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INSTITUTE OF PHARMACEUTICAL TECHNOLOGY UNIVERSITY OF BASEL

Building with the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies, Moscow

剂型设计

巴塞尔的新研究旨在了解并调节制药工艺

Dosage form design

New research in Basel aims to understand and control pharmaceutical processes

Advanced Powder Technol., Vol. 16, No. 1, pp. 3–25 (2005)

Also available online - www.vsppub.com

Invited review paper

Pharmaceutical powder technology — from art to science: the challenge of the FDA's Process Analytical Technology initiative

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FrontPage:

New research building (computer simulation) with facilities for the Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies (www.rs-pharmcenter.ru), at the Mendeleev University of Chemical Technology of Russia (MUCTR) planned in Tushino (High-Tech Park of MUCTR) (see H. 3 Completion of the SCOPES/SNF project 7IP 062613 in cooperation with MUCTR.)	Part of the cover of the program of the seminar at MUCTR organised by rs-pharmcenter
Headline of the invited paper (in chinese and in english) of Pharmaceutical Technology China, describing the Industrial Pharmacy Lab in Basel (see H.3.1 Invited Lectures in China)	Invited paper of Adv. Powder Technology, describing the road map of a future research initiative in pharmaceutical powder technology (see I. 3 Future perspectives)

Tushino (□□□□□□ in Russian) is a former village and town to the north of Moscow, which has been part of the city's area since 1960. The Skhodnya River flows across the southern part of Tushino. In the second half of the 19th century, Tushino saw the first industrial enterprises, such as windmills and a textile mill. In the 1920s, they built Tushino Stocking Factory. In 1929, the Soviets established a flying school of the Osoaviakhim (Осоавиахим, which is short for the Society for Support of the Defence, Aviation, and Chemical Industries) and then an airfield with research faculties and aircraft factories next to Tushino.
From Wikipedia, the free encyclopaedia

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PRESENTATION OF THE INSTITUTE

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] forms together with the Institute of Pharmaceutics of the Federal Institute of Technology Zürich [ETHZ] the Center of Pharmaceutical Sciences of Uni BS and ETHZ.

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 has 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 University Diploma or PhD degree in Pharmaceutical Sciences (for industry, academia, hospital) or a Federal Diploma as a Pharmacist (for hospital and community). In 2003 the curriculum of a BSc in Pharmaceutical Sciences was adopted. Together with the master courses (in development) the MSc degree will subsequently replace the actual University diploma in Pharmaceutical Sciences.
- Pharmacists have excellent job-opportunities in the pharmaceutical industry (see the web page of the Swiss Society of Industrial Pharmacists 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 (Diploma students)

For the preparation of the diploma work (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 pharmacenter 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.pharmacenter.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 Mendeleev 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 4th 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".

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 21st century and FDA's PAT initiative (www.fda.gov/cder/OPS/PAT.htm).

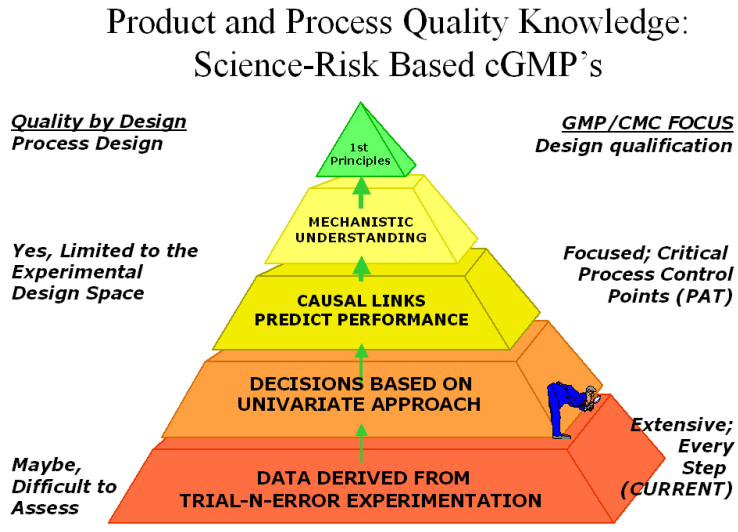


Figure 1 / E. 2 - Science Pyramid
(Courtesy A. Hussain, FDA)

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, Tabletting
- 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 4th Dimension (Moist Agglomeration and Drying Process)
- Supercritical CO_2 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 institute of pharmaceutical technology.

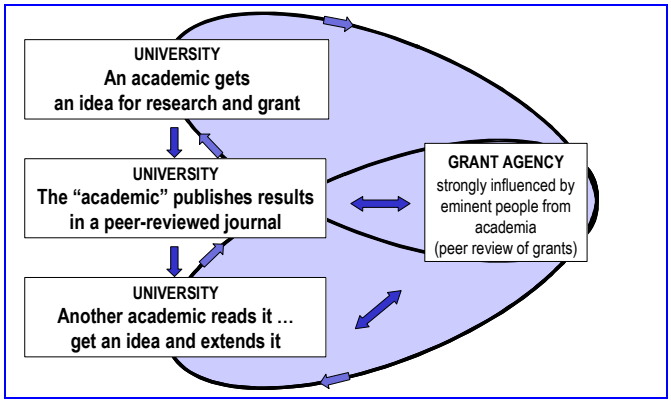


Figure 2 / E. 4 - A "closed loop" model of academic research

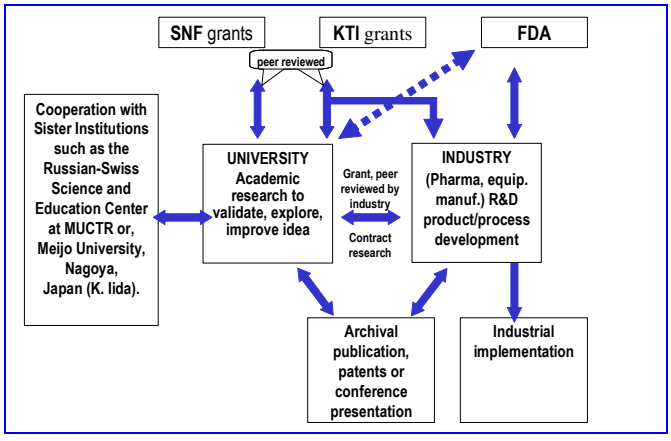


Figure 3 / E. 4 - An "open loop" model of cooperative research and interactions

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.
- Monitoring Mass Transfer Processes in order to control moist agglomeration, H.Leuenberger and G.Imanidis *Pharm.Techn*. **10:**(1986): 56 - 73
- Monitoring the Granulation Process: Granulate Growth, Fractal Dimensionality and Percolation Threshold, H.Leuenberger, M.Usteri, G.Imanidis and S.Winzap Boll. Chim. Pharm. **128:** (1989): 54-61.
- Agglomeration of Binary Mixtures in a High-Speed Mixer, M.Usteri and H.Leuenberger *Int.J.of Pharm*. **55:** (1989): 135-141.
- Design and Modification of Powders - A Must in Pharm. Technology, H.Leuenberger, Proceedings 2nd World Congress Particle Technology, Sept. 19-22, 1990, Kyoto, Japan Vol. III. p. 317-328, The Society of Powder Technology, Japan.
- Design and Optimisation Approaches in the Field of Granulation, Drying and Coating, H.Leuenberger Pharmacy World Congress '93, Tokyo, Proceed. of the 53rd Int. Congress of Pharm. Sciences 1993, Editors: D.J.S.Crommelin, K.K.Midha, T.Nagai, Medpharm. Scientific Publishers, Stuttgart 1994, p. 493-511.

E.6.3 New Process Technologies

- Prozess-Monitoring bei der Emulsionsherstellung; Drehmomentenmessung als Inprozesskontrolle bei der Emulsionsherstellung, R.Randegger, G.Imanidis, R.D.Juch, G.Birrenbach, H.Leuenberger *Pharm.Ind.* **56:**(1994): 648-654
- Wet spherical agglomeration of proteins as a new method to prepare parenteral fast soluble dosage forms, A.Bausch and H.Leuenberger *Int.J.of Pharm*. **101:**(1994): 63-70
- List of Preparation of Liposomes Encapsulating Water Soluble Compounds Using Supercritical Carbon Dioxide, L.Frederiksen, K.Anton, P.vanHoogevest, H.R.Keller and H.Leuenberger *J.Pharm.Sci.* **86:** (1997): 921 –928.

E.6.4 Drug Delivery through Biological and Artificial Membranes

- P.Lütolf, G.Imanidis and H.Leuenberger. Transdermal Iontophoresis of an Amphoteric Compound: Effect of Charge and Interaction with Human Skin, In: P.Couvreur, D.Duchéne, P.Green and H.E.Junginger (Eds.), Transdermal Administration, A Case Study, Iontophoresis, Editions de Santé, Paris, 1997, pp. 360-364.
- 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).
- F.P.Schwarb, G.Imanidis, E.W.Smith, J.M.Haigh and C.Surber. Effect of Concentration and Degree of Saturation of Topical Fluocinonide Formulations on *In Vitro* Membrane Transport and *In Vivo* Bioavailability on Human Skin. *Pharm. Res.* **16:**909-915 (1999).

E. 7. Publications: Institute of Pharmaceutical Technology 2000-2004

2000

A new model for the hardness of a compacted particle system, applied to tablets of pharmaceutical polymers. Publication, in english. Martin Kuentz, Hans Leuenberger, Powder Technol. 111 (1.2), 2000, 145-153. ISSN 0032-5910.

A new theoretical approach to tablet strength of a binary mixture consisting of a well and a poorly compactable substance. Publication - Thesis, in english. Hans Leuenberger, Martin Kuentz, Eur.J.Pharm.Biopharm. 49 (2), 2000, 151-159. ISSN 0939-6411.

Device with rotating blades for fluidized-bed treatment and agglomeration of particles. Patent Specification, in german. Hans Leuenberger, Patentschrift (Switz.), 2000.

Effect of mixing of fine carrier particles on dry powder inhalation property of salbutamol sulfate (SS). Publication, **in japanese**. Kotaro Iida, Hans Leuenberger, Lise-Marie Fueg, Rudi Müller-Walz, Hirokazu Okamoto, Kazumi Danjo, YaZa 120 (1), 2000, 113-119. ISSN 0031-6903.

Focus on research in nanoscience and nanotechnology in Switzerland. Publication, in english. Hans Leuenberger, J.Nanop.Res. 2 (4), 2000, 391-392. ISSN 1388-0764.

Solubilization Systems - The Impact of Percolation Theory and Fractal Geometry. Bookchapter, in english. Hans Leuenberger, Silvia Kocova, Water-Insoluble Drug Form. 2000, 569-607. ISBN 1-57491-105-8. Editor Liu Rong.

The Use of Fluorescence Resonance Energy Transfer to Study the Disintegration Kinetics of Liposomes Containing Lysolecithin and Oleic Aciln in Rat Plasma. Publication, in english. Maja Madörin, Peter van Hoogevest, Rolf Hilfiker, Hans Leuenberger, Pharm.Res. 17 (9), 2000, 1118-1123. ISSN 0724-8741.

2001

A novel approach to the characterization of polar liquids Part 1: Pure liquids. Publication, in english. Andrea Stengele, Stephanie Rey, Hans Leuenberger, Int.J.Pharm. 225 (1.2), 2001, 123-134. ISSN 0378-5173.

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: Menshutina 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.

Heparin penetration into and permeation through human skin from aqueous and liposomal formulations in vitro. Publication, in english. Gabriele Betz, Nowbakht Pegah, Roger Imboden, Georgios Imanidis, Int.J.Pharm. 228 (1.2), 2001, 147-159. ISSN 0378-5173.

How to Avoid Scale-up Problems in Manufacturing Pharmaceutical Granules: The Glatt Multicell Concept. Publication, in english. Hans Leuenberger, Pharm.Technol.Jpn 17 (10), 2001, 1563-1569. ISSN 0910-4739.

Interaction of liposome formulations with human skin in vitro. Publication, in english. Gabriele Betz, Roger Imboden, Georgios Imanidis, Int.J.Pharm. 229 (1.2), 2001, 117-129. ISSN 0378-5173.

Method for producing particulate goods. Patent Specification, in german. Hans Leuenberger, Armin K.T. Prasch, Bernhard Luy, PCT Int. Appl. 2001, 1-54.

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.

Powder - the fourth state of matter? Proceedings, in english. Hans Leuenberger, Proc.18th Symp.Part.Prep.Design 2001, 154-165. 18th Symposium on Particulate Preparations and Design; Toyohashi 24.10.01 - 25.10.01.

