the pharmtech industry - a personal perspective
11.30-11.45	<b>Werner Glatt, Founder and Honorary President GLATT AG</b>	Words of farewell

## Buffet Lunch

## Afternoon Program

14.00-14.30	<b>Prof. Yoshiaki Kawashima</b> Aichi Gakuin University, Japan	Design of nanocomposite with percolation theory for drug delivery system
14.30-14.45	<b>Dr. Martina Burdeska</b> formerly President GSIA	Words of farewell
14.45-15.15	<b>Prof. John Dodds and Prof. Michel Baron,</b> Centre RAPSODEE CNRS-Ecole des Mines d'Albi, France	Powder technology for the pharmaceutical industry
15.15-15.30	<b>Dr. Christine Moll</b> Vice-President SGPhW	Words of farewell
15.30-16.00	<b>Prof. Natalia Menshutina</b> Mendeleyev University of Chemical Technology, Russia	Russian – Swiss Science and Education Center for Pharmaceutical Technologies
16.00-16.30	<b>Prof. Georgios Imanidis</b> School of Life Sciences, University of Applied Sciences Northwestern Switzerland FHNW & Uni Basel	Das wissenschaftliche Leben von Hans Leuenberger The scientific life of Hans Leuenberger
16.30-17.00	<b>Prof. Andres Zuberbühler</b> University Basel, & SATW, WBR	Persönliche Erinnerungen Personal memories

**Please register with:** Prof. Dr. Georgios Imanidis  
**E-mail, Tel:** [georgios.imanidis@fhnw.ch](mailto:georgios.imanidis@fhnw.ch), +41 61 467 46 80  
**Address:** Prof. Dr. Georgios Imanidis, School of Life Sciences  
 FHNW, Gründenstrasse 40, 4132 Muttenz

The Farewell-Symposium was opened by Prof. Dr. Matthias Hamburger, Deputy Head of the Department of Pharmaceutical Sciences. The author of this annual report thanks him and all the speakers for the kind words of farewell. He thanks especially Prof. Dr. Georgios Imanidis (who has kept secret the program till the last moment) for the organisation of this event. Last but not least the author of this annual report wants to thank for all the gifts of farewell he received at this event, which touched him very much.



## Report on the Farewell-Symposium by Dr. Tadatsugu Tanino in Pharm Technology, Japan.

The author of this annual report thanks Dr. T. Tanino from Shionogi for the continuous support of the Shionogi company.



塩野義製薬株式会社 CMC開発研究所 製剤研究部

谷野忠嗣

TADATSUGU TANINO

CMC Development Laboratories, Shionogi & Co., L



退官記念シンポジウム会場の大講義室  
(最前列：ロウエンバーガー教授)



バーゼル大学Pharmazentrum前で筆者



川島教授のご講演  
(舞妓さんを挟んでの写真  
粉体工学世界会議・京都)

### はじめに

去る2006年10月19日にハンス ロウエンバーガー教授の退官記念国際シンポジウムがバーゼル大学ファーマセンター大講堂(Klingelbergstrasse 50 4056 Basel)において開催された。

このシンポジウムでは、ドイツの製剤機械メーカーであるGlatt社の創業者Werner Glatt名誉会長や愛知学院大学の川島嘉明教授、ロシアMendeleyev大学のNatalia Menshutina教授、スイス薬学会の副会長Cristine Mol博士、フランス Centre RAPSODEE CNRS-Ecole de Mines d'AlbiのJohn Dodds教授、そしてMiche Baron教授など、産業界や教育・研究機関からロウエンバーガー教授の業績について感謝と祝辞を交えた詳細な紹介が行われ、約140人の参加者はロウエンバーガー教授の薬剤学・製剤工学の分野における功績の大きさをあらためて再認識した。

### パーコレーション理論を解説したシンポジウム

演者の中でとりわけ注目を受けたのは川島教授で「パーコレーション理論を応用したナノコンポジットの設計」と題した招待講演の中でロウエンバーガー教授が世界で初めてパーコレーション理論を製剤設計に応用されたことを称えとともに、日本での思い出やウィットに富んだスライドを織り交ぜながら20年来の同教授との深い親交を紹介され、会場から盛んな歓声と拍手を受到了。

ロウエンバーガー教授は1971年にバーゼル大学にて核物理学の研究で博士号を取得された後、サンド社(現ノバルティス)に入社され、1979年には米国ミシガン大学のW. I. Higuchi教授の研究室に留学されるなど国際経験を積みながらサンド社の製剤開発部門のグループリーダーを担当された。その後、1982年にバーゼル大学



バーゼル大学 ハンス ローエンバーガー教授  
退官記念国際シンポジウムレポート



ローエンバーガー教授の退官の挨拶



ローエンバーガー教授主催のディナーにてご夫妻を囲んで  
中列左端、川島教授、右端、筆者

教授に就任され、170を超える論文と10件の特許を取得するなど精力的な研究活動をされる一方で、世界各国の研究機関や学会の役員や理事を歴任され、行政との架け橋としてもご活躍されるなど薬学研究へのグローバルな貢献は顕著である。また、第2回粉体工学世界会議(京都)、第6回造粒に関する国際シンポジウム(名古屋)、FIP(東京)、世界薬学会議(京都)、粉体工学会・製剤と粒子設計シンポジウムでの学術賞受賞講演、パウレック製剤技術講演会特別講演、その他の国際会議やシンポジウム等で日本へも頻繁に来られており、実直で熱意に満ちた優しいお人柄の教授をご存知の方は非常に多いであろう。

ローエンバーガー教授はバーゼル大学に就任した当初からPAT(Process Analytical Technology)の概念や重要性についても提唱してこられ、教授が描いた医薬品製

造の理想像である「すべての製造プロセスおよびパラメータがコントロール・モニタリングされた出荷試験不要のシステム構築」に向けた研究の業績は、われわれ医薬品産業に従事する者にとって大きな道標となっている。またバーコレーション理論を製剤設計に応用する研究は、旧来の試行錯誤的あるいは経験的手段による製剤開発方法から、合理的で科学的な製剤開発方法へと新たな扉を開く嚆矢として高く評価されている。

シンポジウムの最後にあたり、ローエンバーガー教授は退官の辞として「人と人との繋がりの大切さ」を熱く語られ、参加者は総立ちとなって惜しめない拍手を送った。

表1にシンポジウムプログラムとポスターを示す。

表1 シンポジウムのポスターとプログラム

**Hans Leuenberger**  
**Farewell Symposium**  
October 19, 2006

at the  
**Pharmacentre**

on the occasion of the retirement of  
Professor Dr. Hans Leuenberger,  
Head of the Institute of Pharmaceutical Technology,  
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16.30-17.00	Prof. Andres Zuberbühler University Basel, & SATW, WBR	Persönliche Erinnerungen Personal memories
Please register with: Prof. Dr. Georgios Imanidis		
E-mail, Tel. georgios.imanidis@fhnw.ch, +41 61 467 46 80		
Address: Prof. Dr. Georgios Imanidis, School of Life Sciences		
FHNW, Grödenstrasse 40, 4132 Muttenz		



バーゼル大学 ハンス ローエンバーガー教授  
退官記念国際シンポジウムレポート



シュバレントール門で  
筆者



市立美術館



旧市庁舎

## バーゼル大学・バーゼル市について

さて 短 ゼル大学 ゼル市に  
紹介 みたい

バーゼル大学は1459年に創立されたスイスで最古の大学であり、『愚神礼賛』を著した人文主義者エラ  
実存哲学の先駆者ニーチェ、18世紀最高の数学者 称さ  
れるオイラー、微積分学の確立に大きく寄与した  
ーイラ歴史に名を残す学者が教鞭を取  
有名である。一方、バーゼル市はスイス北西部を滔滔  
(とうとう)と流れるライン川のほとりに位置し、ドイ  
ツ・フランスと国境を接する要衝として、また盛大なカー  
ニバルや時計見本市が開かれるところとして世界的に  
有名である。このライン川は大型船が北海まで航行可能  
であることから各種工業が盛んとなり、最初に発展を遂  
げた繊維工業に対して染料を供給するために化学工業が  
興り、そして化学工業から薬品工業が派生し、現在では、  
メガファーマのノバルティスやロシュの本社を擁する製  
薬業の世界的な中心都市の1つとして位置づけられている。

バーゼル市は文化芸術の分野でも有名であり、1671年  
から公開されている市立美術館は世界で最も古い公共美  
術館の1つである。1976年にピカソの2つの作品「座る  
アルルカン」と「二人の兄弟」が国外に売却される危機  
に際してはバーゼル市の財政で買い入れるために住民投  
票まで実施して資金を調達したという逸話が残るなど、  
バーゼル市民の芸術に対する造詣は非常に深いものがある。

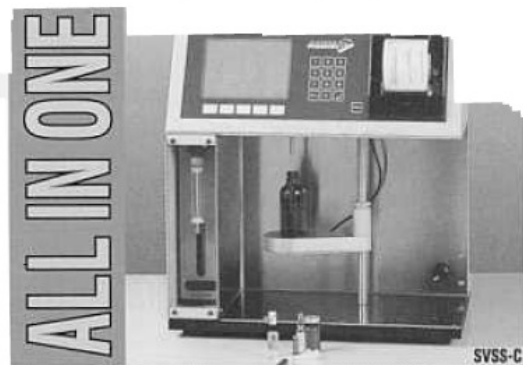
ローエンバーガー教授の研究室に弊社から留学中の明  
星英俊氏の案内でシュバレントール門、旧市庁舎など旧  
市街地を駆け足で散策したが、深まる秋に溶け込む町並  
みの美しさ、そして歴史的な風格とその落ち着いた佇ま  
いには深い感銘を受けた。楽しみにしていた市立美術館

ンス ホルバイ 作の 死せる

カ作の「風の花嫁」など 鑑賞は時間、都  
合で果たせなかったが、歴史あ る市の文化 薫  
りは今もなお強く印象に残っている。

このような素晴らしいバーゼル市そして 伝統ある  
ゼル大学で輝かしい業績を収めてこられ  
ガー教授は新たにInstitute for innovation in industrial  
pharmacyを冠するコンサルティング会社Ifiip GmbH  
(www.ifiip.ch)を設立されており、現在複数の国際プロ  
ジェクトを計画中とのことである。ハンス ローエンバ  
ーガー教授の今後ますますのご健康 舌躍を 筆な  
ら心よりお祈りしたい。

## JP15/USP24/ISO4402完全適合 液体用パーティクルカウンター



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●少量サンプルにも高い容量精度 ●高い最大粒子濃度:(例)110,000個/ml



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## Prof. Hans Leuenberger at Basel University Farewell Symposium report (pg., 133-134)

By Tadatsugu Tanino, CMC Development Laboratories, Shionogi & Co., Ltd.

Farewell symposium of Prof Hans Leuenberger was held at the Pharmacentre at Basel University on Oct. 19. 2006. In the symposium, Mr. Werner Glatt, founder of Glatt, formulation machinery company in Germany; Prof Yoshiaki Kawashima from Aichi Gakuin University; Prof Natalia Menshutina from Mendeleev University in Russia, Dr. Christine Moll, vice president of Swiss Society of Pharmaceutical Sciences, Prof John Dodds, Prof Michel Baron from École des Mines d'Albi, France, so on... about 140 participants from industries, educational or research categories, appreciated again the achievement of Mr. Leuenberger, in the field of pharmacy and formulation engineering.

Comment on percolation theory.

Prof Kawashima, in his lecture, titled "Design of nano-composite with percolation theory", he admired Mr. Leuenberger who applied percolation theory for the formulation design first in the world. Prof Kawashima also introduced some episodes of Mr. Leuenberger with some slides that he has collected for 20 years of their relationship.

After having a PhD, in nuclear physics in 1971 at Basel University, Mr. Leuenberger worked for Sandoz Co. (actually Novartis). In 1979, he went study-abroad to Prof W.I.Higuchi laboratory at the University of Michigan, in USA. As accumulating international experiences; Mr. Leuenberger was a group leader in a division of formulation development in Sandoz Co. In 1982, Mr. Leuenberger was inaugurated as a professor at Basel University and he energetically worked on his researches. Meanwhile, he became an executive or a director of research associations in many countries. His global contribution to pharmaceutical researches is remarkable. The 2<sup>nd</sup> Powder technology world conference (Kyoto), The 6<sup>th</sup> International symposium for producing particles (Nagoya), World pharmaceutical conference (Kyoto), Formulation and particle design symposium by The society of Powder Technology, Formulation technology exhibition by Powrex and so on. Mr. Leuenberger has been to Japan often. Many people might know him, his honest, eager and kind personality.

Since Mr. Leuenberger was inaugurated at Basel University, he has suggested the concept and importance of PAT, and his idealization of medical products producing; "building the system which can control and monitor all the making processes and parameters, and makes final-check unnecessary". ---Effort of researches toward this, gives a meaningful guideline for us who are in a pharmaceutical industry. And the research that is applying percolation theory in formulation design is very much appreciated as a key to open the new door for the rational and scientific formulation development method from the traditional "trial-and-error" method.

At the end of the symposium, Mr. Leuenberger speaks passionately about "importance of link between people". Big lecture hall was in a standing ovation.

Page 135 presents small information about Basel University and the city of Basel. The location of the city, how the city becomes industrial especially for chemicals, and about the museum...so on. At the end of the column, the reporter (Mr. Tanino) wishes Prof. Leuenberger a good health and energetic performance. Translation: Mrs. Megumi Baron.

## Interview by Pharm-Tech Japan

The author of this report thanks Pharm-Tech Japan for this offer to give a interview (published in Japanese, see below the English translation) in presence of T. Takashima, president of the Powrex Corporation Japan and Prof. Dr. Yoshiaki Kawashima, on the occasion of receiving the "50<sup>th</sup> Anniversary Award of the Society of Powder Technology of Japan" (SPTJ).

## Mr. Hans Leuenberger at Basel University established a venture enterprise "Ifip" (pg., 38-39)

Hans Leuenberger, the University of Basel

**Prof. Leuenberger has established the venture company Ifip and started consulting.**

An international symposium to commemorate the retirement of Hans Leuenberger, a University of Basel Professor who has presented more than 170 articles in the powder technology and manufacturing process fields, acquired 10 patents and also taken in large numbers of researchers from Japan, was held on 19<sup>th</sup> October 2006 (for details, please refer to the report in this issue by Dr. Tanino). Prof. Leuenberger has established a venture company, Ifip (Institute for innovation in industrial pharmacy), which is developing consulting business for manufacturing process technologies such as formulation design, scaling-up and PAT.



I listened to Prof. Leuenberger talking about the future development of his business.

#### **Advocating the importance of understanding manufacturing processes.**

Prior to becoming a professor at the University of Basel in 1982, Prof. Leuenberger worked as a Group Leader in the Pharmaceutical Research and Development Department at Sandoz Ltd. (currently Novartis), supervising research related to innovative DDS system and manufacturing processes.

Prof. Leuenberger says “However independent of how epochal the systems that we developed in my time at Sandoz were, conservative people at the company usually asked me ‘Is the FDA going to approve this?’ or ‘Is this a method that can be scaled up?’ and we were really quite unable to answer this question and to convince the Manufacturing Department to invest in our innovative DDS or new manufacturing process. This experience in industry gave me the motivation - after I have moved to university - to start an intensive collaboration with equipment manufacturers for the pharmaceutical industry. A new DDS and a new manufacturing process have only a value if these innovative systems and processes can be really scaled-up. This research concept of Prof. Leuenberger attracted the interest of FDA some 4 to 5 years ago. In 2002, Dr. Ajaz Hussain and Helen Winkle paid a visit to the research labs of Prof. Hans Leuenberger at the University of Basel (see: invited review paper. “Pharmaceutical Powder Technology – from Art to Science: the challenge of FDA’s Process Analytical Technology Initiative, Adv. Powder Techn. 16, (2005) pp.3—25) In 2004 the FDA announced the 21<sup>st</sup> Century Initiative and the positive promotion of the introduction of new technologies including PAT (Process Analytical Technology) to be understood as to build-in and not to test-in the quality. Prof. Leuenberger was advocating this “science based” approach to understand pharmaceutical processes and formulations since his nomination as a professor in 1982 at the University of Basel. He was always demonstrating great interest in his research to the control and monitoring of processes and parameters especially in the manufacturing pharmaceutical solids.

“The concept of PAT came to be incorporated in the manufacturing process for pharmaceutical preparations by Ajaz Hussain Ph.D., the spiritual leader and inventor of PAT, when he, worked at the FDA. Understanding of the manufacturing process is essential in scaling-up, and the construction of a new manufacturing process requires improved manufacturing efficiency and quality. The semiconductor industry with its 6-sigma concept understands the manufacturing process well and has excellently implemented the PAT concept. However, I think the pharmaceutical industry still “lags behind”. Thus, there is room for improvement in the design of formulations and of pharmaceutical processes. This is especially true for pharmaceutical solids and it has to be kept in mind that the majority of the pharmaceutical formulations currently on the market are pharmaceutical solids”. Professor Hans Leuenberger is confident that, by using his research results in the field of powder technology, it becomes possible to guarantee the robustness of quality of pharmaceutical products. This gave him the motivation to found Ifip, the Institute for innovation in industrial pharmacy.

#### **Aiming at Venture Company producing innovation.**

The method for application in pharmaceutical design of the percolation theory Prof. Leuenberger advocates is an opportunity to change pharmaceutical preparation from the conventional trial and error style method to a scientific one. Percolation is a theory intended to answer the questions of how targeted substances are connected within a system and how the characteristics of substances are reflected in the characteristics of a system. It is said that by applying this theory, such things as the probability of a substance within a preparation dissolving due to a solvent can be understood.

“The venture company I established, Ifip, provides optimum formulation designs to which percolation theory has been applied and will also provide freeze-drying technology and product lifecycle extension support. Furthermore, we will also work on the development of expert systems for formulation. In addition, we will be providing consultancy services related to the construction of manufacturing processes that incorporate the concept of Quality by Design and PAT. As formulation design and process technology are integral to each other, I want to develop innovative technologies. Ifip has a network around the world, in Russia (Moscow), Japan and other places apart from Switzerland so it will be possible for us to provide innovation as a driving force aimed at further expansion of our customers’ businesses.”

In Japan, Prof. Yoshiaki Kawashima of Aichi Gakuin University (Nagoya) has applied percolation theory to design nanocomposites for example, and is serving as a partner in Prof. Leuenberger’s research activities.

#### **Acceptance of a Special Overseas Prize from the Society of Powder Technology, Japan.**

Prof. Leuenberger took in a great many visiting students from Japan at the University of Basel and also visited Japan frequently in order to give lectures at academic society meetings in this country. Prof. Leuenberger’s success as a bridge for powder technology between Japan and other countries has been recognized and a Special Overseas Prize was conferred on the professor at the 50th Anniversary Event of the Society of Powder Technology, Japan, which was held on 8th November 2006 at the Makuhari Messe.



Prof. Leuenberger says, "According to my knowledge there is no other society - outside of Japan - as the "Society of Powder Technology of Japan" that has been established for as long as 50 years. This is a splendid thing. Powder technology is an important area of study that can be applied in various fields. Japan can probably lead the way in the field of powder technology. In future, I would like to cooperate with Japan to advance lots of research. I thank you very much for this interview".

## H.2.5 Interview by PharmaJournal (Switzerland)

### Résumé

## A l'occasion du départ à la retraite du Prof. Hans Leuenberger, Bâle

Le Prof. Hans Leuenberger, professeur ordinaire de technologie pharmaceutique au département de pharmacie de l'Université de Bâle pendant de nombreuses années, a récemment pris sa retraite. Il a officiellement pris congé à l'occasion d'un symposium. Claudia Reinke en a profité pour poser quelques questions au scientifique et détenteur de la chaire de technologie pharmaceutique. Voici en quelques mots les principaux jalons de sa carrière professionnelle: soutien politique du département de pharmacie de l'Université de Bâle par le gouvernement en faveur d'un pôle pharmaceutique fort dans la ville de Bâle, travaux de recherche modernes grâce à l'approche scientifique du «Industrial Pharmacy Lab», acceptation de la technologie pharmaceutique comme science universitaire – le véhicule est en effet tout aussi important que le principe actif pour l'effet d'un médicament, encouragement de la collaboration entre les pharmaciens d'industrie et les ingénieurs pharmaceutique, avenir des pharmaciens d'officine et recherche d'un successeur pour la chaire qu'il a quitté fin octobre. ■

The author of this report thanks PharmaJournal and Dr. C. Reinke for this offer to give this interview. (French Résumé on the left, Interview in german, see below).

The context of this interview is linked to the history of pharmacy education and the new building, the Pharmacenter. The author takes the opportunity to thank all the friends, who helped to realize this new building. A special thank is dedicated to the members of the Basel Parliament, who favoured the bill to build the Pharmacenter, strengthening the education of pharmacy in the town of pharmacy of Switzerland.



pharmaJournal spricht mit Prof. Hans Leuenberger, Basel

## Pharmazie Studium Generale mit variablen Berufsbildern

Am 19. Oktober 2006 wurde Professor Dr. Hans Leuenberger, Ordinarius für Pharmazeutische Technologie am Departement Pharmazie der Universität Basel, nach 24-jähriger Tätigkeit im Rahmen eines Symposiums offiziell vom Departement, von Kollegen, ehemaligen Doktorandinnen und Doktoranden und langjährigen Weggefährten aus Industrie und Wissenschaft verabschiedet. Das pharmaJournal hat dies zum Anlass für ein Interview genommen, nicht nur um zurückzublicken, sondern auch um die Zukunft der Pharmazie aus seiner Sicht zu erfragen.



Hans Leuenberger

*Wie haben Sie die Entwicklung der Pharmazie in Basel in Ihrer Zeit als Inhaber des Lehrstuhls für Pharmazeutische Technologie (1982–2006) erlebt?*

Ich erinnere mich gut an ein Mittagessen mit Arnold Schneider, dem damaligen Erziehungsdirektor, nachdem ich 1982 mein Amt angetreten hatte. Er legte mir ans Herz, unbedingt ein neues Gebäude zu suchen. Schon allein aus Gründen der Sicherheit könne das alte Institut am Totengässlein 3 keine dauerhafte Lösung sein. Obwohl die Existenzberechtigung der Pharmazie an der Uni Basel von verschiedener Seite immer wieder in Frage gestellt wurde, hat der Grosse Rat 1992 einem Neubau zugestimmt, in dem die Pharmazie fünf Stockwerke erhalten sollte. Ich hatte dies als ein klares Votum der Regierung und des Parlamentes für eine starke Pharmazie in der Pharmastadt Basel verstanden. Die Universität hat dies nicht so gesehen und unseren Platzbedarf von fünf Stockwerken vehement bestritten. Ein Freund fragte mich damals, ob wir in der Eidgenossenschaft oder in einer Neidgenossenschaft lebten. Mein Kollege Prof. Schaffner wurde damals vom Rektorat überzeugt, für sein Institut Pharmazeutische Biologie Räumlichkeiten in Witterswil zu beziehen. Im Jahre 2000 konnten wir schliesslich in das neue Gebäude einziehen, mussten jedoch zweieinhalb Stockwerke an andere Nutzer abgeben. Der Pharmazeutischen Technologie wurde eine zusätzliche Aussenstation genehmigt, die wir zu einem Industrial Pharmacy Lab ausbauen konnten. Diese Aussenstation ist für unsere Forschung sehr wichtig geworden.

*Und wenn Sie auf diese Jahre nun als Hochschullehrer und Wissenschaftler zurückblicken?*

Entgegen dem damaligen Trend habe ich mich 1982 entschlossen, mich auf die Erforschung der festen Arzneiformen und neuer Prozesstechnologien wie die Sprühgefrier-Trocknung zu konzentrieren. Ich war überzeugt, dass es auch nach dem Jahr 2000 noch Tabletten als Wirkstoffträger geben würde, denn sie sind bequem einzunehmen und leicht zu dosieren. Als sich vor ein paar Jahren sogar die FDA für unsere Forschung und unsere Labors, insbesondere die Aussenstation, interessiert hat, war ich allerdings einigermassen überrascht. Zu der Zusammenarbeit mit der FDA in der Aussenstation waren auch Vertreter der Basler Pharmaindustrie eingeladen. Einer unserer Gäste meinte damals, in unseren Labors sähe es gar nicht GMP-mässig aus. Ajaz Hussain, der eigentliche Vater der Process Analytical Technology Initiative der FDA, bemerkte daraufhin, dass das in der Forschungsphase nur die Kreativität beeinträchtigen würde. Diese Art Forschung, wie wir sie hier am Institut betreiben, sei der richtige Weg, um – im Sinne eines science-based approach – den Prozess der Arzneiformulierung im Detail besser verstehen zu lernen. Damit könnte man letztlich von der Kunst zur Wissenschaft gelangen, was ganz im Sinne der FDA sei, die in Zukunft vermehrt dazu beitragen möchte, dass die Prozesstechnologie und die Arzneiformulierung besser verstanden und kontrolliert werden können. Darüber haben wir uns natürlich sehr gefreut.