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, 1st edition, 118 2001, 151-170. ISBN 0-8247-0625-0. Marcel Dekker Inc., Editor: Levin Michael.

Scale-up in the 4th dimension in the field of granulation and drying. Preprint, in english. Hans Leuenberger, Preprints 7th .Intern.Symp.Aggl. 2001, 375-384. 7th International Symposium on Agglomeration; Albi CT Cedex 29.05.01 - 31.05.01.

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. 15th International Congress of Chemical and Process Engineering; Prague 25.08.02 - 29.08.02.

From Batch to Continuous Processes. A new trend in the Production of pharmaceutical granulates. Proceedings, in english. Werani Jürgen, Grünberg Mads, Ober Christian, Leuenberger Hans, Proceedings 4WCPT CD, 2002. ISBN 085 825 7947. 4th World Congress on Particle Technology; Sydney 21.07.02 - 25.07.02.

Information systems and databases for pharmaceutics. T. Mescheryakova, N. Menshutina, H. Leuenberger, S. Goncharova, Y. Mishina. Textbook **in russian**, MUCTR, 2002, 92 pp.

Nanocomposite drug carriers for low water soluble drugs. Proceedings/Abstracts. Leuenberger Hans, 2002. 2002 PARTICLES; Orlando 20.04.02 - 23.04.02, p. 99.

Physikalische Pharmazie. Book, in german. Leuenberger Hans, Martin Physikalische Pharmazie 4.Aufl 2002. Editor: Leuenberger Hans, ISBN 3-8047-1722-5. 785 pages.

Powder - the fourth state of matter? Publication, **in japanese**. Leuenberger Hans, Pharm.Technol.Jpn 18 (7), 2002, 995-1001. ISSN 0910-4739.

Rise and Fall of Megatrends in Science. Proceedings, in english. Proc.CASS-Symposium2000 2002, 1-126. Editors: Leuthold Margrit, Leuenberger Hans, Weibel Ewald R. ISBN 3-7965-1939-3. 2000 CASS (Conseil des académies scientifiques suisses)-Event; Bern 30.11.00 - 01.12.00.

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.

D. Hummel and G. Imanidis. Structure of Multi-phasic Dermatological Formulations and the Influence of the Structure and of Vehicle Evaporation on Transdermal Drug Permeation. In: R. Marks, J-L. Leveque and R. Voegeli (Eds.), The Essential Stratum Corneum, Martin Dunitz, London, 2002, pp. 119-124.

C. Kochhar and G. Imanidis. Transdermal Iontophoresis of Leuprolide In Vitro under Constant Voltage and Constant Current Conditions: Physicochemical Modelling and the Effect of Adjuvants. In: R. Marks, J-L. Leveque and R. Voegeli (Eds.), The Essential Stratum Corneum, Martin Dunitz, London, 2002, pp. 149-155.

T. Schmidt, N. Widler, F. Gafner and G. Imanidis. Stratum Corneum Lipid Composition as a Predictive Tool for Permeability? In: R. Marks, J-L. Leveque and R. Voegeli (Eds.), The Essential Stratum Corneum, Martin Dunitz, London, 2002, pp. 169-174.

T. Tassopoulos, S. Maeder, G. Imanidis, V. Figueiredo, E.W. Smith and C. Surber. Evaluation of a Direct Spectrophotometric Method for Percutaneous Bioavailability Studies. In: R. Marks, J-L. Leveque and R. Voegeli (Eds.), The Essential Stratum Corneum, Martin Dunitz, London, 2002, pp. 175-178.

2003

Aluminium in over –the-counter-drugs: Risks outweigh benefits? Publication, in english. Reinke Claudia, Breitkreutz Jörg, Leuenberger Hans, DrugSafety 26 (14), 2003, 1011-1025. ISSN 0114-5916.

Batch and Continuous Processing in the Production of Pharmaceutical Granules. Publication, in english. Betz Gabriele, Junker Bürgin Pascale, Leuenberger Hans, Pharm.Dev.Technol. 8 (3), 2003, 289-297. ISSN 1083-7450.

Compression behaviour of the enzyme ß-galactosidase and its mixture with microcrystalline cellulose. Publication, in english. Kuny Tanja, Leuenberger Hans, Int.J.Pharm. 260 (1), 2003, 137-147. ISSN 0378-5173.

Effect of Surface Covering 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. 51 (12), 2003, 1455-1457. ISSN 0009-2363.

Evaluation of Flow properties of Dry Powder Inhalation of Salbutamol Sulfate with Lactose Carrier. Publication, **in japanese**. Iida Kotaro, Hayakawa Youhei, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans, Pharm.Technol.Jpn 19 (3), 2003, 39(359)-46(366). ISSN 0910-4739.

Modeling of freeze drying process in fluidized bed spray dryer. A.E. Korneeva, M.N. Puchkov, A.A. Voynovskiy, N.V. Menshutina, H. Leuenberger. Izvestiya Vuzov (**in Russian**), 2003.

Non-destructive Dissolution Testing Correlation. Publication, in english. Kuny Tanja, Schatz Caspar, Ulmschneider Michel, Marrer Stephan, Leuenberger Hans, Distech 10 (1), 2003, 22-28. ISSN 1521-298X.

Permeation, Metabolism and Site of Action Concentration of Nicotinic Acid Derivatives in Human Skin - Correlation with Topical Pharmacological Effect. B. Müller, M. Kasper, C. Surber and G. Imanidis. Eur. J. Pharm. Sci. 20:181-195 (2003).

Power consumption profile analysis and tensile strength measurements during moist agglomeration. Publication, in english. Betz Gabriele, Junker Bürgin Pascale, Leuenberger Hans, Int.J.Pharm. 252 (1.2), 2003, 11-25. ISSN 0378-5173.

Preparation of Dry Powder Inhalation by Surface Treatment of Lactose Carrier Particles. Publication, in english. Iida Kotaro, Hayakawa Youhei, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans, Chem.Pharm.Bull. 51 (1), 2003, 1-5. ISSN 0009-2363.

Research Activities at the Institute or Pharmaceutical Technology of the University of Basel, Proceedings, in english. Hans Leuenberger. Proc.Albi Intern.Rencontres Pharm.Eng. (2003). Editors: Baron Michel, Dodds John, ISBN 2-9511591-2-9, Albi International Rencontres in Pharmaceutical Engineering, École des Mines Albi-Carmaux; Albi 11.10.2001 - 11.10.2001.

Scale-up in the 4th dimension in the field of granulation and drying or how to avoid classical scale-up. Publication, in english. Leuenberger Hans, Powder Technol. 130 (1.3), 2003, 225-230. ISSN 032-5910.

2004

Atmospheric Spray Freeze Drying with fluidized bed of Manitol. Proceedings, in english. Menshutina Nathalia V., Korneeva Anastasiya E., Goncharova Svetlana V., Leuenberger Hans, Proc.Int. Meet.Pharm., Biopharm.Pharm.Technol. 2004, 303-304. 2004 International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology; Nürnberg 15.3.04 - 18.3.04.

Correlation of Membrane Order and Dynamics Derived from Time-Resolved Fluorescence Measurements with Solute Permeability. M.Sutter, T. Fiechter and G. Imanidis. J.Pharm.Sci. 93, 8; (2004). p.2090- 2107. ISSN 0022-3549.

Differential scanning calorimetry as a tool for the prediction of the compatibility and stability of multicomponent drug systems. Proceedings, in english. Trobradovic Haris, Betz Gabriele, Kocova Silvia, Hadžidedić Šeherzada, Leuenberger Hans, Proc.Int. Meet.Pharm., Biopharm.Pharm.Technol. 2004, 161-162. 2004 International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology; Nürnberg 15.3.04 - 18.3.04.

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.

Effects on the Quality of Granules Obtained in Conventionally Designed Fluid-bed Equipment Compared to Granules Obtained in a Washing In Place/Cleaning In Place Designed Unit. Publication, in english. Schiffmann Axel, Dressler Jochen A., Luy Bernhard, Leuenberger Hans, Pharm.Ind. 66 (8), 2004, 1024-1030. ISSN 0031-711x.

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.

Investigation of granulation and comparison of tablet compaction properties of polymorphs of Mannitol after wet granulation with directcompressible Mannitol using a compaction simulator. Proceedings, in english. Betz Gabriele, Meyer Andrea, Puchkov Maxim, Leuenberger Hans, Proc.Int. Meet.Pharm., Biopharm.Pharm.Technol. 2004, 101-102. 2004 International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology; Nürnberg 15.3.04 - 18.3.04.

In Vitro Transdermal Iontophoretic Delivery of Leuprolide under Constant Current Application. C. Kochhar and G. Imanidis. J. Control. Release 98:25-35 (2004).

Modelling of the spray-freeze drying process. Proceedings, in english. Leuenberger Hans, Plitzko Matthias, Puchkov Maxim, Proc.Int. Meet.Pharm., Biopharm.Pharm.Technol. 2004, 871-872. 2004 International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology; Nürnberg 15.3.04 - 18.3.04.

Multimedia education courses for chemical technology and pharmaceutics. N.V. Menshutina, H. Leuenberger, S.V. Goncharova, D.V. Shishulin, E.O. Lebedev, A.E. Korneeva. Textbook **in russian**, 2004, MUCTR, 132 pp.

Power Consumption Measurement and Temperature Recording during Granulation. Int.J.Pharm. Publication, in english. Betz Gabriele, Junker Bürgin Pascale, Leuenberger Hans, Int.J.Pharm. 272 (1.2), 2004, 137-149. ISSN 0378-5173.

Preface of the POWDER TECHNOLOGY Special Issue on Pharmaceutical Particle Formation. Edited by:. Publication/Editorial, in english. Fukumori Yoshinobu, Leuenberger Hans, Horio Masayuki, Powder Technol. 141 (3), 2004, 171-171. ISSN 0032-5910.

Semicontinuous granulation - the process of choice for the production of pharmaceutical granules?. Publication, in english. Werani Jürgen, Grünberg Mads, Ober Christian, Leuenberger Hans, Powder Technol. 140 (3), 2004, 163-168. ISSN 0032-5910.

Transdermal Drug Delivery Method and System. G. Imanidis, W. Zumbrunn and G. DiPierro. PCT Patent Application No. PTC/IB2004/002947, September 13, 2004.

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 Danièlle 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., Muttenz, 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, is teaching Quality Assurance topics and is tutor in the seminar for Pharmaceutical Technology. Dr. Marrer accepted other responsibilities at F. Hoffmann-La Roche AG and handed over his teaching responsibilities which expired end of summer semester 2005 to Dr. Rolf Altermatt. The significant contribution of Dr. Marrer is acknowledged.
- Dr. Rolf Altermatt from F. Hoffmann-La Roche AG, is successor of Stephan Marrer and takes care of teaching Quality Assurance topics.
- Dr. Rainer Schmidt from F. Hoffmann-La Roche AG, takes care of teaching Quality Assurance topics.
- 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-Wylen 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	27th 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 Rüf Stiftung Basel, Switzerland. NETS Special Award sponsored by Gebert Rüf 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.

F. 3. H. Leuenberger

EDUCATION	
Diploma in Experimental Physics (University of Basel)	1967
PhD-Thesis in Nuclear Physic (University of Basel)	1971
INDUSTRIAL CAREER	
Head of R+D Laboratory (Preformulation work) Analytical R+D Department, Sandoz Ltd., Basel	1971-1973
Research Group Leader, Pharmaceutical R+D, Sandoz Ltd., Basel	1973-1982
SABBATICALS AND EXPERIENCES ABROAD	
University of Hamburg (Prof. Dr. H. Sucker) Germany	1973
University of Michigan, Ann Arbor (Prof. Dr. W.I. Higuchi, Prof. Dr. N.F. Ho, Dr. E.W. Hiestand), U.S.A.	1979
Head Pharma R+D, Sandoz España, Barcelona ad interim (Spain).	1980
CAREER IN ACADEMIA	
Part Time Lecturer at the University of Basel as Private Docent (PD) in Pharmaceutical Technology	1980
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)	1982
Planning of a new building for the Institute of Pharmacy	1982-2000
Member of the Expert Group 12 (Pharmaceutical Technology) of the European Pharmaceutical Commission, Strasbourg, France	1988-1993
Dean of the Faculty of Natural Science at the University of Basel, Founder of the Faculty Committee of Department Heads	1994/95
President of the Scientific Council [SC] of the Swiss Academy of Engineering Science [SATW] and founder of the Lateral Think Tank of the SC	1992-96
Vice President of the Swiss Academy of Engineering Science	1993-2001
President of the Swiss Society of Pharmaceutical Sciences (SGPhW)	Since Oct. 2001

Member of Editorial Advisory Board (such as J.Pharm.Sci. 1990/92, Scientific Advisory Board of Journal of Particuology, China etc.),
Referee for different journals,
Member of peer review committees: ETHZ (1993), University of Groningen and Utrecht (1997),
Publications: more than 250,
Patents: ten.

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

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

Member of Swiss Academy of Engineering Sciences since 1987.

University of Helsinki Medal 1989.

Fellow of the American Association of Pharmaceutical Scientists [AAPS] since 1990.

AAPS Research Award in Pharmaceutical Technologies 1993.

Innovation Award for New Process Technologies of
the Governments Basel-City and Basel-Country 1994.

Honorary Member of the Swiss Society of Industrial Pharmacists [GSIA] since 1994.

Jörg Bider Medal of the Swiss Society of Pharmacists [SAV] 1997.

Corresponding Member of the Royal Academy of Pharmacy of Spain since 1998.

Foreign Member of the Russian Academy of Engineering Sciences since 1998.

IPS Medal 2000 [Industrial Pharmacy Section] of
FIP [Féderation International Pharmaceutique]. 2000.

Member of the Scientific Advisory Board of the Grand École des Mines, Albi, France, since 2001.

Award of Particulate Preparations and Design of the Society of Powder Technology of Japan,
Kyoto, Japan, 2001.

Member of Board of Directors of CAETS (International Council of Academies of Engineering and Technological Sciences) 2001

Honorary member of the Swiss Academy of Engineering Sciences since 2001.

International Council of Academies of Engineering and Technological Sciences (CAETS):
Certificate of Appreciation for Outstanding Service, May 2004.

For development of the portal of distance and multimedia education we received the bronze medal and diploma at the 4th Moscow International Salon of Innovations Investments, 2004.

The International Symposium on Agglomeration Certificate of Agglomeration Award in Recognition of The Outstanding Contribution To the Development Of Agglomeration Sciences, 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 (www.muctr.ru)].

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*

Mendeleev 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

* Based on formal agreements. (Activity depending on projects, time and resources).

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

H. Progress Report 2005

PD Dr. Georgios Imanidis was promoted to Titular Professor and elected as head of the competence center Pharma Technology at the University of Applied Sciences Northwestern Switzerland (UAS), School of Life Sciences, Muttenz.

H. 1. Special Events 2005

H.1.1 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, Muttenz (www.fhnw.ch/lifesciences)]
has 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 UASBCC.

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 L. Attachment, as part of the report - Cooperation with the University of Applied Sciences Northwestern Switzerland). The concept suggests a close cooperation between the School of Life Sciences (HSLS) in Muttenz 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".

H.1.2 Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies at the Mendeleev University of Chemical Technology of Russia (MUCTR), Moscow

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 within the University and that MUCTR will provide special space (office, labs) in a new research building of MUCTR, located in the north of Moscow (Tushino, high tech parc). The idea of the center is described in the following poster (see next page).

H.1.3 International Seminar: "Innovative Technologies and Equipment for Pharmaceutical Industry" MUCTR September 2005, Moscow

The first international event of the center was the above mentioned seminar which took place from 29 to 30 September 2005, 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 next page - the English version).

Russian Swiss Science and Education Center for Pharmaceutical and Biological Technologies at the Mendeleev University of Chemical Technology of Russia (MUCTR), Moscow

International Education and Scientific Centre for pharmaceutical and bio-technologies transfer

Prof. N. Menshutina, executive director
High-tech department, MUCTR

Prof. H. Leuenberger, honorary director
Institute of Pharmaceutical Technology, University of Basel

The center has been established as the structural unit of MUCTR as the result of team-work between the Institute of Pharmaceutical Technology, University of Basel and MUCTR supported by SNSF SCOPES project 71P 62613 "Development of new courses and scientific work in the field of pharmaceutical education". The development of the center is supported by:

?Swiss National Science Foundation
?Swiss Embassy in Moscow
?Russian Ministry of Science and Education

The focus of the Center is to enhance the Russian-Swiss relationship in the area of science, technology and education for mutual benefit.

Course Materials. Lectures

- Dosage dispersial forms (671 slides)
- Solid drugs forms (~400 slides)
- Liquid sterile drug forms (~250 slides)
- Equipment and Technologies of Pharmaceutical Industry (~700 slides, 18 lectures)

AWARD:

At the IV MOSCOW INTERNATIONAL SALON OF INNOVATIONS AND INVESTMENTS (February 25-28, 2004 Moscow, All Russian Exhibition Centre) the portal of distance and multimedia education "Pharmaceutics-online" got awarded with the bronze medal and diploma

Web-portal «Pharmaceutics-online»

Availability
Quality
Usability

A lot of taxonomic information, useful for education of specialists in pharmaceutics technology area:

- Videos (with audio explanations)
- High-quality photos
- 2D and 3D animations, explaining physical and chemical processes, processes taking place inside apparatus
- Schemes of general types of apparatus
- Textual information with binding hyperlinks
- Technical descriptions of all the processes, useful in pharmaceutics technology

http://www.muctr.edu.ru/~cache/claroline

Ongoing activities: SCOPES 2005-2008

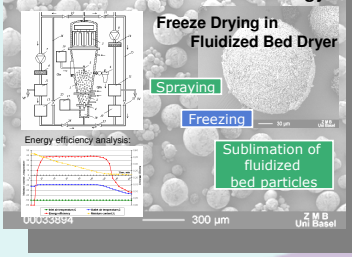
It is an important issue that SNSF has decided to give a continuous support of this collaboration through the grant "**New Concepts in training industrial pharmacists and pharmaceutical engineers**" to be developed and implemented at the Russian Swiss Scientific and Education Center in MUCTR (Grant IB74BO-110911/1).

This grant is a continuation SCOPES program from 2001-2004, IP No. 7IP 62613 "Development of new courses and scientific work in the field of scientific education".

The main goals of the Centre are:

1) Guarantee the legal assistance for domestic and/or international technology transfer;
2) Provide the technical support for science-intensive projects;
3) Development of a domestic and/or international information exchange network with the focus on pharmaceutical and bio- technologies;
4) Carrying out the research at the Center's technological facilities on demand from clients of the Center;
5) Organization of technology transfer seminars;
6) Monitoring the intellectual property market in the field of pharmaceutics and biotechnology and distributing the market analysis within the target group;
7) Organization of domestic and/or international conferences for leading specialists and official representatives of governmental institutions;
8) Development and implementation of special-purpose study courses for MUCTR students;
9) Providing the special training for students and personnel of the Centre's client organizations;
10) Organizing the extension and retraining courses for the specialists in the field of pharmaceutical and bio- technologies;
11) Information systems development for international technology transfer centers with Russian participation.

Industrialization of Nanotechnology:



International
Education and Scientific
Centre for pharmaceutical and
bio-technologies transfer

Dear Ladies and Gentlemen!

Russian-Swiss Center of Transfer of Pharmaceutical Technologies at D.I. Mendeleev University of Chemical Technology of Russia with the support of the State Secretariat for Education and Research of Switzerland and 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 **29 to 30 September 2005**
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: **P.D. Sarkisov**
Rector of D.I. Mendeleev University of Chemical Technology of Russia, Academician of Russian Academy of Science

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 Center of Pharmaceutical Technologies Transfer

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

Secretary: **Dr. S. Goncharova**
Vice-Director of 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. The topics will cover a wide spectrum of pharmaceutical manufacture including production of pharmaceutical powders, ointments and creams and technologies for granulation, drying, packing and quality control of pharmaceutical preparations.

THE SEMINAR PROGRAM

September 29, 2005

Pavel SARKISOV	Rector of MUCTR, academician of Russian Academy of Sciences.
10.00 – 10.10	**Welcome participants to the seminar**
Erwin H.HOFER	Ambassador of Switzerland in the Russian Federation
10.10 – 10.20	**Welcome to participants to the seminar**
Hans LEUENBERGER	Vice-President of Swiss Engineering Academy, President of Swiss Society of Pharmaceutical Sciences, Head of Institute of Pharmaceutical Technology, Pharmacenter of Basel University, Professor
10.20 – 10.50	**"New regulatory requirements concerning pharmaceutical process technology"**
Rosa YAGUDINA	Director of Information and informational technologies institute at Federal State Department "Examination scientific center of medical applications", Professor
10.50 – 11.20	**"Modern control systems of drugs quality in Russian Federation"**
11.20 – 11.50	***Coffee-break***
YuriLELIKOV	Director of Moscow representative of company DONAU LAB Moscow (Switzerland)
11.50 – 12.20	**"Modern equipment for quality control laboratories of pharmaceutical plants according to GMP standards"**
Paul RUFFIEUX	Vice-President of company SKAN AG (Switzerland).
12.20 – 12.50	**"Parenteral facility for sterile non-toxic and toxic products from design till operation"**
12.50 – 14.00	***Lunch***
Alexander ROSOL	Director of Russian representative of company BAUSCH+STROEBEL (Germany/Switzerland)
14.00 – 14.30	**"Equipment for production of infusion solutions in plastic bags"**
Jörg BRUNEMANN	Senior Technical Sales Manager of company SYNTAPHARM Harke Group (Germany)
14.30 – 15.00	"**Excipients in solid dosage forms"**
Walter MURBACH	Regional sales manager of company ROMMELAG (Switzerland)
15.00 – 15.30	"**Aseptic filling with the blow-fill-seal technology**"
15.30 – 16.00	***Coffee-break***
Alexander ROSOL	Director of Russian representative of company BAUSCH+STROEBEL (Germany/Switzerland)
16.00 – 16.30	**"Insulator technologies in pharmaceutical industry"**
GünterBUSSIN	Area sales manager of East-European region of company FETTE GmbH (Germany)
16.30 – 17.00	**"Perspectives and production tendencies in modern tabletting"**
19.00	***Banquet***

September 30, 2005

Zoran BUBALO	Managing director of Russian representative office of company ROMACO (Germany/Switzerland)
10.00 – 10.30	**"Modern methods of drugs production. Packaging"**
Odilio ALVES-FILHO	Director of company NEW & IMPROVED DRYING TECHNOLOGIES (Norway)
10.30 – 11.00	**"Perspectives in production of pharmaceutical powders based on innovative R&D"**
Peter MERIMECHE	Head of Sales of company HÜTTLIN (Germany)
11.00 – 11.30	**"Coating technology in fluid bed. Comparison with conventional technologies"**
11.30 – 12.00	***Coffee-break***
Frank HUEBNER	Regional Sales Manager of company IWK Verpackungstechnik GmbH (Germany)
12.00 – 12.30	**"New packing equipment"**
Ilya MAYKOV	Sales engineer of company NIRO Pharma Systems (Denmark/Switzerland/Great Britain/Germany/Belgium)
12.30 – 13.00	**"Comparison of different technologies of granulation-drying"**
13.00 – 14.15	***Lunch***
Klaus EICHLER	Head of Department of business and corporative relations development of company "GLATT INTERNATIONAL" (Germany/Switzerland/USA)
14.15 – 14.45	**"GLATT – pharmaceutical equipment and services"**
Zoran BUBALO	Managing director of Russian representative office of company ROMACO (Germany/Switzerland)
14.45 – 15.15	**"Production of ointments and creams, validation. Homogenizers"**
15.15 – 15.45	***Coffee-break***
Jarmo HUJANEN	Area manager of East-European, Middle Asian and African region of company STERIS (Finland)
15.45 – 16.15	**"New products for pharmaceutical market"**
Leonid KOVALENKO	Dean of Pharmaceutical Faculty of MUCTR, Professor
Grigoriy AVRAMENKO	Vice-Rector of MUCTR, Head of Department of chemical, pharmaceutical and cosmetics technology, Professor
16.15 – 16.45	**"Specialists training for Russian pharmaceutical enterprises»**
Elena GUSEVA	Assistant Professor of Chair of Cybernetics of Chemical Technological Processes
16.45 – 17.00	"**Multimedia courses for training of specialists of pharmaceutical production**"

All coffee-breaks and lunches will be available for all registered participants.
The banquet will take place on 29 September at 7 p.m (paid).