Auch in anderem Zusammenhang ist mir klar geworden, dass wir mit unserer

Forschung recht modern sind. In Basel sollen ja im Rahmen des geplanten neuen Life-Science-Institutes komplexe (biologische) Systeme von der Molekülstruktur bis zur biologischen Funktion untersucht werden, was später möglicherweise auch zu neuen Erkenntnissen über die Entstehung und Therapie verschiedener Krankheitsbilder führen wird («Systems Biology»). In gewisser Weise arbeiten wir in der Pharmazeutischen Technologie auch mit komplexen Systemen: Jede Formulierung, die aus einem Wirkstoff und vielen Hilfsstoffen besteht, ist ein komplexes System – wenn auch in ganz kleinem Massstab. Dennoch lassen sich die Gesetzmässigkeiten komplexer Systeme schon an diesem Beispiel studieren. Die Ziele sind vergleichbar: Wir suchen ja alle nach geeigneten Methoden, um das Verhalten solcher Systeme besser zu verstehen, damit wir sie letztlich entsprechend steuern können.

*Dann sind Sie nach wie vor der Ansicht, dass die Pharmazeutische Technologie Hochschullwissenschaft sein und bleiben sollte?*

Auf jeden Fall. Es ist ja nicht nur der Arzneistoff, der für die Wirkung eines Medikaments ausschlaggebend ist, sondern auch das entsprechende Vehikel. Ohne optimales Vehikel, das für die entsprechende Bioverfügbarkeit verantwortlich ist, wird auch der bestmögliche Arzneistoff keine Wirkung haben. Kenntnisse über die verschiedenen Formulierungen und ihre Gesetzmässigkeiten sind daher meines Erachtens wichtige Grundlagen für Industrie-, Offizin-, Spital- und Amtsapotheker und erfordern eine gemeinsame universitäre Ausbildung.



Nach der, nach dem Massstab der ETH Zürich durchgeführten, Evaluation der beiden Schwesterinstitutionen des Pharmazentrums Basel-Zürich, wo Basel sehr gute Noten erhielt, wurde 2003 von Prof. Dr. Gian-Reto Plattner, Vizerektor Forschung, angeregt, neben dem klinischen Teil des Departements auch die Pharmazeutische Technologie zu stärken. Er deutete dabei die Möglichkeit der Schaffung von Doppelprofessuren mit der in Planung befindlichen Fachhochschule für Life-Science der neuen Fachhochschule (FH) Nordwestschweiz an. Die FH hätten viel Geld. Da die Industrieapotheker in der Regel mit einem Doktorat abschliessen, das nur an der Universität erworben werden kann, war selbst zur Zeit von Staatssekretär Ursprung, der die Offizinapotheker-Ausbildung an die FH abgeben wollte, eine Verschiebung der Ausbildung von Industrieapothekern an die FH kein Thema. Dies könnte jedoch aktuell werden, sobald die FH das Promotionsrecht erhalten.

Im Zusammenhang mit der geplanten Stärkung der Pharmazeutischen Technologie an der Universität hatten wir von der Universität Basel und der Fachhochschule beider Basel (heute FH Nordwestschweiz) mit starker finanzieller Unterstützung durch das Bundesamt für Bildung und Technologie den Auftrag bekommen, ein Modell für eine optimale Zusammenarbeit zwischen der Universität und der Fachhochschule zu erarbeiten. Das Resultat, das von einer hochkarätigen Arbeitsgruppe mit Vertretern der drei Institutionen zusammen mit der Industrie erarbeitet wurde, hat Muster-Charakter. Neben internationalen waren auch mittelständische Unternehmen beteiligt und so konnten die Profile der beiden komplementären Berufsbilder, nämlich das des Industrieapothekers mit universitärer Ausbildung sowie des Pharma-Ingenieurs mit Fachhochschulausbildung, hervorragend definiert werden. Die Idee dahinter ist die enge Zusammenarbeit, wobei der Industrieapotheker für die Entwicklung der Formulierungen und der Pharma-Ingenieur für die technischen Belange, also Maschinen, Anlagen, Raumkonzepte usw. zuständig ist. Eine solche Zusammenarbeit fördert eine klare Kompetenz- und Aufgabenteilung auch zwischen der Universität und der Fachhochschule. Ausserdem fördert dieses Modell eine fruchtbare Kooperation zwischen Universität, Industrie und Fachhochschulen am Standort

Basel, dem Pharma-Hub mit Weltruf. Gedacht wurde dabei u.a. an die gemeinsame Nutzung einer Technologie-Plattform durch die Universität und die FH im Rahmen eines entsprechend gross dimensionierten Industrial Pharmacy Labs.

*Zum Berufsbild des Offizin-, Spital- und Industrieapothekers käme also noch der Pharma-Ingenieur dazu. Das würde eine weitere Bereicherung des pharmazeutischen Berufsbildes bedeuten.*

Ja, das ist so. Das Beste an den Pharmazeutischen Wissenschaften ist diese breite Fächerung – es ist wahrscheinlich das einzige Studium Generale. Die verschiedenen Berufsbilder können sich gegenseitig befruchten, wenn sie eng miteinander zusammenarbeiten. Darüber hinaus wird es in Basel durch den neuen, von pharmaSuisse gesponserten Lehrstuhl für den Bereich klinische Pharmazie/Pharmaceutical Care eine weitere Bereicherung des Pharmaziestudiums geben, von der vor allem die Ausbildung der Offizinapotheker profitieren wird. Diese Entwicklung finde ich sehr positiv. Diese Stossrichtung ist ebenfalls völlig im Sinne der FDA, die der Meinung ist, dass der Bereich des «Drug Discovery» heute kein Flaschenhals mehr darstellt, während Forschungen im Bereich der Umsetzung vom Wirkstoffmolekül zum Medikament vermehrt gefördert werden sollten. Zu diesem Bereich gehören Fragen der Toxikologie, der Klinik (Nachweis der Überlegenheit des neuen Medikaments) und der Pharmazeutischen Technologie (Frage des Vehikels, der Arzneiform).

*Im Gegensatz zu den Spital- und den Industrieapothekern inklusive dem neuen Pharma-Ingenieur sehen die Offizinapotheker durch die Turbulenzen in einem sich zunehmend wandelnden Gesundheitssystem einer möglicherweise etwas schwierigeren Zukunft entgegen. Die Selbstdispensation erschwert das Ganze zusätzlich. Wie sehen Sie die Zukunftsaussichten des Apothekerberufs?*

Der Apothekerberuf wurde schon oft totgesagt, ich bin da nicht so pessimistisch. In den USA beispielsweise besteht ein Riesenbedarf an Apothekerinnen und Apothekern, die in den Drug Stores tätig sind und dort die Kundschaft beraten.

Die amerikanischen Universitäten haben deshalb die pharmazeutische Ausbildung vorwiegend auf die Offizinapotheker fokussiert.

*Offiziell sind Sie Ende Oktober von Ihren Aufgaben als Lehrstuhlinhaber zurückgetreten. Wie sieht es denn mit Ihrer Nachfolge aus?*

Hier ist das letzte Wort noch nicht gesprochen, aber ich gehe davon aus, dass diese Stelle neu besetzt werden wird. Wie das so üblich ist, bin ich natürlich nicht in die Nachfolge involviert. Soweit ich aber weiss, ist neben dem Lehrstuhl für Pharmazeutische Technologie, für den offenbar zwei Kandidaten in Diskussion stehen, auch die Schaffung eines Lehrstuhls in Biopharmazie im Gespräch. Ich hoffe natürlich sehr, dass die Lehrstühle für Technologie und Biopharmazie nicht aus Spargründen zusammengelegt werden und so wieder ein Lehrstuhl wegfällt. Das wäre schade für den Pharma-Hub Basel. Andererseits bin ich sehr glücklich, dass die Pharmazieausbildung in Basel nun nicht mehr in Frage gestellt wird. Dazu hat u.a. der neue Ansatz des Bundes zur Hochschulfinanzierung beigetragen: Die Universität Basel erhält für jeden auswärtigen Studierenden Geld, das dann unter anderem auch für den Ausbau des Departements Pharmazeutische Wissenschaften genutzt werden kann. Die Voraussetzungen sind also gut. In dieser Hinsicht hat sich die Situation der Pharmazie im Vergleich zu 1982 total gewandelt und eindeutig verbessert. Ich möchte hier die Gelegenheit nutzen, allen – und es sind nicht wenige – zu danken, die mitgeholfen haben, die Pharmazieausbildung an der Universität Basel zu stärken. Schade finde ich einzig, dass sich das Pharmazentrum Basel-Zürich, also die Zusammenarbeit zwischen unseren beiden Schwesterinstitutionen, nicht so entwickelt hat, wie ich es mir bei der Berufung von Hans-Peter Wessels als Geschäftsführer vorgestellt hatte. Die damals vom Präsidenten der ETH Zürich Jakob Nüesch und vom Basler Erziehungsdirektor Hans-Ruedi Striebel initiierte Idee einer engeren Zusammenarbeit zwischen der Universität Basel und der ETHZ ist für mich nach wie vor zukunftsweisend. ■

#### Interview:

Dr. Claudia Reinke

E-Mail: claudia.reinke@medsciences.ch



## H.2.6 The Engineering Research Center ERC for Structure Organic Particulate Systems (C-SOPS)

The US National Science Foundation is supporting special ERC for the advancement of Science. Prof. Dr. H. Leuenberger became member of the scientific board of the Engineering Research Center ERC for Structure Organic Particulate Systems (C-SOPS). The center consists of the following universities:



## H. 3. Diploma/Master Studies

In the year 2006 seven students have completed their diploma work in the area of Pharmaceutical Technology. Diploma studies were performed in the Pharmacenter as well as in laboratories of partner institutions (see H.3.2, List of Diploma/Master Students with topics in Pharmaceutical Technology 2006).

### H.3.1 Final report on the development of the MSc curriculum with the major "industrial pharmacy"

The department of pharmaceutical sciences has decided in 2004 to introduce not only a study program for MSc in Pharmacy but also in parallel a MSc program in Pharmaceutical Sciences with the three majors "Drug Discovery", "Toxicology/Pharmacology" and "Industrial Pharmacy". The leading house for the development of the major "Industrial Pharmacy" is the Institute of Pharmaceutical Technology, which has established a task force together with experts from the pharmaceutical industry.

This working party, which is supported by

- the BBT (Federal Office for Professional Education and Technology OPET), by
- the University of Basel and
- the FHNW [University of Applied Sciences Northwestern Switzerland (UAS), School of Life Sciences, Muttensz ([www.fhnw.ch/lifesciences](http://www.fhnw.ch/lifesciences))]

had as a task to develop in parallel the curriculum of MSc Pharm.Sci with major "Industrial Pharmacy" at the University of Basel and a Master in "Pharmaceutical Engineering" at the UASB.

The idea is to look for synergies in the curricula, to establish a close cooperation and to have as a goal an MSc in Pharmaceutical Sciences with a Major in Industrial Pharmacy, who understands also the language of an engineer and that a Master in Pharmaceutical Engineering understands better the job and language of the Industrial Pharmacist at his working place.

A model concept for both curricula was completed and documented in a report, which was submitted to the rectorate of the University of Basel on May 25, 2005 (see attachment of the annual report 2005 of the Pharm. Technology). The concept suggests a close cooperation between the School of Life Sciences (HSLF) in Muttensz and the Department of Pharmaceutical Sciences of the University of Basel. The HSLF has decided to create a competence center in Pharma Technology, which will provide a pharmaceutical technology platform (labs) to be used by pharmacy students of the University of Basel to become future "industrial pharmacist" and by students of HSLF to become "pharmaceutical engineers".

A final report of these activities was completed in July 2006 including a financial report. It has to be kept in mind that the project was initiated by the former Vice-President of Research of the University of Basel, Prof. Dr. Gian-Reto Plattner (successor: Prof. Dr. Peter J. Meier-Abt).

The concept offers a clear definition of the tasks of the University of Basel, being responsible for the curricula of industrial pharmacists and of the HSLF for the education of pharmaceutical engineers.

An implementation of such a concept of collaboration is favoured by the fact that Prof. Dr. G. Imanidis was elected as head of the division Pharma Technology at the HSLF and left the University Basel on May 15, 2006.

In 2006 the department has established a working party for the introduction of the **MSc in pharmaceutical sciences**, which will include a major in industrial pharmacy. Concerning the latter major guests from industry have been invited to participate at this working party from Actelion, Novartis, Roche and Mepha.