H.1.4 Academic session: Pharmaceutical powder technologies: state of the art and perspectives, MUCTR October 1, 2005, Moscow

On October 1, 2005 a special scientific program was organised by MUCTR which included the following speakers:

Prof. Dr. Hans Leuenberger	A Road Map for a Research Initiative in Pharmaceutical Powder Technology
Prof. Alexander Archakov, Academician of RAMS (Russian Academy of Medical Sciences), presented by Dr. Olga Ipatova	Nanotechnology in medicine
Prof. Dr. Theodor Güntert	Biopharmaceutical Aspects of Particulate Systems
Prof. Heinrich Hofmann, ETH, Lausanne	Chemical Synthesis and Processing of Nanoparticles
Nikolay Kudryashov, Academician of RAMS, presented by Prof. Eugeny Korotkov	Identification of latent periodicity of protein families
Dr. Margaretha Hofmann	Nanoparticulate drug delivery systems
Prof. Dr. Georgios Imanidis	Solubilization and Absorption of poorly water soluble drug powders
Dr. Gabriele Betz	New Concepts in Powder Process Technology and Solid Dosage Form Design
Prof. Eleonora Koltsova	Investigations and Mathematical Modeling of Nanoproducts (Nanofibers, Nanotubes, Nanothreads) Production
Prof. Dr. Ernst Hungerbühler	Resolution process by enantioselective complexation for manufacturing cristalline chiral drug products
Dr. Maxim Puchkov	Application of Mathematical Modeling in Processing of Powders
Prof. Natalia Menshutina	Decision support system for creation of new drugs

The Swiss delegation was pleased to announce that the Swiss National Science Foundation has decided to continue supporting this Swiss-Russian collaboration 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".

H.1.5 Ideas for similar partner institutions

The foundation of the Russian-Swiss Science and Education Center for Pharmaceutical and Biological Technologies prompted follow-up ideas to create similar institutions
in France ("Institut Franco-Suisse des Sciences et Procédés Pharmaceutiques" at the new technical university École des Mines, Albi-Carmaux, EMAC)
in Spain ("Centro Iberoamericano-suizo de desarollo de medicamentos" at the University of Seville) and **in Japan**.

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.

Such institutions may have a similar function like the existing Sino-German Research Promotion Center of the Institute of Process Technology of the Chinese Academy of Sciences, under the guidance of Prof. Dr. Jinghai Li, in Beijing.

H. 2. Diploma Studies

In the year 2005 15 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.2.1, List of diploma thesis students, topics and location).

H.2.1 List of Diploma Students with diploma thesis topics in Pharmaceutical Technology 2005

Student	Topic	Supervisor/Location
Brügger Reto	Neue Methode zur Untersuchung diffusiver, binärer Mischungen sphärischer Partikel	Thomas Meyer, Prof. H.Leuenberger, Institute of Pharmaceutical Technology, University of Basel
Brunner Isabelle	Entwicklung eines Mikrobiologischen Monitoring - Konzeptes in der Spitalapotheke KSB	Carla Meyer-Massetti Hospital of the University of Basel
Fankhauser Thomas	Bestimmung von Arzneimitteln und Hilfsstoffen mit Raman-Spektroskopie	PD Dr. D. Giron, Dr. S. Monnier Novartis Pharma AG, Basel
Feierabend Yvonne Nicole	Transdermale Permeation und Penetration von SYN®-AKE	Prof. Dr. G. Imanidis, S. Reutlinger, Institute of Pharmaceutical Technology, University of Basel
Gagno Lidia	Untersuchung der anti-inflammatorischen Effekte von Ligusticum Extrakten auf periphere mononukleäre Blutzellen	Dr. J. Schwager, DSM Nutritional Products AG, Basel
Gentis Nicolaos	Microkristalline Zellulose: Ein attraktiver Hilfstoff in festen Arzneiformen	Dr. G. Betz, V. Balzano, Institute of Pharmaceutical Technology, University of Basel
Gremaud Amélie	Optimierung der Herstellulng niedrig dosierten Kapseln	M. Endres, V. Figueiredo, Dr. R. Leu, Dr. R. Werner, Prof. Dr. C. Surber, Institute of Pharmaceutical Technology, University of Basel
Krömler Chantal	Quantifizierung von Absorption, Metabolismus und apikalem Efflux in Caco-2 Zellen bei Wirkstoffgemischen	Dr. G. Imanidis, D. Blaser Institute of Pharmaceutical Technology, University of Basel
Mahlknecht Rainer	Gezielte Modifikation von Eigenschaften pharmazeutischer Wirkstoffe über die Bildung von Cokristallen am Beispiel des Ibuprofen	Dr. F.Blatter, Dr. H.Süss, Solvias AG, Basel
Manetsch Melanie	In-situ forming Implantate zur Langzeit-prophylaxe von Herzwurminfektionen	Dr. K.Schalper Novartis Animal Health, Basel

Neuenschwander Annina	For the prediction of sun protection factors - comparison of in vitro measurements and model calculations	Dr. B. Herzog, CIBA Specialty Chemicals, Grenzach, Germany
Oggier Stefanie	Einfluss struktureller Parameter phospholipidhaltiger Dermatika auf transdermale Wirkstoffpermeation von Coffein als Modellsubstanz	Dr. G. Imanidis, H. Nalenz Institute of Pharmaceutical Technology, University of Basel
Tscheulin Michael	Herstellung einer Tablettenformulierung mit dem Wirkstoff Paracetamol	Dr. G. Betz, E.Krausbauer Institute of Pharmaceutical Technology, University of Basel
Weber Philipp	Stabilisierung des Blutzuckerspiegels bei Diabetikern	Dr. G. Betz, Institute of Pharmaceutical Technology, University of Basel Rolf Müller, NovoGEL Holding AG
Witschi Robert	Entwicklung und in vitro Freisetzung von nasalen Midazolam Formulierungen	K.Zimmermann, Prof.Dr.C.Surber Prof. Dr. G. Imanidis Institute of Pharmaceutical Technology, University of Basel

H.2.2 Visiting Diploma Student

Murad Rumman	Investigation of the acetylsalicylic acid stability in the presence of UICEL	Institute of Pharmaceutical Technology, University of Basel

H. 3. Completion of the SCOPES/SNF project 7IP 062613 in cooperation with MUCTR

As a result of the grant 7IP 062613 the Russian-Swiss Science and Education Venter could be established, which will gain an additional momentum by the successive grant of the Swiss National Science Foundation (SCOPES IB 74 BO – 110911 project) and by receiving rooms (office, labs) in a new building at Tushino in the high-tech park of MUCTR in the northern area of Moscow.

Figure 4 / H. 3 Building with the Russian-Swiss Education and Scientific Centre for pharmaceutical and bio-technologies transfer

The building (see Figure 4) should be completed in 2006.

The excellent cooperation between the institute of pharmaceutical technology and the high-tech department of MUCTR became also a them of the report of the Swiss National Science Foundation "Lässig, R.; Seidl, I.; Stark, A.; Hille, S., Glättli, E.; Pfister, J. (eds) 2005: Scientific cooperation with Eastern Europe: A Swiss contribution to the countries in transition. Berne, Swiss National Science Foundation. 42 pp". An extract of this report is presented below, as this collaboration has lead to a platform to transfer Swiss experience of training pharmacists to the eastern part of northern hemisphere:

> "Like Manen, Hans Leuenberger from the Institute of Pharmaceutical Technology at the University of Basel has met scientists in Moscow who have tremendous faith in the future. Leuenberger, a physicist and pharmacist, and his research partner Natalia Menshutina, an expert in informatics from the Mendelev University of Chemical Technology of Russia, have been engaged in interdisciplinary collaboration for years. "Disciplines like the nanosciences and system biology show that sciences such as biology, chemistry and physics are increasingly merging with information technology," Leuenberger explains, adding, "In research, including pharmaceutics, modelling and computer simulation are becoming more important all the time". Leuenberger and his team have learned a lot from their Russian colleagues about artificial intelligence, artificial neuronal networks and database management. Together, the scientists developed an e-based learning and expert system in pharmaceutical technology that is now in use in both Basel and Moscow. "We were especially pleased that the Russian Ministry of Research and Technology awarded us a prize for this e-learning platform," Leuenberger says. "Multimedia teaching modules and e-platforms for distance learning have great potential," Menshutina adds. "In a country as big as Russia, we need to

be able to access electronic teaching materials simultaneously from Kaliningrad to Vladivostok". Collaboration thrives on differences. Many scientists in Switzerland are impressed by the talent for improvisation demonstrated by their colleagues from Eastern Europe. "Necessity is the mother of invention," Leuenberger says, "but this is less evident in contemporary Switzerland because our country has reached a saturation state in which inaction is not uncommon."

H.3.1 Invited Lectures in China

The head of the Institute H.Leuenberger and G.Betz, head of the Industrial Pharmacy lab, both received a letter to give an invited presentation at the 3rd Annual Congress of International Drug Discovery Science and Technology (IDDST) 2005, organized by the World High Technology Society (WHTS), in Shanghai.

Instead of H. Leuenberger Prof. Dr. Natalia V. Menshutina, Director of the Russian-Swiss Science and Education Center for Pharmaceutical and Biological Technologies at MUCTR, Moscow gave the invited presentation with the title: "Nano-composites by atmospheric spray-freeze drying as carriers for thermosensitive and low water soluble drugs", as the head of the institute had obligations as a visiting professor and member of the Scientific Advisory Board at the new technical university École des Mines, Albi-Carmaux, EMAC, France.

Figure 5 / H.3.1 - Cover of the Pharma Technology Journal for China written in Englisch and Chinese

The topic of the invited lecture of G.Betz "Dosage form design" described the research activities of the Industrial Pharmacy Lab at the Institute of Pharmaceutical Technology.
Dr. G.Betz was invited to publish the contents of this presentation in the chinese edition of pharmaceutical technology, winter 2005, with the focus on Switzerland (see Figure 5).

H.3.2 Invited lectures in the USA and Canada

The head of the institute was invited to give the following presentations in the US:

- June 2005, in Montreal, Plenary Lecture at the Engineering Conferences International "Particulate Processes in the Pharmaceutical Industry", (*FDA's PAT initiative and wet agglomeration as a critical process*).
- July 2005, in Rockville, Invited Lecture and round table discussion at the FDA, (*The signification of FDA's PAT initiative for Academia*).
- November 2005, in Nashville, Invited Lecture at the AAPS Annual Meeting and Exposition. Due to obligations in Basel, the lecture was represented by Ph.D. Metin Çelik, (*Continuous Processing in Wet-Agglomeration and Tabletting - the Future of Manufacturing Solid Dosage Forms?*).

H. 4. Research

H.4.1 Publications 2005

Absorption of Poorly Water Soluble Drugs Subject to Apical Efflux using Phospholipids as Solubilizers in the Caco-2 Cell Model. S.B. Kapitza, B.R. Michel, P. van Hoogevest, M.L.S. Leigh and G. Imanidis. Eur. J. Pharm. Biopharm. in press (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. in press (2006).

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

Cutaneous Metabolism of a Dipeptide Influences the Iontophoretic Flux of a Concomitant Uncharged Permeant. M. Altenbach, N. Schnyder, C. Zimmermann and G. Imanidis. Int. J. Pharm. 307:308-317 (2006).

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.

Development of novel pharmaceutical hydrogenated soybean oil for hot melt coating applications. Publication, in english. Chansanroj Krisanin, Praserthdam Piyasan, Betz Gabriele, Leuenberger Hans, Mitrevej Ampol, Sinchaipanid Nuttanan. Submitted to S.T.P.Pharma Sci. 2005. ISSN 1157-1489.

In vivo comparison of various liposomal formulations for cosmetic application. Publication, in english. Betz Gabriele, Aeppli Angela, Menshutina Nathalia V., Leuenberger Hans. Int.J.Pharm. 296 (1.2), 2005, 44-54. ISSN 0378-5173.

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.

Modeling of Atmospheric Freeze Drying in a Spouted Bed. Publication, in english. Menshutina Natalia V., Korneeva Anastasiya E., Leuenberger Hans. (Theoretical Foundations of Chemical Engineering) **TFCEAU** 39 (6), 2005, 594-598. ISSN 0040-5795.

Pharmaceutical Powder Technology - From Art to Science: The Challenge of FDA's PAT Initiative. Publication, in english. Leuenberger Hans, Lanz Michael. Advanced Powder Technol. 16 (1), 2005, 3-25. ISSN 0921-8831.

Preparation of dry powder inhalation with lactose carrier particles surface-coated using a wurster. Publication, in english. Iida Kotaro, Todo Hiroaki, Okamoto Hirokazu, Danjo Kazumi, Leuenberger Hans. Chem.Pharm.Bull. 53 (4), 2005, 431-434. ISSN 0009-2363.

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. Journal of Drug Delivery Science and Technology. Invited contribution to theme issue 2006 on stimulated drug delivery systems. In press (2006)

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 in press (2006).