### H.3.2 List of Diploma/Master Students with topics in Pharmaceutical Technology 2006

Student	Topic	Supervisor/Location
Duthaler Urs	Bestimmung der Wirkstoffabsorption in Caco-2 Zellkulturen bei passivem und carrier-vermitteltem Transport	David Blaser
Ehrenhöfer Barbara	Intradermale Messung der Photostabilität von Sonnenschutzmitteln im Schweinehautmodell	Dr. Bernd Herzog (Ciba Spezialitätenchemie) und Dipl. Ing. Stephan Bielfeld (proDERM)
Felber Judith	Neue Methode zur Untersuchung des diffusen Mischprozesses mittels binärer Mischungen von Granulaten	Thomas Meyer, Hans Leuenberger
Guerra Alessandra	UICEL, ein attraktiver Hilfsstoff in festen Arzneiformen	Vincenzo Balzano
Hug Susanna	Study of Diffusion of Solute Molecules through Lipid Bilayer Membranes by Molecular Dynamics Simulation	Prof. A. Poso (Finland) / G. Imanidis (Basel)
Schmid Alexandra	Stabilisierung des Blutzuckerspiegels bei Diabetikern	Gabriele Betz, Rolf Müller
Walter Nicole	Schweinehaut, Humanhaut und künstliche Haut (SkinEthic) als Modelle zur Untersuchung der Penetration, Permeation und des Metabolismus	Dominik Imfeld, Head R&D Biotechnology, G. Imanidis

### H.3.3 Visiting Diploma Student

Murad Rumman	Investigation of the acetylsalicylic acid stability in the presence of UICEL	Institute of Pharmaceutical Technology, University of Basel
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## H. 4. Research

### H.4.1 Publications 2006

An Extended Model Based on the Modified Nernst-Planck Equation for Describing Transdermal Iontophoresis of Weak Electrolytes. G. Imanidis and P. Luetolf. *J. Pharm. Sci.* 95:1434-1447 (2006).

Cutaneous metabolism of a dipeptide influences the iontophoretic flux of a concomitant uncharged. Publication, in english. Altenbach Melanie, Schnyder Nathalie, Zimmermann Christine, Imanidis Georgios. *Int.J.Pharm.* 307 (2), 2006, 308-317. ISSN 0378-5173.

E-Learning and Development of New Courses and Scientific Work in the Field of Pharmaceutical. Publication, in english. Leuenberger Hans, Menshutina Natalia V., Betz Gabriele, Puchkov Maxim. *CHIMLA* 60 (1.2), 2006, 80-82. ISSN 0009-4293.

Experimental design and optimization of the hydrogenation process of soybean oil. Publication, in english. Chansanroj Krisanin, Praserttham Piyasan, Betz Gabriele, Leuenberger Hans, Mitrevaj Ampol, Sinchaipanid Nuttanan. *J.DrugDeliveryPharmTechn* 16 (3), 2006, 229-234. ISSN 1773-2247.

From "Functional Excipients" towards "Drug Carrier Systems". Publication, in english. Leuenberger Hans. *Chemistry Today* 24 (5), 2006, 64-66. ISSN 0392-839X.

Granulation Process Control – Production of Pharmaceutical Granules: The classical batch concept and the problem of scale-up. Bookchapter, in english. Leuenberger Hans, Betz Gabriele. In: Handbook of Powder Technology, Volume 11, ISSN 0167-3785. *Granulation, HPT 11*, 705-734, Amsterdam [etc.], Elsevier 2007. Editors: Salman Agba D., Hounslow Mike J., Seville Jonathan P.K., ISBN 0444518711

Influence of loading volume of mefenamic acid on granule characteristic and compression behavior using a compaction simulator. Publication, in english. Kimura Go, Betz Gabriele, Leuenberger Hans. *Pharm.Dev.Technol.* 2006. ISSN 1083-7450. In press

Pharmaceutical Powder Technology - Building the pyramid of knowledge and the challenge of FDA's PAT. Bookchapter, in english. Leuenberger Hans, Kocova Silvia, Betz Gabriele. In: Water-Insoluble Drug Formulation, 2<sup>nd</sup> Edition, *Interpharm Press*. Editor: Liu Rong. ISBN 0849396441. In press

Pharmaceutical Technology: Drug Delivery, Formulation and Process Research. Publication, in english. Leuenberger Hans. *CHIMLA* 60 (1.2), 2006, 40-45. ISSN 0009-4293.

Quantitative Assessment of Tissue Retention, Lipophilicity, Ionic Valence and Convective Transport of Permeant as Factors Affecting Iontophoretic Enhancement. M. Altenbach, N. Schnyder, C. Zimmermann and G. Imanidis. *J. Drug Del. Sci. Tech.* 16:91-98 (2006) (invited contribution to theme issue on stimulated drug delivery systems).

Quantitative Concepts in Drug Formulation and Absorption and their Relevance for Drug Delivery. G. Imanidis, M.Sutter, S. Reitbauer, S.B. Kapitza, P. van Hoogevest, D. Hummel, B. Müller, P. Luetolf. *Chimia* 60:46-49 (2006).

Scale-up in Granulation and Drying. 2nd edition, Chapter 8. Bookchapter, in english. Leuenberger Hans, Betz Gabriele, Jones David M., In: Drugs and the Pharmaceutical Sciences, Volume 157, ISSN 0360-2583. *Pharmaceutical Process Scale-Up*, 2nd Ed., 199-236. *Taylor & Francis Ltd.* 2006. Editor: M. Levin ISBN 1574448765.

Spray-freeze drying in a fluidized bed at normal and low pressure. Publication, in english. Plitzko Matthias, Puchkov Maxim, Leuenberger Hans. *Drying Technology* 24 2006, 711-719. ISSN 0737-3937.

Percolation theory and the role of maize starch as a disintegrant in the case of a low water soluble drug. Publication, in english. Kimura Go, Puchkov Maxim, Betz Gabriele, Leuenberger Hans. *Pharm.Dev.Technol.* 12, 1; 2007, p.11- 19. ISSN 1083-7450.



The Industrial Pharmacy Lab: New Concepts in Powder and Process Technology. Publication, in english. Betz Gabriele. *CHIMIA* 60 (1.2), 2006, 50-53. ISSN 0009-4293.

Topical Bioavailability of Triamcinolone Acetonide: Effect of Dose and Application Frequency. C. Pellanda, E. Ottiker, C. Strub, V. Figueiredo, T. Rufli, G. Imanidis and C. Surber. *Arch. Dermatol. Res.* 298:221-230 (2006).

Topical Bioavailability of Triamcinolone Acetonide: Effect of Occlusion. *Skin Pharmacol.* C. Pellanda, C. Strub, V. Figueiredo, T. Rufli, G. Imanidis and C. Surber. *Physiol.* 20:50-56 (2007)

#### H.4.2 List of Presentations as an Invited Speaker, Participation in Symposia, Workshops, Project/coordination Meetings, Organisation of workshops etc.

16.1.2006, Basel H.Leuenberger, A.S.Hussain, FDA	Meeting on the future of PAT- Initiative and cooperation	
23.1.2006, Basel H.Leuenberger, D.Daneshvari, Dr.Y.Pittini (EMPA/Material Technology Dept.)	Meeting concerning the cooperation project between the EMPA/Material Technology Department and the Uni- versity of Basel.	Project: "Investigation of Paraffin based derivatives using dielectric spec- troscopy"
27.1.2006, Basel H.Leuenberger, G.Betz	Arzneimittelseminar	Nutraceuticals
7.2.2006, Jena H.Leuenberger	Invited Lecture, University of Jena	Brauchen wir eine europäische For- schungsinitiative im Bereich der phar- mazeutischen Pulvertechnologie?
16.2.2006, Bern H.Leuenberger	SNF Event, Information meeting for the co- ordinators of SCOPES 2006-2008	From a promising drug substance to a marketed product - the complex task to develop a solid dosage form
28.2.2006, Strasbourg H.Leuenberger	Invited Lecture, Université Illkirch	From a promising drug substance to a marketed product - the complex task to develop a solid dosage form
20.3.2006, Gabriele Betz	Agglomerations- und Schüttguttechnik und Lebensmittelverfahrenstechnik, VDI-Gesellschaft, Verfahrenstechnik und Chemieingenieurwesen GVC, Reinbek, Germany	New Concepts in Powder and Process Technology
21.3.2006, Bangkok H.Leuenberger	Invited Lecture Mahidol University, Bangkok	A Road Map for a Research Initiative in Pharmaceutical Powder Technology
21.3.2006, Bangkok H.Leuenberger	Mahidol University - Faculty of Phar- macy Mahidol - Department of Indus- trial Pharmacy	Participating at the PhD-Defence of Krisanin Chansanroj



21.-23.3. 2006 Gabriele Betz	PDA-Workshop	Practical Aspects of Aseptic Processing
21.3. 2006, Gabriele Betz	Labtalk 2006 Mettler-Toledo, Giessen, Germany	Grundlagen und Überblick der Grundoperation Granulieren
30.3.2006 H.Leuenberger, I.Caraballo	Meeting concerning collaboration with the proposed Center CISDEM (Cátedra Iberoamericana-Suiza de Desarrollo de Medicamentos) at the University of Seville.	
31.3.2006 H.Leuenberger C.Meier (CCSO)	Meeting concerning the future of the collaboration-project University of Basel and FHNW Fachhochschule Nordwestschweiz).	
5.4.2006, Bavois H.Leuenberger	Suisse-Russie: rencontre à Bavois	Suisse-Russie: suivi de la visite officielle du SE Kleiber et esquisse d'une stratégie de coopération scientifique et technologique
10.4.2006, Athens, Greece G.Imanidis	Lecture at the Faculty of Pharmacy, National and Kapodistrian University of Athens	Penetration and Permeation of Drugs in the Skin
25.-1.5.2006, Basel, Leuenberger Hans, Menshutina Natalia Betz Gabriele Hun- gerbühler Ernst Meier Christoph Gon- charova Svetlana Puchkov Maxim Guseva Elena	Visit of Russian Delegation. <ul style="list-style-type: none"> <li>Pharmaceutical powder technologies: state of the art and perspectives</li> </ul> The Management of Innovation, Significance of the Swiss Russian Science and Education Centre for Pharmaceutical and Biological Technologies at the Mendeleev University of Chemical Technology of Russia (MUCTR)	New concepts in training industrial pharmacists and pharmaceutical engineers. The Russian-Swiss scientific and educational centre in MUCTR
25.-1.5.2006, Basel, Gabriele Betz	Modern Pharmaceutical Technologies, 2nd Russian Swiss Seminar, Basel, Switzerland	New concepts in training industrial pharmacists and pharmaceutical engineers to be developed at the Russian Swiss Scientific and Educational Center at MUCTR
4.-6.5.2006 Gabriele Betz	First Congress on Pharmacy Bosnia and Herzegovina	New concepts in process technology and solid dosage form design
22.5.2006 H.Leuenberger, Dieter Imboden	Meeting with Prof. Dr. Dieter Imboden (SNF, Swiss National Science Foundation) concerning the future of powder technology research in Switzerland	
13.-16.5.2006, Orlando, Florida, H.Leuenberger	Particles 2006, Medical/Biochemical Diagnostic, Pharmaceutical, and Drug Delivery Applications of Particle Technology	FDA's pharmaceutical cgmpts for the 21 <sup>st</sup> century: do we need a special research INITIATIVE in pharmaceutical powder particle technology to comply with the new requirements?