Scale-up in the field of Granulation and Drying, **2nd ed**.. Chapter 8. Bookchapter, in english. Leuenberger Hans, Betz Gabriele, Jones David M.. Drugs and the Pharmaceutical Sciences, Volume 118, ISSN 0360-2583.
Pharmaceutical Process Scale-Up, **2nd ed.**, 2005, 151-170. Marcel Dekker Inc. New York. Ed. Levin Michael. ISBN 0-8247-0625-0.

Transdermal Drug Delivery Method and System. G. Imanidis, W. Zumbrunn and G. DiPierro. PCT Patent Application No. PTC/IB2004/002947, September 13, 2004. Endorsed February 15, 2005.

The characterization of aprotic polar liquids and percolation phenomena in DMSO/water mixtures. Publication, in english. Hernandez Perni Maria Engracia, Leuenberger Hans. Eur.J.Pharm.Biopharm. 61 (3), 2005, 201-213. ISSN 0939-6411.

Towards a better understanding of the parameter Ei/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.

H.4.2 Doctorate Colloquia

25.01.2005	Caroline Sautter	Sustained release injectables formed in situ for veterinary use
26.04.2005	Go Kimura	Influence of compression force on the disintegration time of mefenamic acid containing tablet using a compaction simulator
24.05.2005	Matthias Plitzko	Die Kugel in der Pharmazie (Pellets, manufactured by means of spray freeze drying at atmospheric pressure)
15.07.2005	Chosei Kaseda, Yamatake, Japan	Software for multidimensional spline approximation: dataNesia
22.11.2005	Krisanin Chansanroj	Metoprolol controlled release pellets by hot melt coating

H.4.3 List of Presentations as an Invited Speaker, Participation in Symposia, Workshops, Project/coordination Meetings, Organisation of workshops etc.

06.01.2005, Japan, Go Kimura	Lecture at Formulation and Packaging Department, Shionogi, Japan	Formulation study of mefenamic acid.
20.1.05, Basel, H.Leuenberger	2005 PDA Central Europe Chapter Forum	The evolutionary process of FDA's PAT initiative
25.01.2005, Muttenz, Gabriele Betz	Trends in der anwendungsorientierten Forschung und Entwicklung, FHBB	From Powder to Tablet-Scale up of the tabletting process
26.1.05, Basel, H.Leuenberger	Meeting of the study deans of the University of Basel, headed by Prof. Dr. Ulrich Druwe, Vice rector Teaching	Presentation of the planned major master in industrial pharmacy at the University of Basel and the cooperation project with the University of Applied Sciences Northwestern Switzerland (UAS) to establish at the UAS a master in pharm. Engineering
11.2.05, Uppsala, H.Leuenberger	Invited Member of the jury, participating at the PhD-Defence of Albert Mihranyan	Pharmaceutics and the Role of FDA's PAT Initiative
21.2.05, Strasbourg, H.Leuenberger	Meeting with Prof. Hasselmann, Dean of the Dean of the Faculty of Pharmacy, Strasbourg	Discussion of possible cooperation between the Institute of Pharm.Technology and the Faculty of Pharmacy of the 'Université Louis Pasteur, Strasbourg'.
14.-15.03.2005, Tübingen Maxim Puchkov	Fachausschuss-Sitzung "Agglomera-tions- und Schüttguttechnik", Schloss Hohentübingen	Application of artificial neural networks for controlling of granulation process in fluidized bed
16.- 18.3.05, Bangkok, H.Leuenberger	8th International Symposium on Agglomeration	The Challenge of FDA's PAT Initiative
16.-18.03.2005, Bangkok, Thailand, Go Kimura	8th International Symposium on Agglomeration	Influence of loading amount of mefenamic acid on granulation and tablet characteristic using a compaction simulator
16.-18.03.2005, Bangkok, Thailand, Gabriele Betz	8th International Symposium on Agglomeration	New Concepts in Powder Technology and Solid Dosage Form Design

26.-29.4. 2005, Paris, France, G. Imanidis	Oral presentation at the 4th Annual European Drug Delivery Partnerships 2005 Conference	Chrono-Pharmacology: Applying Novel Drug Delivery Technologies to Meet the Challenges of Time-Controlled Drug Therapy
28.4.05, Binzen/Lörrach, H.Leuenberger	2005 Event of the Glatt GmbH. Full day moderation of the symposium	Jubiläumsveranstaltung "50 Jahre Glatt"; Symposium im Konzerthaus Freiburg
01.-03.06.2005 Gabriele Betz	PDA, course in cooperation with the Industrial Pharmacy Lab	Practical Aspects of Aseptic Processing
12.-17.06.2005, Nice, France Gabriele Betz	Pharmaceutical Sciences Fair	Investigations of matrix systems from network-forming starch
12.-17.06.2005, Nice, France Brigitte Meyer on behalf of Maxim Puchkov	Pharmaceutical Sciences Fair	Application of Artificial Neural Networks in Granulation Process Control
15.6.05 to 17.6.05, Karlstad-Sweden, H.Leuenberger	3rd Nordic Drying Conference NDC	New trends in FBD of pharmaceuticals including freeze drying of biological materials
18.-22.6. 2005, Miami Beach, FL, USA, H. Nalenz and G. Imanidis	Oral presentation at the 32nd Annual Meeting and Exposition of the Controlled Release Society	Evaluation of Phase Transitions of Dermatological Formulations due to Loss of Volatile Components during Application
17.-20.07.2005, Philadelphia, PA Gabriele Betz	Water-Insoluble Drug Delivery-Innovative Preformulation and Formulation Approaches for Improved Delivery	The impact of percolation theory and fractal dimension on formulation design
21.6.05 to 23.6.05, Binzen/Lörrach, H.Leuenberger	No. 88 Technology Training Center (TTC)- Workshop. Introductory Lecture	From Art to Science
26.6.05 to 30.6.05, Montreal, H.Leuenberger	2005 Engineering Conferences International; Particulate Processes in the Pharmaceutical Industry. Plenary Lecture	FDA's PAT initiative and wet agglomeration as a critical process
30.6.05, Somerset, New Jersey, H.Leuenberger	Presentation at Cardinal Health, NJ, USA. Invited lecture	Research at the University of Basel & the FDA's PAT initiative
01.7.05, Rockville, H.Leuenberger	Invited Lecture and round table discussion at the FDA	The signification of FDA's PAT initiative for Academia

08.9.05 to 9.9.05, Basel, H.Leuenberger	Swiss Society of Thermal Analysis and Calorimetry (STK) congress	Member of the scientific board of this event
29.9.05 to 30.9.05, MUCTR, Moscow, H.Leuenberger	H. Leuenberger, Honorary Director of the Swiss-Russian Center and invited speaker. Industry session: Innovative technologies and equipment for pharmaceutical industry	New regulatory requirements concerning pharmaceutical process technology
01.10.05, Moscow, MUCTR, H.Leuenberger	Academic session: Pharmaceutical powder technologies: state of the art and perspectives	A Road Map for a Research Initiative in Pharmaceutical Powder Technology
01.10.2005, MUCTR, Moscow, Gabriele Betz	Scientific Seminar of the Russian-Swiss Science and Education Center for Pharmaceutical and Biological Technologies, Mendeleev University	New Concepts in Formulation and Process Technology
01.10.2005, MUCTR, Moscow, Maxim Puchkov	Scientific Seminar of the Russian-Swiss Science and Education Center for Pharmaceutical and Biological Technologies, Mendeleev University	Application of Mathematical Modelling in Powder Technology
01.10. 2005, Moscow, Russia, G. Imanidis	Oral presentation at the seminar on Pharmaceutical Powder Technologies: State of the Art and Perspectives, D.I. Mendeleev University of Chemical Technology of Russia	Solubilization and Absorption of Poorly Water Soluble Drug Powders
07.10.05 to 19.10.05, Albi CT Cedex, EMAC, France, H.Leuenberger	Visiting Professor at the École des Mines Albi-Carmaux (EMAC), France. 16 Lessons on Pharmaceutical Technology for the students at the École des Mines Albi-Carmaux	From a promising drug substance to a marketed product- the complex task to develop a suitable drug delivery system
13.10.05, Albi CT Cedex, EMAC, France, H.Leuenberger	PhD defence Severine Hutin, member of the jury	Recherche de conditions d'optimisation de la complexation d'actifs avec des cyclodextrines en milieu semi-solide, de la preformulation a l'étude de faisabilité industrielle
20.10.05, Albi CT Cedex, EMAC, France, H.Leuenberger	Invited speaker at the Seminar CNRS UMR	Do we need a european research initiative to promote pharmaceutical powder technology?
28.10.-03.11.2005, Shanghai, China, Gabriele Betz	3rd Annual Congress of International Drug Discovery Science and Technology, organized by World High Technology Society (WHTS). Theme: From Concepts to Market	New Concepts in Powder and Process Technology

6.11.05 to 10.11.05, Nashville, H.Leuenberger, Metin Çelik	2005 AAPS Annual Meeting and Exposition. Invited Lecture, presented by Metin Çelik, PhD on behalf of H.Leuenberger	Continuous Processing in Wet-Agglomeration and Tabletting - the Future of Manufacturing Solid Dosage Forms?
20.-23.11. 2005, Versailles, France, G. Imanidis, S.B. Kapitza, B. R. Michel, P. van Hoogevest and M.L.S. Leigh	Oral presentation at the 2nd EUFEPS Conference on Optimizing Drug Delivery and Formulation - Evaluation of Drug Delivery Systems Issues and Perspectives	Delineation of Passive and Carrier-Mediated Transport Parameters of Poorly Water Soluble Drugs Subject to Apical Efflux with Phospholipids as Solubilizers in Caco-2 Cells using Mathematical Modeling
29.11.-01.12.2005 Gabriele Betz	PDA, course in cooperation with the Industrial Pharmacy Lab	Practical Aspects of Aseptic Processing
6.12.05, Albi CT Cedex, EMAC, France, H.Leuenberger	PhD defence Emeline Touzis, member of the jury	Contribution à la formulation de produit solide: Dispositif expérimental de suivi de la porosité for CEE et perméabilité ou cours de la libération d'un soluté
7.12.05, Albi CT, Cedex, EMAC, France, H.Leuenberger	PhD defence Ana Vilela, member of the jury	Influence d'une action mécanique en voie sèche sur l'amélioration et l'association d'actifs pharmaceutiques et d'excipients Application de l' Hybridizer Nara

H.4.4 Panel discussion / Moderation

18.01.2005, Bern, Gabriele Betz	SwiTi Conference "Innovation made in Switzerland" Kultur Casino	The Industrial Pharmacy Lab
16.-18.03.2005, Bangkok, Thailand Chair person: Gabriele Betz	8th International Symposium on Agglomeration	Foods and Pharmaceuticals
28.10.-03.11.2005 Shanghai, China, Chair person: Gabriele Betz	WHTS 3rd Annual Congress of International Drug Discovery Science and Technology, Theme: From Concepts to Market	Drug Delivery Technology

H.4.5 Poster Presentation

10.-11.03.2005, **Go Kimura**, Gabriele Betz, Hans Leuenberger	Pharmaday, Center of Pharmaceutical Sciences Basel-Zurich	Influence of compression force on the disintegration time of mefenamic acid containing tablet using a compaction simulator
10.-11.03.2005, **Anja Guntermann**, Maxim Puchkov, Gabriele Betz, Hans Leuenberger	Pharmaday, Center of Pharmaceutical Sciences Basel-Zurich	Evaluation of Presster™ Compaction Simulator by Comparative Studies on a Routine Production Formulation
16.-18.03.2005, Bangkok, Thailand Gabriele Betz, **Hiroshi Tanaka**, Hans Leuenberger	8th International Symposium on Agglomeration	Crystallization Behaviour of Polyethylene Glycol 4000 from Indomethacin melts
17.-20.04.2005 Barcelona, Spain **Go Kimura**, Gabriele Betz, Hans Leuenberger	3rd World Conference on Drug Absorption, Transport and Delivery	Influence of compression force on the disintegration time of mefenamic acid containing tablet using a compaction simulator
12.-17.06.2005, Nice, France **Go Kimura**, Gabriele Betz, Hans Leuenberger	Pharmaceutical Sciences Fair	Influence of amount of maize starch on the disintegration time of mefenamic acid containing tablet using a compaction simulator
12.-17.06.2005, Nice, France **Ursula Bausch**, Gabriele Betz, Hans Leuenberger	Pharmaceutical Sciences Fair	Impact of Filling Process on Protein Solutions
18.-22.6. 2005, Miami Beach, FL, USA, H. Nalenz and G. Imanidis	Poster at the 32nd Annual Meeting and Exposition of the Controlled Release Society	How the Alteration of Dermatological Formulations During Application Affects Transdermal Permeation of a Hydrophilic Model Drug
07.-08.09.2005 Basel, Switzerland, **Krisanin Chansanroj** Gabriele Betz, Hans Leuenberger	Thermal Analysis and Calorimetry Conference, 30th anniversary meeting Basel, organized by the swiss society of thermal analysis and calorimetry	Thermal characterization of hydrogenated soybean oil as a controlled release regulator for hot melt coated pellets