23.6.2006, Basel, H.Leuenberger	Solvias Science Day - Invited Lecture at Solvias	Pharmaceutical formulation and process technology: from Art to Science
3.-13.7.2006, Athens, Greece G.Imanidis	Lecture at the EU Erasmus Socrates Intensive Programme on Innovative Therapeutics: From molecules to medicines, National and Kapodistrian University of Athens	Properties of the Phospholipid Bilayer Membrane Determining Passive Drug Permeability
3.-13.7.2006, Athens, Greece G.Imanidis	Lecture at the EU Erasmus Socrates Intensive Programme on Innovative Therapeutics: From molecules to medicines, National and Kapodistrian University of Athens	Passive Permeation and Carrier Medi- ated Apical Efflux in the Intestinal Absorption of Solubilized Poorly Wa- ter Soluble Drugs
5.-8.7.2006 Zagreb, Croatia, Maja Pasic	13th Young Investigators' Seminar on Analytical Chemistry	Investigation on the thermal behaviour of lansoprazole
5.-8.7.2006 Zagreb, Croatia, Ervina Brka	13th Young Investigators' Seminar on Analytical Chemistry	Development of theophylline con- trolled release tablet using roll compac- tion
10.8.2006, Kuopio, Finland G.Imanidis	Lecture at the Department of Pharma- ceutics, University of Kuopio	Drug Delivery to the Skin and As- sessment of Topical Bioavailability
13.9.2006 Gabriele Betz	Strategies and trends in pharmaceutical development and production, Continu- ing Education Course of the Center of Pharmaceutical Sciences Basel-Zurich	Scale-up of the tableting process
5.10.2006, Beijing H.Leuenberger	Meeting with Prof. Dr. Jinghai Li and Prof. Dr. Mooson Kwauk (Prof.Kwauk retired 2002 from serving as the president of the Chinese Society of Particuology for 16 years, and Jinghai Li is his successor) concerning the experience made with the RSSC (Russian-Swiss Science and Education Center for the Transfer of Bio- pharma-ceutical Technologies) at MUCTR in Moscow <a href="http://www.rs-pharmcenter.ru/eng-/main/index.php">www.rs- pharmcenter.ru/eng-/main/index.php</a>	
9.10.2006, Nanjing H.Leuenberger	Visit of the ICIFP (Institute of Chemi- cal Industry of Forest Prod- ucts/Chinese Academy of Forestry)	Topics: • Spray Freeze Drying • Research in Powder Technology at the University of Basel
13.10.2006, Wuxi H.Leuenberger	Visit of two companies collaborating with the ICIFP (Institute of Chemical Industry of Forest Products/Chinese Academy of Forestry)	
19.10.2006, Basel G.Imanidis	Oral presentation at the Symposium on the occasion of the retirement of Professor Hans Leuenberger, Univer- sity of Basel	The Scientific Life of Hans Leuenber- ger



19.10.2006, Basel	Farewell Symposium Hans Leuenberger at the Pharmacentre	Organised by Prof. Dr. Georgios Imanidis
25-27.10.2006, Lawrence, KS, USA, D. Blaser, C. Krömmler, U. Duthaler, G. Imanidis	Oral Presentation at the Global Pharmaceuticals Education Network Meeting GPEN2006	Development of a Mathematical Model for Determining Drug Absorption Parameters in Caco-2 Cell Monolayers
13-14.11.2006, Basel G.Imanidis	Oral presentation at the Indo-European API Forum	New Technologies: Intestinal Delivery of Poorly Water Soluble HIV Protease Inhibitors
6.11.2006 H.Leuenberger	Meeting with Mr. Takeshi Takashima (President, Powrex Corporation). Interview on the occasion of the “50 <sup>th</sup> Anniversary Award of the Society of Powder Technology of Japan” (SPTJ) dedicated to H.Leuenberger (see Nov. 8, 2006) for Pharm Tech Japan. Vol.23 No.1 (2007)	
7.-10.11.2006, Tokyo, H.Leuenberger	16 <sup>th</sup> International Powder Technology Exhibition Tokyo	
8.11.2006, Tokyo, H.Leuenberger	50 Years Memorial Ceremony of The Society of Powder Technology, Japan	Prof. Dr. Hans Leuenberger was awarded and gave a 5-min speech
9.-10.11.2006, Tokyo, Japan H.Leuenberger	2 <sup>nd</sup> International Technical Forum Inspiring Powder Technology. PowtexForum 2006. The latest powder technology for highly functional materials from all over the world.	<ul style="list-style-type: none"> <li>• Do we need a special research initiative in pharmaceutical powder particle technology to meet the challenges of the 21st century?</li> <li>• The impact of percolation phenomena on agglomeration processes</li> </ul>
13. 11. 2006, Tokyo, Japan H.Leuenberger	Invitation to a lunch by the Swiss Ambassador in Tokyo, Mr. Paul Fivat on the occasion of H.Leuenberger’s award of the 50 <sup>th</sup> Anniversary of the Society of Powder Technology of Japan” (SPTJ). Guests: H.Leuenberger and his wife, Prof.Kawashima and his wife and the Science & Technology Attaché Dr. Felix Moesner.	
16.11.2006, Strasbourg, France G.Imanidis	Lecture at the Faculty of Pharmacy, University Louis Pasteur	Intestinal Absorption of Solubilized Poorly Water Soluble Drugs - Passive Permeation and Carrier Mediated Apical Efflux
16.11.2006, Strasbourg, France G.Imanidis	Lecture at the Faculty of Pharmacy, University Louis Pasteur	Quantitative Aspects of Dermal and Transdermal Drug Delivery
28.11-2.12.2006 Gabriele Betz	4th International Congress in Pharmaceutical Sciences Serbia, Belgrade	New concepts in process technology and pharmaceutical drug formulation design
4.-6.12.2006 Gabriele Betz	PDA-Workshop	Practical Aspects of Aseptic Processing



4.-7.12.2006, Moscow, H.Leuenberger	Seminar of the Russian Swiss Science and Education Center for Biopharma- ceutical Technologies	<a href="http://www.rs-pharmcenter.ru/eng/-seminars/2006/3rd_seminar.php">www.rs-pharmcenter.ru/eng/- seminars/2006/3rd_seminar.php</a>
11.12. 2006 H.Leuenberger	Invitation and Visit of the US NSF, National Science Foundation	Discussion of the role of ERC (Engi- neering Research Center) and on the future of Nanotechnology and Nanoscience

#### H.4.3 Poster Presentations

March 27-30 2006 E.Krausbauer, M.Tscheulin, M.Puchkov, G.Betz, H.Leuenberger	5 <sup>th</sup> World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Geneva, Switzerland	Development of paracetamol tablet formulations using 3D factorial design
March 27-30 2006 S.Sehic, G.Betz, S.Hadzidedic, S.Kocova El-Arini, H.Leuenberger	5 <sup>th</sup> World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Geneva, Switzerland	Carbamazepine Polymorphs and Di- hydrate Comparative Study
March 27-30 2006 P.Weber, R.Müller, F.Innerebner, G.Betz	5 <sup>th</sup> World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Geneva, Switzerland	Stabilisation of the glucose blood level in diabetics using network forming starch formulations
March 27-30 2006 V.Balzano, N.Gentis, M.Puchkov, G.Betz, H.Leuenberger	5 <sup>th</sup> World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Geneva, Switzerland	Technological and Mechanical Proper- ties of three types of microcrystalline cellulose
April 26-27 2006 S.Sehic, G.Betz, S.Hadzidedic, S.Kocova El-Arini, H.Leuenberger	EUFEPS conference “When Poor Solubility Becomes an Issue: From Early Stage to Proof of Principles”, Verona, Italy	Carbamazepine Polymorphs and Di- hydrate Comparative Study
May 4-6 2006 H.Trobradović, G.Betz, Š.Hadžidedić, S.Kocova El-Arini, H.Leuenberger	First Congress on Pharmacy, Bosnia and Herzegovina	Differential scanning calorimetry as a tool for the prediction of the compati- bility and stability of multicomponent drug systems
Sept. 10-13 2006. G.Borini, L.Alexandre P.deFreitas, G.Betz, H.Leuenberger	13th Int. Technology Symposium, Marmara Otel, Antalya, Turkey	Preparation and Characterization of Particles Coated with Solid Dispersions of Curcumin and PEG 4000



September 10-13 2006 H.Myojio, G.Betz, H.Leuenberger	13 <sup>th</sup> Int. Technology Symposium, Marmara Otel, Antalya, Turkey	Investigation of ethylcellulose coated fine drug-layered pellets using a confo- cal laser scanning microscope (CLSM)
Oct. 3-6 2006 H.Myjo, T.Hayashi, K.Takeshima	Freeze-Drying of Pharmaceuticals and Biologicals, Garmisch Partenkirchen, Germany	Effect of sodium chloride (NaCl) on stability of lyophilized new parenteral cephem compound (S-3578)
Oct. 19-20 2006 E.Krausbauer, M.Puchkov, G.Betz, H.Leuenberger	FMC Tablet tech, Solid dosage form manufacturing, Genval, Belgium	Rational estimation of the optimum amount of disintegrant applying perco- lation theory for binary formulation
October 19-20 2006 M.Puchkov, E.Krausbauer, G.Betz, H.Leuenberger	FMC Tablet tech, Solid dosage form manufacturing, Genval, Belgium	Determination of the critical amount of Ac-Di-Sol® for binary formulations with Indomethacin with respect to water uptake
25.-27.10.2006, Law- rence, KS, USA M. Schneider, G.Imanidis	Poster at the Global Pharmaceutics Education Network Meeting GPEN2006	Influence of Lipid Content of a Lipo- some Formulation Used for Solubiliza- tion of a Poorly Water Soluble Drug on Absorption through Caco-2 Monolayers
Nov.28-Dec.2, 2006. S.Sehic, G.Betz, S.Hadzidedic, S.Kocova El-Arini, H.Leuenberger	4th International Congress of Pharma- cists of Serbia, Belgrade	Carbamazepine Polymorphs and Di- hydrate Comparative Study
Nov.28 - Dec.02 2006 M.Pasic, G.Betz, S.Hadzidedic, S.Kocova El-Arini, H.Leuenberger	4th International Congress of Pharma- cists of Serbia, Belgrade	Influence of enteric coating polymer on gastric resistance and dissolution of lansoprazole pellets
Nov.28-Dec.2, 2006. E.Brka, G.Betz, S.Hadzidedic, S.Kocova El-Arini, H.Leuenberger	4th International Congress of Pharma- cists of Serbia, Belgrade	Effect of Roll Compaction on Poly- morphic Forms and Compressibility of Theophylline

#### H.4.4 Visiting scientists

Sept. 25, 2006 – March 16. 2007	Cooperation with Mahidol University, Prof. Dr. Ampol Mitrevej, Visiting Scientist Wichan Ketjinda	Development of a chitosan based os- motic controlled release system
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#### H.4.5 List of PhD-Theses in Pharmaceutical Technology completed in 2006

PhD student	Title	Funding/Location
Fässler-Tassopoulos Tatiana	Evaluation of topical bioavailability of MBC in human stratum corneum by tape stripping using a direct spectroscopic method	Kantonsspital Basel
Nalenz Heiko	Dependence of Skin Drug Permeation on Microstructure and Time Dependent Alterations Following Application of Multi-phasic Dermatological Formulations Studied by the Continuous Phase Concentration Concept	Universität Basel
Pellanda Carolina	Topical Bioavailability of Glucocorticosteroids - Dermatopharmacokinetics and Dermatopharmacodynamics of Topically Applied Triamcinolone Acetonide in Humans	Kantonsspital Basel
Plitzko Matthias	The production of nanocomposites using the spray-freeze-drying technique	Universität Basel, Glatt GmbH
Rehorik Lars	Process modeling as a tool to indicate quality aspects in the pharmaceutical production	F. Hoffmann - La Roche AG
Valporsson Hedinn	PAT Implementation in Pharmaceutical Manufacturing and its Economical Impact	Novartis Pharmaceuticals
Walter Marijke	Integration und Evaluation neuer Medien: Angewandt in der Lehre der Pharmazeutischen Technologie an der Universität Basel	Universität Basel



## NEWS & ANALYSIS

### The trouble with making combination drugs

Drug compound interactions in a tablet are still difficult to predict

Simon Frantz

Combining treatments into one tablet is becoming a more popular strategy than ever, and with good reason. Reducing the number of treatments that a patient needs to take increases compliance for long-term drug therapies, and simplifying disease management has proved to be crucial for treating conditions such as HIV in developing countries and cardiovascular disease in the Western world (see BOX 1). In lucrative developed-world markets, combination drugs have the added benefit of helping to cushion the impact of generic competition and to extend the life-cycle of top-selling drugs (BOX 2).

Two announcements in the past few weeks, though, have highlighted both the promise and pitfalls in creating combination treatments. The World Heart Federation has announced an initiative together with the Spanish National Centre for Cardiovascular Research to develop a polypill containing an angiotensin-converting enzyme (ACE) inhibitor, statin and aspirin for the secondary prevention of cardiovascular disease as early as 2009. Within days, Merck announced that it was delaying the approval submission of its 3-in-1 combination pill MK-524B for cholesterol because of an 'unspecified formulation problem'.

Although no one in the field disagrees with Merck's statement that the formulation issues with MK-524B are not a significant setback for the drug, they say that this serves as a vivid reminder that formulating and manufacturing combination drugs is not as straightforward as is widely thought. With more ambitious



Formulating combination drugs is much more difficult than widely thought.

combination drugs being proposed at a growing rate, researchers say they need to find ways of improving the science behind formulating combination drugs.

"Trial and error has worked pretty well for easy molecules, so there hasn't really been a great financial incentive to try to improve this situation," says Kenneth Morris, Professor of Industrial and Physical Pharmacy at Purdue University. "But as interest grows in developing more,

and more complex, combination drugs, we will need to develop the science that will allow the process to occur in a timely enough manner."

The difficulties in formulating and manufacturing combination drug products are often invisible to the wider community, and so the problems behind developing these drugs can be trivialized. Part of the problem is that an air of mystery still surrounds the field — perhaps unsurprisingly, as industry scientists are reluctant to discuss any company or product-sensitive information regarding the development of these treatments.