02.-08.09.2005, Cairo, Egypt **Selma Sehic**, Haris Trobradovic, Gabriele Betz, Seherzada Hadzidedic, Silvia Kocova El-Arini, Hans Leuenberger	World Congress of Pharmacy and Pharmaceutical Sciences	Effect of Variability of Primary Active Material on the Performance of Carbamazepine Generic Products
09.-11.11.2005, Ho Chi Minh City, Vietnam Krisanin Chansanroj, Gabriele Betz, Hans Leuenberger, **Ampol Mitrevej**, **N. Sinchaipanid**	4th Pharma Conference Indochina	Solid suspension coating for controlled release metoprolol pellets using hot melt fluid bed coating technique

H.4.6 Visiting scientists

June 2005 – November 2005	Cooperation with Mahidol University, Prof. Ampol, Visiting Scientist Krisanin Chansanroj	Preparation and characterization of hydrogenated soybean oils as controlled release regulator for metoprolol tartrate pellets

H.4.7 List of PhD-Theses in Pharmaceutical Technology completed in 2005

PhD student	Title	Funding/Location
Sautter Caroline	Sustained release injectables formed in-situ for veterinary use	Institute of Pharmaceutical Technology, University of Basel
Thürlemann Charles	Entwicklung eines Biosensor-Systems für ein Patienten-Selbstmanagement der Behandlung mit Vitamin K-Antagonisten	Insel-Spital, Bern, Asulab S.A., Marin/NE
Lanz Michael	Pharmaceutical Powder Technology: Towards a science based understanding of the behaviour of powder systems	Swiss National Science Foundation, Bern, Grant No 20-58941.99; Institute of Pharmaceutical Technology; Basel
Reitbauer Susanne	Einfluss pharmazeutischer Hilfsstoffe auf die Plasmamembran von Caco-2 Zellmonolayern ermittelt durch Fluoreszenzdepolarisation	Institute of Pharmaceutical Technology, University of Basel; Glatt GmbH Binzen
von Orelli Johannes	Search for technological reasons to develop a capsule or a tablet formulation	Institute of Pharmaceutical Technology, University of Basel
Egger-Heigold Barbara	The effect of excipients on pharmacokinetic parameters of parenteral drug	Institute of Pharmaceutical Technology, University of Basel

I. Outlook 2006

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 Pharmacenter 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 then 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 ($N<<N_a$) 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. A special working party of Eufeps (European Federation for Pharmaceutical Sciences) under the guidance of Prof. Peter York (Bradford) will make a proposal to the EU to integrate this special research topic related to PAT in the next research frame-work program of the EU. The head of the Institute of Pharmaceutical Technology is member of this working party.

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

An introduction of a Master course MSc in Pharmaceutical Sciences Major "Industrial Pharmacy" at the University of Basel and a Bachelor/Master curricula "Pharmaceutical Engineering" at the University of in Muttenz will need a careful planning.

So far it has been decided that a common pharmaceutical technology platform will be created, which will be used by students of the University of Basel and by students of the School of Life Sciences in Muttenz.

I. 5. On-Going Research Activities

I.5.1 PhD-Students

PhD Student	**Topic (Working Title)**	**Funding and Location**
Balzano Vincenzo	Development of Multiple Unit Pellet Systems	Institute of Pharmaceutical Technology, University of Basel; Mepha
Bausch Ursula Johanna	Steriles Abfüllen von Lösungen mit Zellen	Alphacos SA, CH 2822 Courroux; Institute of Pharmaceutical Technology, University of Basel
Blaser David	Wirkstoffabsorption mit Caco-2 Zellkulturen	Institute of Pharmaceutical Technology, University of Basel
Brka Ervina	Parametrization of the roller compaction process	Institute of Pharmaceutical Technology, University of Basel
Daneshvari Dana	Dielectric Spectroscopy of binary hydrophilic solvent mixtures	Private source and Institute of Pharmaceutical Technology, University of Basel

Faatz Susan	Vergleich Irland-Schweiz betreffend der bildungspolitischen Rahmenbedingungen für die Pharmaindustrie	Private source
Fueg Lise-Marie	Einblick in die Entwicklung von Pulvern zur Inhalation mit dem SkyePharma multidose Dry Powder Inhaler (mDPI)	Skye Pharma AG, Muttenz
Guntermann Anja	Scale-up of tablet formulations using the Presster™ equipment	Pfizer GmbH, Arzneimittelwerk Gödecke, Freiburg i.Br.; Institute of Pharmaceutical Technology, Industrial Pharmacy Lab, Basel
Krausbauer Etienne	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	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	Nicht-destruktive Inprozess-Kontrollen mittels NIR in der Tablettenproduktion als potentielle PAT Anwendung	F. Hoffmann -La Roche AG, Basel
Meyer Thomas A.	The behaviour of disordered particulate systems: flow properties and diffusive mixing	Institute of Pharmaceutical Technology, University of Basel
Müller Franziska Simone	Comparison of Avicel and Uicel as excipient in fast-disintegrating tablets	Institute of Pharmaceutical Technology, University of Basel
Nalenz Heiko	Einfluss der Struktur mehrphasiger topischer Formulierungen auf die Absorption	Institute of Pharmaceutical Technology, University of Basel
Pellanda Carolina	Topical bioavailability of glucocorticosteroids	Institute of Hospital Pharmacy, University Hospital Basel
Plitzko Matthias PhD-Defence January 2006.	The production of nanocomposites using the spray-freeze-drying technique	NCCR (National Center of Competence in Research) Nano-Center, Basel; Glatt GmbH Binzen Institute of Pharmaceutical Technology, University of Basel
Rehorik Lars	Process modeling as a tool to indicate quality aspects in the pharmaceutical production	F. Hoffmann -La Roche AG, Basel

Reiser Miriam	Transdermale Iontophorese	Institute of Pharmaceutical Technology, University of Basel
Russell Frauke	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	Absorbtionsstudien an Caco2 Monolayern	Institute of Pharmaceutical Technology, University of Basel
Sehic Selma	Effect of variability of primary materials on the performance of carbamazepine formulation	Industrial Pharmacy Lab, Bosnalijek, Bosnalijek, Pharmaceuticals and Chemicals Industry
Fässler Tassopoulos Tatiana PhD-Defence March 2006	Evaluation of topical bioavailability of MBC in human stratum corneum by tape stripping using a direct spectroscopic method	Institute of Hospital Pharmacy, University Hospital Basel
Valporsson Hedinn PhD-Defence February 2006	PAT and new Strategies in the pharmaceutical production and their economical impact	Novartis Pharma Stein AG, Stein
Walter Marijke PhD-Defence January 2006.	Konzeption, Entwicklung und Realisierung eines vernetzten e-Lehr-und-Lernprogrammes der Pharm.Technologie	Private source

I.5.2 Postdoctoral Positions

Dr. Betz Gabriele	Implementation of Research and Teaching in the Industrial Pharmacy Laboratory Mülhauserstrasse 49/51	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. 6. Grants and Operating Budget

I.6.1 Contribution of the University (figures 2002 costs - 2005 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	ca. 90 000	not yet assigned
	Budget: (investment in equip.)	CHF	zero*	(incl. EDV)

I.6.2 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 (2005-2008).

I.6.3 Other third party funds not administered by the University

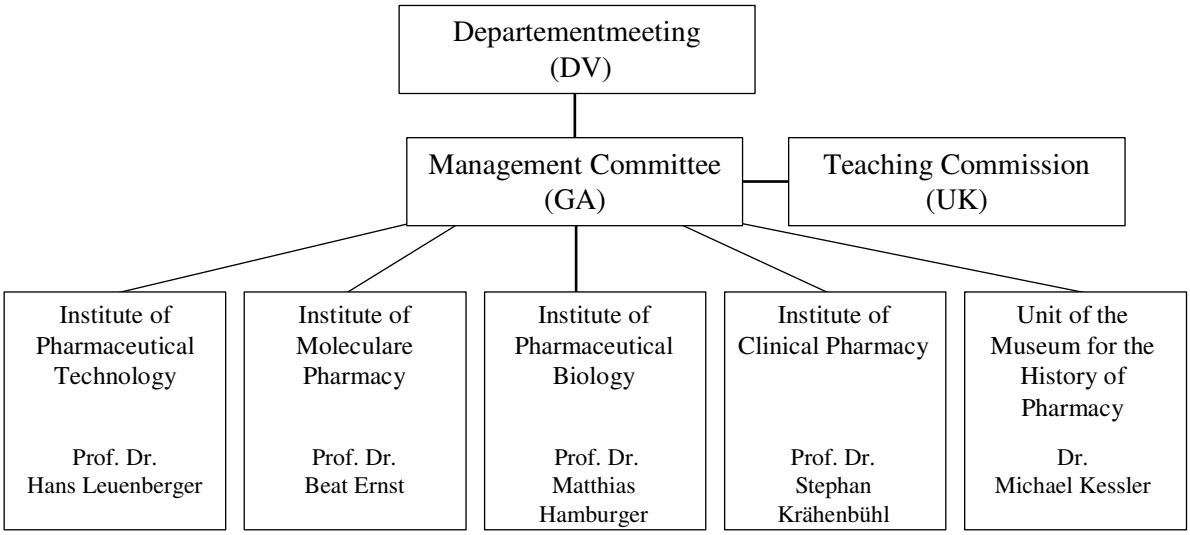
Direct payments to PhD students **CHF 525 000 (estimate ± 20%)**

(individual salaries, 15 x 35'000)

* 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.

J. Organization charts

Organization Department of Pharmaceutical Sciences



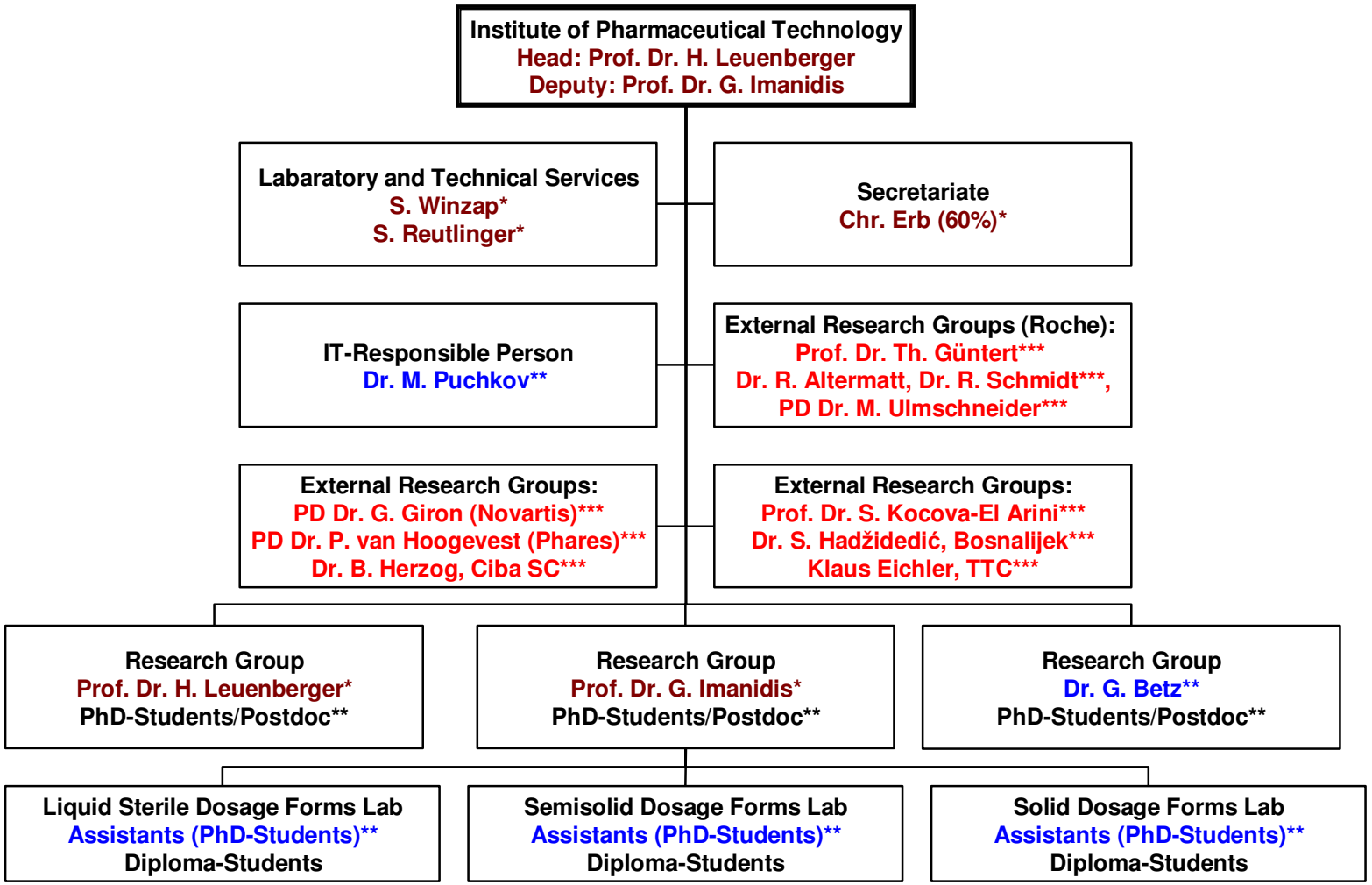
Management Committee 2005

- B. Ernst (chairmanship)
- G. Imanidis
- H. Leuenberger
- A.B. Utelli
- M. Hamburger
- J. Krähenbühl

Teaching Commission

- B. Ernst (Vorsitz)

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. In collaboration with the Swiss Society of Pharmaceutical Sciences (SGPhW) a special event with the title "From Art to Science" was organized.

K. 2. PD Dr. D. Giron

K.2.1 Activities

Symposium organisation/scientific committee

- As President of STK: 30th anniversary, 2 days meeting in Basel, 8-9 September

Lectures

March 2005	Symposium IQPC, London., 15.3.2005	The solid state of pharmaceutical compounds: Impact of the ICH guideline on industrial development
March 2005	Symposium CPE stabilité, LYON	Le principe actif, fondement de la stabilité du medicament
November 2005	ICH Q6, Invited lecture, APV Seminar Polymorphism and Apomorphism of Drugs, Darmstadt,	Polymorphism and regulatory aspects

Workshops, lectures at university

June 2005	Pharmaceutical University of Nancy	Le rôle de l'analytique dans le développement pharmaceutique des nouvelles substances actives
December 2005	Chemical and Physical Institut (CPE), Lyon, Formation continue	Analyse thermique appliquée à la pharmacie

K.2.2 Publications

- D.Giron « Le principe actif, fondement de la stabilité du médicament/The active substance as basis for the stability of drug product » STP Pharma Prat., 2005, 15, 314-336.
- D.Giron, « Polymorphism : Thermodynamic and Kinetic Factors to be considered in Chemical development", American Pharmaceutical Review, Part 1:, vol 8, p.32-37, Part 2: p.72-79.

- D. Giron, Chapter 5.24 , Solid-State physicochemistry in "Comprehensive Medicinal Chemistry", Volume 5: "ADME-Tox: The Fate of Drugs in the Body" Ed. Prof. Testa, Lausanne

Posters/co-lectures

- S. Monnier, T. Buser, D. Giron, M. Mutz "Microcalorimetry and routine control of amorphous content, validation examples" STK 30th anniversary 2005, Basel
- D. Giron, S. Monnier, T. Buser, P. Piechon, "Thermogravimetry as routine analyse, determination of accuracy" STK 30th anniversary 2005, Basel
- M. Mutz, S. Monnier, P. Schwab, T. Buser, D. Giron, "Determination of Crystallinity by Microcalorimetry and Solution Calorimetry as Standard Tests in Pharmacopoeia" STK, Basel September
- F. Stowasser, D. Giron, P. Piechon, "Crystal modelling and polymorphism" STK, Basel September

Diplomarbeit

Thomas Fankhausen, Institute of Pharmaceutical Technology, Basel, Mai-September "

K. 3. T.W. Guentert

In addition to the lectures in Biopharmaceutics, 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 modules.

K.3.1 List of Dissertations

Ongoing Dissertations: none

Completed Dissertation: none

K.3.2 Invited Speaker

March 20-22, 2005, Leiden, The Netherlands	Expert Meeting on Drug Safety. Sponsored by EUFEPS	Improving Prediction of Drug Safety - An Industry Perspective
October 1, 2005, Moscow	Seminar at D.I. Mendeleyev University of Chemical Technology of Russia. Umbrella topic: „Pharmaceutical Powder Technologies State-of-the-Art and Perspectives	Biopharmaceutical Aspects of (Micro-) Particulate Systems
December 9, 2005	Roche Research & Development Center China (RRDCC)	Safety expectations for a viable clinical candidate

K.3.3 External Courses

- Faculty Member in Workshop in Basic Pharmacokinetics, Dept. of Pharmacy, Univ. Manchester: Arosa, July 10 – July 15, 2005

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

- "New Sunscreen Actives", Bernd Herzog, Dietmar Hueglin, Uli Osterwalder, in: "Sunscreens – Regulation and Commercial Development", ed. Nadim Shaath, 3rd ed., Taylor & Francis, Boca Raton 2005
- "Prediction of Sun Protection Factors and UV-A Parameters by Calculation of UV Transmissions Through Sunscreen Films of Inhomogeneous Surface Structure", Bernd Herzog, in: "Sunscreens – Regulation and Commercial Development", ed. Nadim Shaath, 3rd ed., Taylor & Francis, Boca Raton 2005
- "Broad spectrum UV protection and its assessment", Uli Osterwalder, Werner Baschong, Bernd Herzog, Australian Society of Cosmetic Chemists, 39th Annual Conference, Brisbane 2005, proceedings
- "Physical properties of organic and inorganic particulate UV absorbers used in sunscreens"; B. Herzog, International Sun Protection Conference: 2010 – A Sun Odyssey, 2005, The Royal Academy, London, conference proceedings

K.4.2 Vorträge und Poster:

2005 New Orleans S. Müller B. Herzog U. Osterwalder	American Academy of Dermatology, (poster)	Microfine organic particles – a new class of 'physical' sunscreen actives

2005 New Orleans U. Osterwalder, W. Baschong, D. Mettler, B. Herzog	American Academy of Dermatology, (poster)	Progress in UVA protection – impact of new photostable sunscreen actives in Europe
2005 Brisbane Uli Osterwalder, Werner Baschong, Bernd Herzog	Australian Society of Cosmetic Chemists, 39th Annual Conference, (oral presentation)	Broad spectrum UV protection and its assessment
2005 Göttingen Bernd Herzog und Stefan Müller	91st Bunsen-Colloquium: Spectroscopy and Dynamics of Molecular Coils and Aggregates	Physical Properties of Microfine Organic Particulate UV Absorbers Used in Sunscreens

K. 5. PD Dr. Peter van Hoogevest

K.5.1 Activities

Invited Lecture

November, 2005	APV Symposium, Berlin FRG	Colloidal Carriers and their Product Applications"; Seminar: Liposomes, Mixed Micelles and Microemulsions

K.5.2 Publication 2005

- Fahr, A., Van Hoogevest, P., May, S., Bergstrand, N., Leigh, M.L.S., Transfer of lipophilic drugs between liposomal membranes and biological interfaces: Consequences for drug delivery, Eur. J. Pharm. Sci. (2005), 26, 3-4, 251-265.

K. 6. PD Dr.Stephan Marrer and Dr. Rainer Schmidt

K.6.1 Contributions to research and teaching

PD Stephan Marrer, PhD, responsible for Strategy and Asset Management at F. Hoffmann-La Roche Ltd, Roche Basel and Dr. Rainer Schmidt, responsible for Manufacturing Department of sterile products at F. Hoffmann-La Roche Ltd, Basel, were teaching Quality Management topics. In 2005 the lecture "Quality Management in der pharmazeutischen Praxis" was held as interactive joint lecture at the Department of Pharmacy, University Basel, and Institute of Pharmaceutical Sciences, Swiss Federal Institute of Technology Zürich using the Telepoly infrastructure. This joint lecture is strengthening the function of the Center of Pharmaceutical Sciences Basel-Zürich.

The operating costs for the Telepoly infrastructure were sponsored by F. Hoffmann-La Roche Ltd.

K.6.2 On-going research activities

PhD-Students, topics (working title), supported by

Rehorik	Lars	Prozesssimulation im Einsatz für eine ganzheitliche Qualitätsbetrachtung in der Produktion fester Arzneiformen	F. Hoffmann-La Roche Ltd.
Lema Martinez	Carmen	Nahinfrarotspektroskopie eine Methode der Wahl zur Optimierung und Verbesserung von gefriergetrockneten Produkten	F. Hoffmann-La Roche Ltd.

K. 7. PD Dr. Michel Ulmschneider

K.7.1 Activities

Oral Communications

April 2005, Auckland , P. Chalus, M. Ulmschneider, S. Walter	ICNIRS 2005 (Class Session)	Comparison of NIR spectrometers for determination of active content in low-dosage tablets
January 2005, Grenoble, Y. Roggo, P. Chalus, M. Ulmschneider	Journées Thématiques du Groupe Français de Spectroscopie Vibrationnelle	Imagerie infrarouge et proche infrarouge pour l'analyse de formes galéniques solides
September 2005, Heidelberg, M. Ulmschneider	NIR Conference 2005	Performing quantitative NIR : still a challenge?
September 2005, Heidelberg, M. Ulmschneider	NIR Conference 2005	PAT : methods, techniques and drivers

Posters

- *C. Lema Martinez, C. Roeseler, H. Leuenberger,* On-line Water Content Analysis in Lyophilized Products by means of Near-Infrared Spectroscopy: a Comparison Study, (Pharmaday, March 2005, Basel)

- *P. Chalus, Y. Roggo, M. Ulmschneider, S. Walter,* Comparison of Near-Infrared Spectrometers for the Determination of Active Ingredients in Low-Dosage Pharmaceuticals (ICNIRS 2005, Auckland, April 2005)
- *Y. Roggo, A. Edmond, P. Chalus, N. Jent, C. Roeseler, M. Ulmschneider,* Understanding differences between pharmaceutical Batches by Near-Infrared Spectroscopy (ICNIRS 2005, Auckland, April 2005)
- *F. Russell, M. Ulmschneider, H. Leuenberger,* Dissolution testing by NIR spectroscopy: a comparison between diffuse reflectance and transmittance measurements (ICNIRS 2005, Auckland, April 2005)
- *S. Freitag, P. Chalus, S. Walter, M. Ulmschneider, A. Hadj-Mebarek, Z. Gabelica,* The Potential Use of Near-Infrared Spectroscopy for Safety Applications in Organometallic Chemistry. (ICNIRS 2005, Auckland, April 2005)

K.7.2 Publications

Submitted Articles.

- *P. Chalus, Y. Roggo, S. Walter, M. Ulmschneider,* Comparison of Near-Infrared Spectrometers for the Determination of Active Ingredients in Low-Dosage Pharmaceuticals, Proceeding ICNIRS 2005
- *Y. Roggo, A. Edmond, P. Chalus, N. Jent, C. Roeseler, M. Ulmschneider,* Understanding differences between pharmaceutical Batches by Near-Infrared Spectroscopy, Proceeding ICNIRS 2005
- *S. Freitag, P. Chalus, S. Walter, M. Ulmschneider, A. Hadj-Mebarek, Z. Gabelica,* The Potential Use of Near-Infrared Spectroscopy for Safety Applications in Organometallic Chemistry. Proceeding ICNIRS 2005.

Published Articles.

- *P. Chalus, Y. Roggo, S. Freitag, M. Ulmschneider,* Etude comparative de spectromètre proche infrarouge pour l'analyse quantitative, Spectra Analyse, 247 (2005) 44-49.
- *P. Chalus, Y. Roggo, S. Walter, M. Ulmschneider,* Near infrared determination of active substance content in intact low-dosage tablets, Talanta, 66 (2005) 1294-1302.
- *Y. Roggo, N. Jent, A. Edmond, P. Chalus and M. Ulmschneider,* Characterizing process effects on pharmaceutical solid forms using near-infrared spectroscopy and infrared imaging, European Journal of Pharmaceutics and Biopharmaceutics, Volume 61, Issues 1-2, September 2005, Pages 100-110.
- *Y. Roggo, C. Roeseler, P. Chalus, A. Fischer,* Comparison of pharmaceutical batches by near infrared spectroscopy, NIR News Vol 16- n° 5 (2005) 12-14.
- *Y. Roggo, A. Edmond, P. Chalus, M. Ulmschneider,* Infrared imaging for qualitative analysis of pharmaceutical solid forms and trouble shooting, Analytica Chimica Acta, 535 (2005) 79-87

L. Attachment, as part of the report - Cooperation with the University of Applied Sciences Northwestern Switzerland

Zusammenarbeit der Uni Basel mit der FHBB / Nordwestschweiz im Rahmen der neuen Studiengänge Major in «Industrie-Pharmazie» (Uni) und Master in «Pharma-Ingenieurwesen» (FH)

Submitted to the Rectorate of the University of Basel on May 25, 2005.