For chemists and engineers in the field, however, the issues behind formulating and manufacturing combination drugs are all too familiar. "Making a tablet out of one drug is an underrated problem in itself, so making a tablet out of multiple active pharmaceutical ingredients is a much tougher proposition," says Allan Myerson,

Making a tablet out of one drug is an underrated problem in itself, so making a tablet out of multiple active pharmaceutical ingredients is a much tougher proposition.



## NEWS & ANALYSIS

Professor of Chemical Engineering at Illinois Institute of Technology.

Just because two or more treatments work in combination in a patient does not mean that they are amenable to packing into a single tablet. If the solid form of one drug is less soluble than another, this can affect how each drug gets released into the bloodstream. If one dose is much lower than another there can be problems in making sure that the low-dose drug is distributed uniformly in the tablet. Compounds can react with each other, either chemically or physically, or one compound might be chemically more stable than another, or more sensitive to moisture than another, all of which can affect the shelf-life of the drug.

At the moment formulating these combinations relies to a large degree on trial and error. To create a stable and effective combination drug, formulators typically try simple approaches first, such as altering formulations, and then move onto increasingly complex solutions like isolating the compounds in different layers. Naturally, the more complex the solution, the more time and effort that has to be spent finding it. "All the problems are, in a sense, solvable," says Myerson. "It is just a matter of time and money."



The development of Atripla, a 3-in-1 treatment for HIV that was approved by the FDA in July this year, illustrates some of the difficulties faced when developing combination drugs. Combining Gilead's

### Box 2 | Sustaining the success of statins through combination drugs

As well as increasing patient compliance, fixed-dose combinations can help prolong the life-cycle for lucrative drugs in Western markets. So it's no surprise that companies are looking to combine the blockbuster statins with other drugs.

- Zocor (simvastatin) plus niacin (MK-0524A) — Merck
- Crestor (rosuvastatin) plus fibrate (ABT-335) — AstraZeneca/Abbott
- Lipitor (atorvastatin) plus cholesteryl ester transfer protein (torcetrapib) — Pfizer
- Statin plus ACE inhibitor plus aspirin (specific treatment and company details unknown)

Truvada, itself a combination of tenofovir and emtricitabine, with Bristol-Myers Squibb's Sustiva (efavirenz) produced a mixture that melted easily — the first formulation in effect turned to glue. It took a year and four more formulations to produce a combination drug that could release the same level of the three drugs in a patient's blood as the three drugs taken separately. After much deliberation, the solution was to separate Truvada and Sustiva in layers within the tablet to allow each drug to dissolve at its own rate.

 Trial and error has worked pretty well for easy molecules, so there hasn't really been a great financial incentive to try to improve this situation. 

The difficulty that researchers face is that they still have a poor understanding of how powdered drug compounds can interact within a tablet. A great deal is known about the behaviour within materials like metal powders. But much less is known about the interactions that go on between small organic molecular crystals, whose structures are much more flexible and held together with much weaker forces. Add to that the interactions of binders and excipients used in tablets, such as cellulose and starch, which can enhance and mask properties of an active pharmaceutical ingredient, and it's easy to see why formulators say that a greater theoretical understanding of the physical interactions that can take place between the solid forms of drug compounds is sorely needed.

There has been good progress in this area of material science over the years. For instance, engineers are now beginning to understand how compacting drugs into tablets can deform the particles of the active compound. But understanding the interactions that can go on in a drug is a long way from being a predictive science. What is really needed, says Morris, is a set of 'mixing

rules': guidelines that could help researchers predict what mixtures of components in what proportion will result in the drug product properties that are needed, or best avoided.

Some big companies have become very strong in the area of particle-particle interaction and prediction. But by and large companies have been reluctant to invest significant resources into this field, says Morris, as many view this part of the process "as a cost centre, not a profit centre". Stephen Byrn, Head of the Department of Industrial and Physical Pharmacy, at Purdue, agrees. "These are long-term issues; this isn't something that companies are going to fund and get something that they are going to be able to use in a year," says Byrn.

Byrn says the best solution is for governments to step in and fund academic research that actively includes industrial members. In Europe, there are already centres that specialize in drug formulation, such as the Basel-based Institute of Pharmaceutical Technology, led by Hans Leuenberger, and the Institute of Pharmaceutical Innovation headed by Peter York in the University of Bradford in the UK.

In the US, funding for industrial pharmacy programmes has decreased markedly over the past decade and a half, to the extent that a whole generation of potential expertise has effectively been lost. But a consortium of 11 universities led by several Purdue scientists called the National Institute of Pharmaceutical Technology and Education (NIPTE) hopes to change this. NIPTE is trying to stimulate the development of centres of excellence that combine the expertise of pharmaceutical sciences and engineers.

"These centres of excellence would help train scientists who could then go out and develop new strategies," says Byrn. "The goal is to create some form of predictive rules so that we can look at particles, make some kind of measurements and then predict whether we could mix them without having something like degradation going on." A bill to help set up these centres of excellence is now in Congress, and the consortium hopes to receive funding in 2008.

### Box 1 | HIV and CVD combination drugs

Several fixed-dose combination drugs have been approved for HIV and cardiovascular disease, filling a real healthcare need for simpler and less costly treatment regimens.

#### HIV\*

- Combivir (GlaxoSmithKline): zidovudine and lamivudine
- Truvada (Gilead): emtricitabine and tenofovir
- Epzicom (GlaxoSmithKline): abacavir and lamivudine
- Atripla (Gilead/Bristol Myers Squibb): emtricitabine/tenofovir and efavirenz
- Trizivir (GlaxoSmithKline): zidovudine/lamivudine and abacavir

#### Cardiovascular disease

- BiDil (NitroMed): isosorbide dinitrate and hydralazine hydrochloride
- Vytorin (Merck/Schering Plough): ezetimibe and simvastatin
- Caduet (Pfizer): amlodipine and atorvastatin

\* Lamivudine/zidovudine and nevirapine has been tentatively approved by the FDA



## The National Institute of Pharmaceutical Technology

**“The goal of NIPTE will be to become the pre-eminent interdisciplinary national resource for research and education on science and engineering based understanding of pharmaceutical development and manufacturing.”**

The goal of NIPTE will be to become the pre-eminent interdisciplinary national resource for research and education on science and engineering based understanding of pharmaceutical development and manufacturing. Scientists, researchers and engineers from academia, the FDA and the industry will collaboratively engage in developing state-of-the-art science and technology to enable the pharmaceutical industry to develop products faster, and at a significantly lower cost with less variability and higher predictability of performance.

### NIPTE Board of Directors ([www.purdue.edu/dp/nipite/board.php](http://www.purdue.edu/dp/nipite/board.php))



**Ali Cinar**  
Professor of Chemical Engineering, Vice  
Provost for Research  
Dean of the Graduate College  
Illinois Institute of Technology



**Rolland I. Poust**  
Professor, Division of Pharmaceutics  
Director, Division of Pharmaceutical  
Service  
University of Iowa



**Lesbia Hernandez**  
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University of Puerto Rico



**James Roberts**  
Vice Provost for Research  
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**Marilyn K. Speedie**  
Dean and Professor, College of Pharmacy  
University of Minnesota



**Chuck Staben**  
Acting Vice President of Research  
University of Kentucky



## **S. 2793**

To enhance research and education in the areas of pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing, analytical technologies, modeling, and informatics.

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### **IN THE SENATE OF THE UNITED STATES**

May 11, 2006

Mr. LUGAR introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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### **A BILL**

To enhance research and education in the areas of pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing, analytical technologies, modeling, and informatics.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### **SECTION 1. SHORT TITLE.**

This Act may be cited as the “Pharmaceutical Technology and Education Enhancement Act”.

#### **SEC. 2. FINDINGS.**

Congress makes the following findings:

(1) Developing medical products targeted for important public health needs, less common diseases, prevalent third world diseases, prevention indications, or individualized therapy is increasingly challenging.

(2) A typical compound that is discovered today may not be approved by the Food and Drug Administration for 12 to 15 years.

(3) Current costs of bringing new medicines to market are estimated to be as high as \$800,000,000 to \$1,700,000,000 and are a major barrier to innovation and investment in higher-risk areas such as rare diseases and genetic conditions.

(4) Product development in areas crucial to public health, such as antibiotics, has slowed significantly in the past decade.

(5) Approximately 50 percent of new drug candidates fail to produce adequate evidence of safety or effectiveness in the late stages of clinical studies and cannot be approved. The resulting overall investments are raising the cost of developing an approved therapy to approximately \$1,700,000,000.

(6) Problems in physical design, characterization, manufacturing scale-up, and quality control routinely derail or delay development programs and delay patient access to new treatments.

(7) Many product failures during development are ultimately attributable to problems relating to the transition from laboratory prototype to industrial product.

(8) Recent data suggests that the investment required to launch a new therapy has risen 55 percent during the last 5 years. Pharmaceutical, biotechnology, and medical device productivity appears to be declining at the same time that the costs to develop treatments are rising.

(9) During the last several years, the number of new drug and biologic applications submitted to the Food and Drug Administration has declined significantly. The



number of innovative medical device applications to the Food and Drug Administration also has decreased.

(10) Industry has been hesitant to introduce state-of-the-art science and technology into its manufacturing processes due to concern about potential regulatory impact. This led to high in-process inventories, low factory utilization rates, significant product waste, and compliance problems, driving up the costs and decreasing productivity.

(11) It is crucial that improved methods for design, characterization, and production manufacture are available to improve predictability.

(12) United States academic institutions have the capacity to assist in discovering and introducing science-based standards for product characterization and manufacturing to help reduce the cost of new therapies.

(13) Federal investments in a major pharmaceutical technology and education initiative led by the Food and Drug Administration in collaboration with university research partners will produce multiple benefits in health care quality and access.

### **SEC. 3. PHARMACEUTICAL TECHNOLOGY RESEARCH AND EDUCATION.**

#### **(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES-**

##### **(1) IN GENERAL-**

(A) **EXPAND AND INTENSIFY CERTAIN PROGRAMS-** The Commissioner of Food and Drugs (referred to in this Act as the "Commissioner") shall expand and intensify certain research and education programs regarding pharmaceutical science and engineering through the National Institute for Pharmaceutical Technology and Education (referred to in this Act as the "NIPTE") and the member institutions of the NIPTE, including Purdue University, Duquesne University, Illinois Institute of Technology, University of Puerto Rico (Mayaguez and San Juan), University of Connecticut, University of Iowa, University of Kentucky, University of Kansas, University of Maryland, University of Minnesota, and Rutgers University.

(B) **FOCUS-** The research and education programs described in subparagraph (A) shall focus on medical therapy development and manufacturing, analytical technologies, modeling, and informatics.

(2) **COORDINATION-** The Commissioner shall coordinate activities carried out pursuant to this Act with the member institutions of the NIPTE identified in paragraph (1), and other Federal agencies with an interest in such activities, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the National Science Foundation, the Department of Veterans Affairs, and the Department of Defense.

(3) **ALLOCATIONS-** The Commissioner shall allocate amounts appropriated to carry out this subsection for each fiscal year to the NIPTE.

#### **(b) COORDINATING COMMITTEE-**

(1) **IN GENERAL-** The Commissioner shall assist with and coordinate research and develop strategies to allow for the rapid design, enhanced manufacturing processes, and improved quality related to new medical technology development by establishing a Coordinating Committee pursuant to this subsection.

(2) **COMPOSITION-** The Coordinating Committee shall consist of 15 members to be appointed by the Commissioner for 2-year terms, of which--

(A) 8 members shall represent the Federal agencies described in subsection (a)(2) and the Food and Drug Administration; and

(B) 7 members shall be representatives from the public, including a broad cross section of academic, industry, consumer advocacy, and other interested persons affected by the costs of prescription drugs.



(3) CHAIR-

(A) IN GENERAL- The Coordinating Committee shall be headed by a Chair who shall serve as the principal advisor to the Commissioner and to the heads of the Federal agencies represented on the Coordinating Committee.

(B) APPOINTMENT- The Commissioner shall appoint the Chair of the Coordinating Committee for a 2-year term. The Commissioner may reappoint the Chair for not more than 1 additional 2-year term.

(4) ADMINISTRATIVE SUPPORT- The Coordinating Committee shall receive necessary and appropriate administrative support from the Food and Drug Administration.

(5) MEETINGS OF THE COORDINATING COMMITTEE- The Coordinating Committee shall meet as appropriate, as determined by the Commissioner in consultation with the Chair.

**(c) PLAN FOR FOOD AND DRUG ADMINISTRATION ACTIVITIES-**

(1) IN GENERAL- Not later than 1 year after the date of enactment of this Act, the Coordinating Committee shall develop a plan for supporting research and education efforts through the NIPTE and the relevant Federal agency participants that--

(A) provides for a broad range of research and education activities to enhance medical technology manufacturing and development;

(B) identifies areas of involvement for the participating Federal agencies; and

(C) reflects input from a broad range of academic, industry, and patient advocacy interests.

(2) CERTAIN ELEMENTS OF THE PLAN- The plan under paragraph (1) shall provide, with respect to medical technology development and manufacturing, for the following elements, as appropriate:

(A) Basic and applied research.

(B) Information and education programs.

**(d) REPORTS TO CONGRESS-**

The Coordinating Committee shall submit a biennial report to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives that describes the research, education, and other activities conducted or supported pursuant to this Act.

**(e) PUBLIC INPUT-**

The Commissioner shall provide for a means through which--

(1) the public can obtain information on the existing and planned programs and activities carried out pursuant to this Act; and

(2) the Commissioner can receive comments from the public regarding such programs and activities.

**(f) AUTHORIZATION OF APPROPRIATIONS-**

(1) IN GENERAL- For the purpose of carrying out this Act, there are authorized to be appropriated \$25,000,000 for each of fiscal years 2007 through 2012.

(2) ADDITIONAL AVAILABLE APPROPRIATIONS- The authorization of appropriations under paragraph (1) is in addition to any other appropriations available for conducting or supporting medical technology development and research activities through the Food and Drug Administration.

END



## I. Outlook 2007

### *I. 1. Excellent job opportunities for pharmacists*

Since decades pharmacists - having completed their studies at the University of Basel - have excellent job opportunities in all branches, i.e. as a community, hospital or as an industrial pharmacist. In case of a job position in the hospital or industry, it is advisable to have a PhD degree.

### *I. 2. Increasing number of students*

The number of students registered to study pharmaceutical sciences is sharply increasing and has reached the level of the years 1990's. It was necessary at that time to introduce a "Numerus Clausus" as the lab space for the practical training was limited despite of the existing external labs. In order to manage the number of students, interested to study pharmacy, a commission was formed in Bern (CEPREM, Arbeitsgruppe der Kommission für medizinische Fragen) of the SHK (today SUK, Schweiz. Universitätskonferenz) with the task to collect the wishes for the preferred location to do the studies in Pharm. Sciences (Basel, Lausanne, Geneva, Zürich) and to "distribute" the students in order to match the limited number of study places. This procedure was an analogue one which was already established for students interested to study medicine, leading to a dissuasion effect to choose such a study. The discussion was effective and the task of the commission could be abandoned. At the same time the Department of Pharmacy could move to its new location at the Pharmazentrum with new modern labs. Since that time the number of students is now steadily increasing. Thus, it is important to have enough laboratory space available. This is critical for the area of pharmaceutical technology with its special equipment. To take care of the increasing number of students and to accommodate the students it will be necessary to invest also in the infrastructure of the Industrial Pharmacy Lab for an improved use of that lab space.

### *I. 3. Future perspectives*

In 2004 it became evident that the area of pharmaceutical powder technology is becoming an extremely important topic as a consequence of the Process Analytical Technology (PAT) Initiative of the Food and Drug Administration (FDA), which revealed that this research area is still in an infant state. Due to the fact that ca. 80% of medicinal products on the market are solid dosage forms (tablets, capsules etc), i.e. products based on the science and technology of pharmaceutical powders. This topic is a research focus of the Institute of Pharmaceutical Technology. Thus the recent research paper "Pharmaceutical Powder Technology - From Art to Science: The Challenge of FDA's PAT Initiative" received a high attention.

In the invited paper the idea is put forward to start a research initiative based on a "road map" to "translate" existing laws in physical chemistry into the area of powder technology taking into account the fact that powder consists of particles having "hard core" properties similar to "atoms" but that the number of "atomistic" articles in the powder is much less than the Avogadro Number  $N_A$ . Thus in this respect the area of powder technology meets the research field of nanoparticles consisting of a limited number of real atoms/molecules with a number much lower than  $N_A$ . This low number of atoms in a nanoparticle leads to its special properties such as colour etc. On the other hand the low number of particles ( $N \ll N_A$ ) in powder technology leads to the special properties of powders which often do not behave as a solid having features like a fluid or a gas.

### *I. 4. Future perspectives in education: collaboration with the School of "Life Sciences" of the University of Applied Sciences Northwestern Switzerland*

A working party consisting of Prof. Dr. Beat Ernst (Head of the Department of Pharmaceutical Sciences University of Basel), Dr. Gabriele Betz (Head of the Industrial Pharmacy Lab of the Institute of Pharmaceutical Technology), Prof. Dr. Gerda Huber (Head of the School of Life Sciences HLS, University of Applied Sciences Northwestern Switzerland, UAS) and Prof. Dr. Georgios Imanidis (Head of the Division Pharma Technology of HLS, UAS) has as a goal to explore a close cooperation between the University of Basel and the School of Life Sciences UAS.



## *I. 5. Waiting for the successor of Prof. Dr. H. Leuenberger*

### **Interview by the pharmaJournal, January 2007**



Figure 8 / Totengässlein 3, Basel

At the University of Basel it is a tradition that the person, who is retiring from his/her chair, is not involved in the selection of his successor. pharmaJournal was interested to know his views on the evolution of pharmaceutical sciences at the University of Basel, which is closely related to the creation of the Pharmacenter at the Klingelbergstr. 50 in 4056 Basel. When Prof. Dr. H. Leuenberger started in 1982 the Pharmacy building was located at the Totengässlein 3, i.e. down-town in Basel at a historical site (see Figure 8 / Totengässlein 3, Basel).



Figure 9 / Pharmacenter, Basel

The Minister of Education, Arnold Schneider of the government of Basel-City, who hired Prof. Leuenberger, was convinced that this location is not appropriate for the future development of the pharm. sciences in Basel and suggested to look for a new building. It took till the year 2000 that this new building, the Pharmacenter (see Figure 9 / Pharmacenter, Basel) could be realized.

Many obstacles, time with many ups and downs, had to be removed during this period. The author of this annual report thanks all the persons who have contributed to this project of this new building. The interview was given in german (see H.2.5).

### **Who will be the successor of the chair of the Institute of Pharmaceutical Technology?**

This question is still (26.4.2007) open. It is wishful that this vacancy will be occupied as soon as possible for the benefit of the students and for the benefit of the image of the University of Basel. Prof. H. Leuenberger has a lectureship in Pharmaceutical Technology at the University of Basel and is coaching the PhD students as indicated in the following table.



## I. 6. On-Going Research Activities

### I.6.1 PhD-Students

HL = Prof. Dr. Hans Leuenberger

GI = Prof. Dr. Georgios Imanidis

PhD Student	Faculty Responsibility	Topic (Working Title)	Funding and Location
Balzano Vincenzo	HL	Development of Multiple Unit Pellet Systems	Institute of Pharmaceutical Technology, University of Basel; Mepha
Bausch Ursula Johanna	HL	Steriles Abfüllen von Lösungen mit Zellen	Alphacos SA, CH 2822 Courroux; Institute of Pharmaceutical Technology, University of Basel
Blaser David	GI	Wirkstoffabsorption mit Caco-2 Zellkulturen	Institute of Pharmaceutical Technology, University of Basel
Brka Ervina	HL	Parametrization of the roller compaction process	Institute of Pharmaceutical Technology, University of Basel
Daneshvari Dana	HL	Dielectric Spectroscopy of binary hydrophilic solvent mixtures	Private source and Institute of Pharmaceutical Technology, University of Basel
Faatz Susan	HL	Vergleich Irland-Schweiz betreffend der bildungspolitischen Rahmenbedingungen für die Pharmaindustrie	Private source
Fueg Lise-Marie	HL	Einblick in die Entwicklung von Pulvern zur Inhalation mit dem SkyePharma multidose Dry Powder Inhaler (mDPI)	Skye Pharma AG, Muttenz
Krausbauer Etienne	HL	Pharmaceutical process optimization of disordered particulate systems using computer aided design and artificial neural networks	Swiss National Science Foundation, Bern, Grant No ; 2000 21 - 105245/1 nph 1502
Lema Carmen	HL	NIR based process analytical technology: in-line residual moisture determination for a complete batch inspection of lyophilized end-products	F. Hoffmann -La Roche AG, Basel



Maurer Lene	HL	Nicht-destruktive Inprozess-Kontrollen mittels NIR in der Tablettenproduktion als potentielle PAT Anwendung	F. Hoffmann -La Roche AG, Basel
Meyer Thomas A.	HL	The behaviour of disordered particulate systems: flow properties and diffusive mixing	Institute of Pharmaceutical Technology, University of Basel
Müller Franziska Simone	HL	Comparison of Avicel and Uicel as excipient in fast-disintegrating tablets	Institute of Pharmaceutical Technology, University of Basel
Katrin Oppel	HL	Taste masking of active ingredients for veterinary application	Novartis Animal Health Inc., Basel
Reiser Miriam	GI	Transdermale Iontophorese	Institute of Pharmaceutical Technology, University of Basel
Russell Frauke	HL	Near-infrared Transmission Spectroscopy – a fast and non-destructive method for dissolution testing of solid dosage forms	F. Hoffmann -La Roche AG, Basel
Schneider Marcel	GI	Absorptionsstudien an Caco2 Monolayern	Institute of Pharmaceutical Technology, University of Basel
Sehic Selma	HL	Effect of variability of primary materials on the performance of carbamazepine formulation	Industrial Pharmacy Lab, Bosnalijek, Bosnalijek, Pharmaceuticals and Chemicals Industry

### I.6.2 Postdoctoral Positions

Dr. Betz Gabriele	Implementation of Research and Teaching in the Industrial Pharmacy Laboratory Mülhauserstrasse 49/51, Basel	Institute of Pharmaceutical Technology, University of Basel
Dr. Puchkov Maxim	New Learning and Teaching Technologies and expert systems, Industrial Pharmacy Laboratory	IT specialist for Expert Systems and Computational Science. On leave from MUCTR (cooperation project)



## I. 7. Grants and Operating Budget

### I.7.1 Contribution of the University (figures 2002 costs - 2006 budget):

2002	(running costs):	CHF	105 115	
	(investment in equipment):	CHF	155 674	(incl. CHF 20 000 for EDV)
2003	Budget: (running costs)	CHF	77 500	
	Budget: (investment in equip.)	CHF	81 505	(incl. CHF 18 205 for EDV)
2004	Budget: (running costs)	CHF	72 500	
	Budget: (investment in equip.)	CHF	40 385	(incl. CHF 10 000 for EDV)
2005	Budget: (running costs)	CHF	99 000	
	Budget: (investment in equip.)	CHF	89 000	(incl. CHF 17 300 for EDV)
2006	Budget: (running costs)	CHF	104 000	
	Budget: (investment in equip.)	CHF	zero*	(incl. EDV)

### I.7.2 External funding administered by the University

External funding administered by the University incl. Swiss National Science Foundation (SNF):

SNF-Project 2000 21 - 105245/1: CHF 175 005 (2004-2007).

SCOPES-Project (SNF) IB 74 BO - 110911: CHF 100 000 (2006-2008).

### I.7.3 Other third party funds not administered by the University

Direct payments to PhD students **CHF 525 000 (estimate  $\pm$  20%)**  
(individual salaries, 15 x CHF 35'000)

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\* Decision by Department Management Committee (at the meeting of January 19, 2006) due to retirement of Prof. Dr. Hans Leuenberger end of October 2006, with the goal to boost the investments in pharm. technology for the successor in 2007.



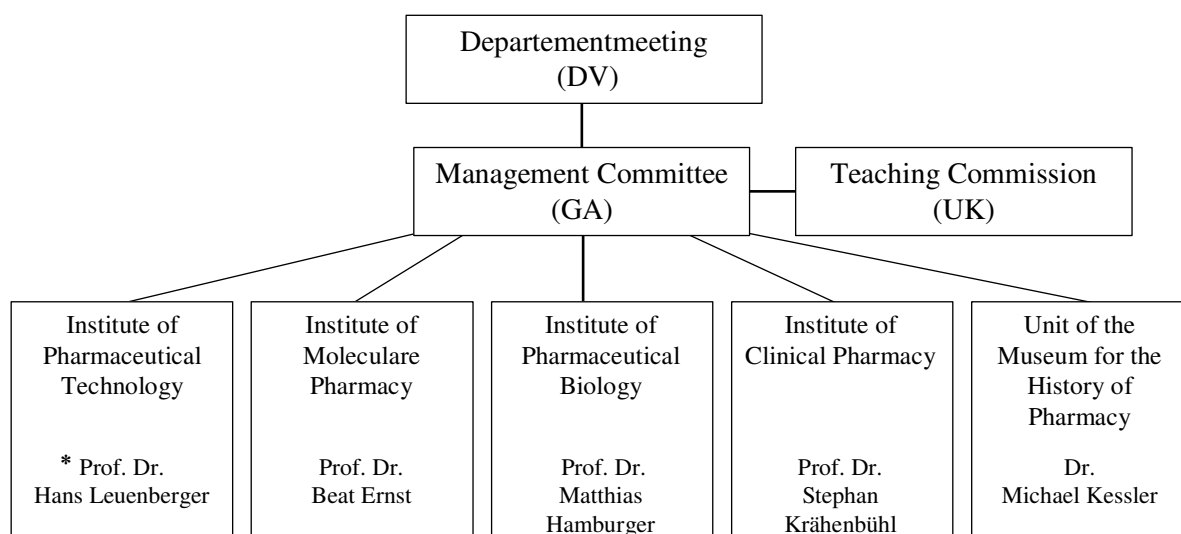
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# ATTACHMENT

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## J. Organization charts

### Organization Department of Pharmaceutical Sciences



### Management Committee 2006

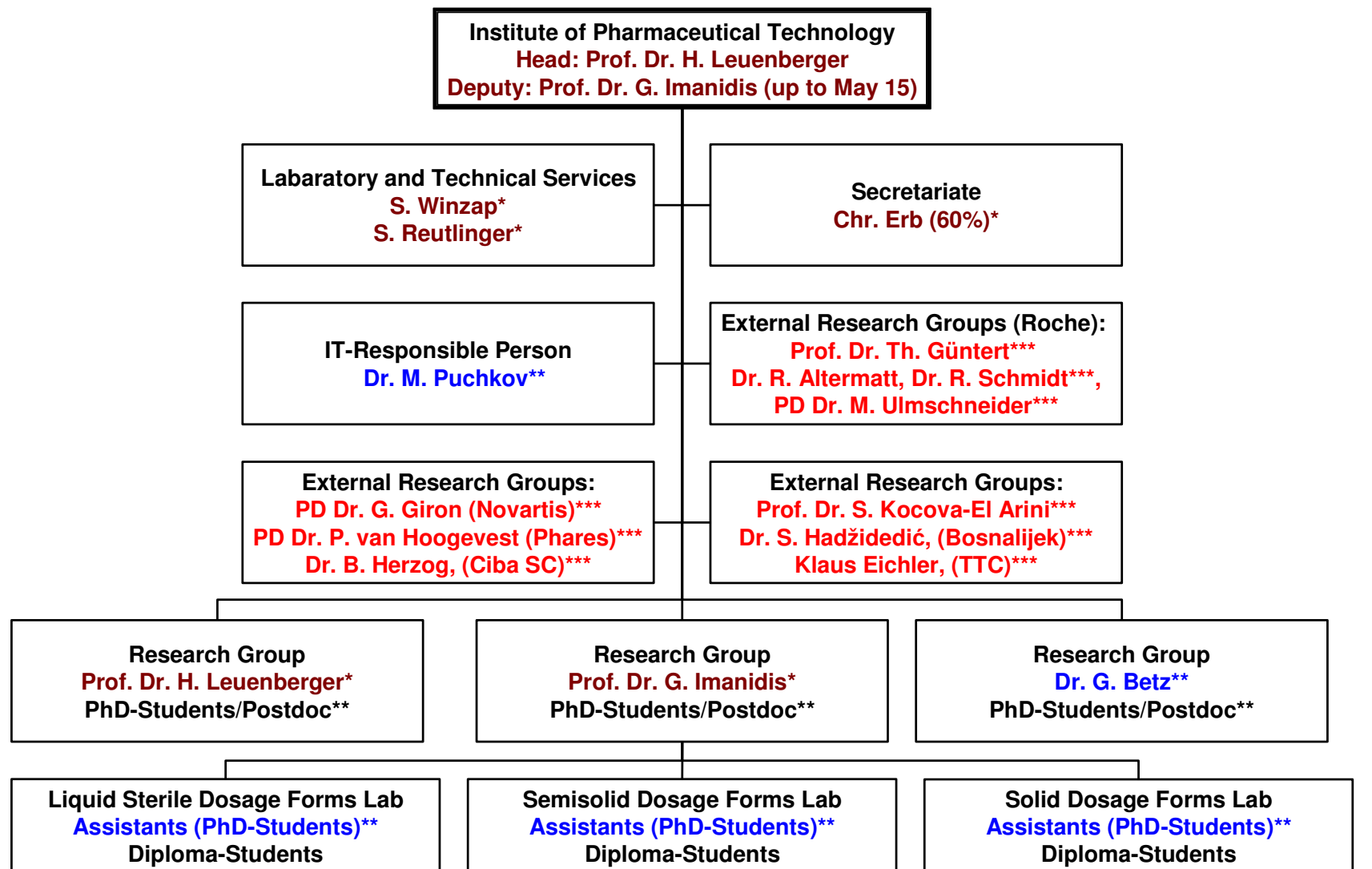
- B. Ernst (chairmanship)
- G. Imanidis (till May 15, 2006)
- H. Leuenberger (\*till Oct.31, 2006, after N.N. and G.Betz)
- A.B. Utelli
- M. Hamburger
- J. Krähenbühl

### Teaching Commission

- B. Ernst (Chair)



# Organisational Chart Institute of Pharmaceutical Technology



\*Employees of the University

\*\*PhD/Postdoc students  
 non-permanent positions, support by  
 University, SNF, private grants etc.

\*\*\*External docents/researchers  
 not employees of the University



## K. Reports / Contributions from External Docents

### K. 1. K. Eichler

#### K.1.1 Activities

As in the past PhD students had the chance to attend events of the Technology Training Center (TTC) in Binzen, Germany.

### K. 2. PD Dr. D. Giron

#### K.2.1 Activities

##### Symposium organisation/scientific committee

- STK as president, 1 day meeting, Freiburg, June 8th
- Scientific committee PhandTA 9, Düsseldorf September 10-13
- Scientific committee for ESTAC Krakow, August 26-28

##### Lectures

April 24, 2006 D.Giron	The Second Annual Global Pharmaceutical Conference, Dublin	Polymorphism in Pharmaceuticals
11.9. 2006 D.Giron, S.Monnier, F.Stowasser, M.Mutz, P.Piechon, M.Bellus	PhandTA9, Düsseldorf	Comparison of quantitative methods for analysis of polyphasic pharmaceutical
13 Sept. 2006 D. Giron	Continuous Education in pharmaceutical development and production, Pharmaceutical University Zürich& Basel	Analytical development for active ingredient: salt form, polymorphism, stability, impurities
20.07.06 D. Giron	The 4th New Pharmaceutical Technology and Engineering Conference, Tokyo	Polymorphism and pseudopolymorphism in Pharmaceuticals-Impact by ICH Q6

##### Workshops, lectures at university

June 2006	Pharmaceutical University of Nancy	Le développement analytique des nouvelles substances actives
September 2006	Pharmaceutical University Zürich& Basel Workshop following lecture	Continuous Education in pharmaceutical development and production
November 2006	WAHLPRATIKA University Basel. Pharmaceutical Institut	Theory and exercices about solid state characterization



December 2006	Chemical and Physical Institut (CPE), Lyon, Formation continue	Analyse thermique appliquée à la pharmacie
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### K.2.2 Publications

- D.Giron, "Thermal Analysis and Microcalorimetric Methods in the Industry: Essential Techniques for proper Development of Pharmaceuticals" European Pharmaceutical Review, September 2006
- D. Giron, Physicochemical Characterization of the solid state in Drug Development" in "Pharmacokinetic Profiling in Drug Research, Biological, Physicochemical and computational Strategies, Ed. Prof. Testa, S.D.Krämer, H.Wunderli-Allenspach, G. Folkers, Wiley, Verlag Helvetica Chimica Acta, 2006, p.307-329
- D. Giron, Chapter 5.24 , Solid-State physicochemistry in "Comprehensive Medicinal Chemistry", Volume 5: ", Elsevier, 2007

### Posters/co-lectures

- D. Giron, S. Monnier, T. Buser, P. Piechon," A compatible system for microscale HTS Raman and XRPD" STK, Freiburg, June 8th
- M. Mutz, A. Motreff, P. Schwab, T. Buser, S. Monnier, D. Giron, "Use of high throughput microcalorimetry for faster determination of amorphous content" STK, Freiburg, June 8th.
- F. Stowasser, D. Giron, P. Piechon, "Use of X-ray Powder Diffraction in Pharmaceutical Industry" EPDIC 2006 in Genf

## K. 3. T.W. Guentert

In addition to the various lectures in Biopharmaceutics and Drug Metabolism extensive restructuring took place to achieve a higher degree of coordination within the Pharmacy curriculum and to accommodate the new structure of lecture and examination modules. .

### K.3.1 List of Dissertations

Ongoing Dissertations: none

Completed Dissertation: none

### K.3.2 Invited Speaker

March 14-15, 2006, Basel	APV Course	Elementary and Applied Pharmacokinetics und Biopharmaceutics: Drug Disposition – Distribution, Elimination"
February 20, 2006, , Basel	ECPM Course, University Hospital	Toxicology and Clinical Pharmacology, Principals of Pharmacokinetics and Therapeutic Implications
November 13-14, 2006, Japan	The 4th COE International Symposium on "Target Validation, Lead Optimization and Clinical Development", University of Tokyo	



### K.3.3 External Courses

- Faculty Member in Workshop in Basic Pharmacokinetics, organized by Prof. M. Rowland, Manchester, UK and Stratégie Santé, Paris, FR, Arosa July 9 – July 14, 2006
- Faculty Member in Workshop in Basic Pharmacokinetics, organized by Prof. M. Rowland, Manchester, UK and Stratégie Santé, Paris, FR, Strasbourg Nov 6 – Nov 10, 2006

### K.3.4 Research 2005

- In vitro absorption models
- Influence of galenical factors on drug absorption
- Prediction of drug behavior in humans based on animal and in vitro data
- Simulation techniques
- Pharmacogenomics
- Optimizing Drug Development

## K. 4. Dr. Bernd Herzog

Ciba Specialty Chemicals G-9001.2.28  
PO Box 1266  
D-79630 Grenzach-Wyhlen

### K.4.1 Publikationen

- “Emerging standards in UVA protection”, U. Osterwalder, B. Herzog, Household and Personal Care Today – supplement to ChimicaOggi / Chemistry Today, April 2006, 24 - 26
- “Novel Nanotubes from a Cationic Surfactant and an Anionic Stiff Aromatic Counter-Ion”; L. Zhai, B. Herzog, M. Drechsler, H. Hoffmann, J. Chem. Phys. B Letters, Published on Web 08/19/2006
- “Improved Simulation of Sun Protection Factors and UVA-Parameters – A Useful Tool for the Development of Sunscreen Formulations”, Bernd Herzog, Stefan Müller, Annina Neuenschwander, Cyrille Deshayes, Stephanie Acker, and Uli Osterwalder, Proceedings of the 24th IFSCC Congress, Osaka, 2006

### K.4.2 Vorträge und Poster:

2006, San Francisco, U. Osterwalder, S. Müller, A. Gril, B. Herzog	American Academy of Dermatology, (poster)	Understanding sunscreens – new Insights into the role of photostability through in vivo, in vitro and in silico experiments
March 2006, Olten, B. Herzog	Oral Presentation, Kosmetikseminar Christ-Chemie	Bewertung der UVA-Schutzleistung von Sonnenschutzmitteln – Überblick und neue Entwicklungen
Sept.2006, Ottawa, JP. Cesarini, U. Osterwalder, B. Herzog	Oral Presentation at the CIE Conference Division 6 meeting	UVA-Protection and Sunscreens



Oct.2006, Osaka, S. Müller, A. Neuenschwander C. Deshayes, S. Acker, U. Osterwalder	Oral Presentation at the 24th IFSCC Congress	Improved Simulation of Sun Protection Factors and UVA-Parameters – A Useful Tool for the Development of Sunscreen Formulations
6.12.06, Basel, B. Herzog	Seminars on Drug Discovery & Development, University of Basel	Recent Advances in the Development and Assessment of UV-Absorbers for the Protection of Human Skin

#### K.4.3 Teaching 2006

- Betreuung Diplomarbeit von Barbara Ehrenhöfer (Pharmazeutische Technologie), Titel: „Intradermale Messungen der Photostabilität von Sonnenschutzmitteln am Schweinehautmodell“
- Tutor für Galenik-Seminar, „Sonnenschutzmittel I + II“
- Vorlesung “Disperse Arzneiformen” im WS 06/07

### K. 5. PD Dr. Peter van Hoogevest

#### K.5.1 Publication 2006

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