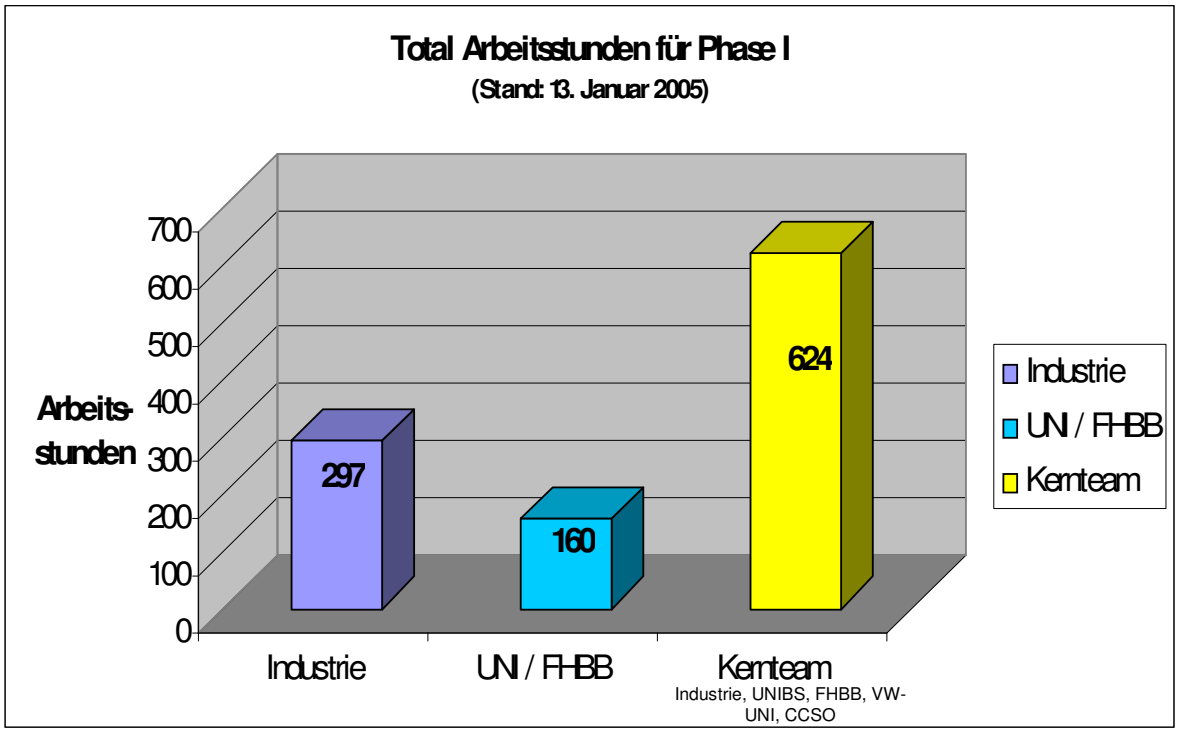
L. 1. Anhang 1: Projektorganisation

L.1.1 Steuerungsgremium, Kernteam und Arbeitsgruppen

STEERING COMMITTEE			
Name	***Vorname***	***Titel***	***Firma***
Baertschi	Markus	Prof. Dr.	FHBB
Hungerbühler	Ernst	Prof. Dr.	FHBB
Leuenberger	Hans	Prof. Dr.	Uni Basel
Meier	Christoph	Dr.	CCSO
Meinzer	Armin	Dr.	Novartis Pharma AG
Plattner	Gian-Reto	Prof. Dr. Phil.	Uni Basel
Rummelt	Andreas	Dr., CEO	Sandoz
Zimmerli	Walther	Prof. Dr.	Volkswagen AutoUni
KERNTEAM			
Betz	Gabriele	Dr.	Uni Basel
Hungerbühler	Ernst	Prof. Dr.	FHBB
Leuenberger	Hans	Prof. Dr.	Uni Basel
Meier	Christoph	Dr.	CCSO
Zeller	Andreas	Dr.	Novartis Pharma AG
ARBEITSGRUPPE I (Industrie-Pharmazeut)			
Bonny	Jean-Daniel	Dr.	Novartis Pharma AG
Giron	Danielle	Dr.	Novartis Pharma AG
Guentert	Theodor	Prof.	F. Hoffmann-La Roche AG
Gygax	Daniel	Prof. Dr.	FHBB
Kimura	Go	Pharmazeut	Uni Basel
Leuenberger	Hans	Prof. Dr.	Uni Basel
Lueckel	Achim	Dr.	Novartis Pharma AG
Luy	Bernhard	Dr.	Glatt International GmbH
Merino	Esther	Lic. sociologie & anthropologie	CCSO *(I-II)*
Surber	Christian	Prof. Dr. Phil. Nat.	Uni Basel
Ulmschneider	Michel	PD Dr.	F. Hoffmann-La Roche AG
van Hoogevest	Peter	PD Dr.	Phares Drug Delivery AG
Zeller	Andreas	Dr.	Novartis Pharma AG
Zimmerli	Walther	Prof. Dr.	Volkswagen AutoUni
Zehnder	Beat	Prof. Dr.	FHBB
ARBEITSGRUPPE II (Pharma-Ingenieur)			
Barblan	Gabriele	Prof. Dr.	FHBB
Bärtschi	Markus	Prof. Dr.	FHBB
Betz	Gabriele	Dr.	Uni Basel
Dittler	Martina	Dr.	Uni Basel *(Gast)*
Eichler	Klaus	Internationale Kfm. Ausbildung	Glatt International GmbH
Flury	Urs	Dr.	Novartis Pharma AG
Hungerbühler	Ernst	Prof. Dr.	FHBB
Imanidis	Georgios	PD Dr.	Uni Basel
Marrer	Stephan	PD Dr.	F. Hoffmann-La Roche AG
Nyfeler	Peter	Dipl. Masch. Ing. HTL	Novartis Pharma AG
Puchkov	Maxim	Dr.	Uni Basel
Reinke	Claudia	Dr.	Med. Sciences Limited Basel
Schmutz	Hans-Rudolf	Prof. Dr.	FHBB
Steinegger	Fred	Prof. dipl. Ing. ETHZ	FHBB
Stocker	Simon	Dipl. Ingenieur FH	F. Hoffmann-La Roche AG

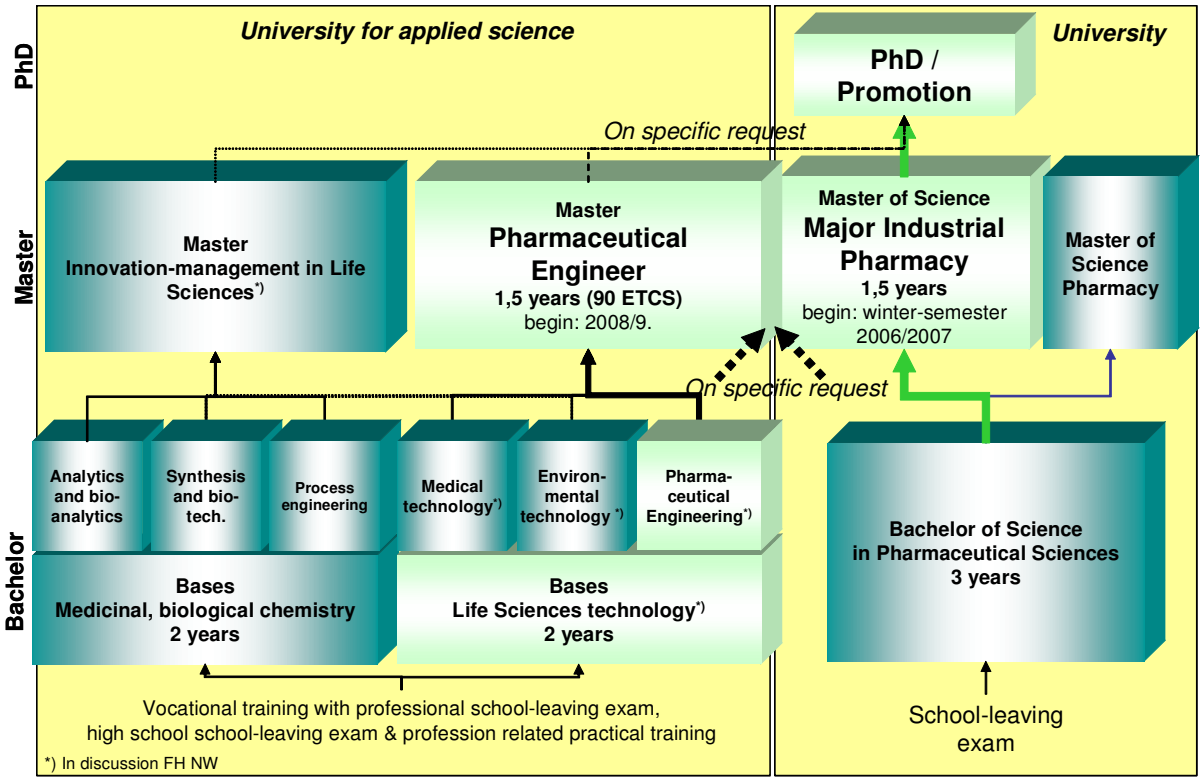
Prof. Richard Bührer wurde ab Januar 2005 durch Prof. Markus Bärtschi ersetzt !

L.1.2 Zeitliches Engagement der Mitglieder

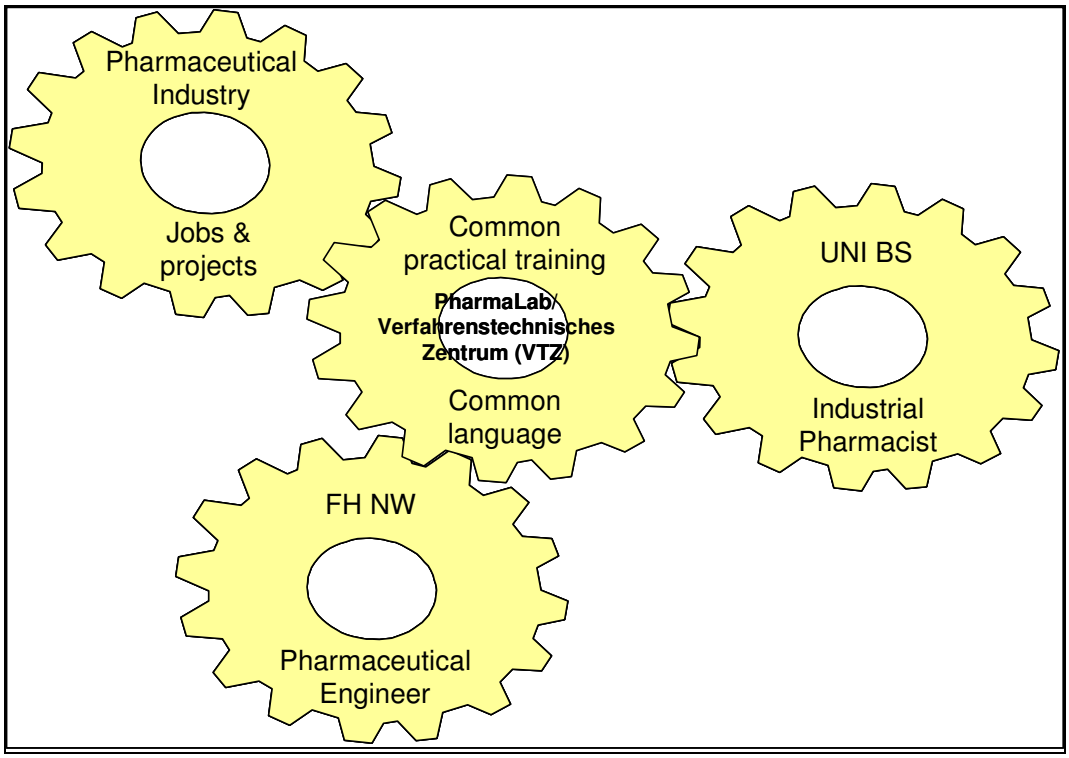


Geleistete Arbeitsstunden in der Periode Juni 2004 bis Januar 2005

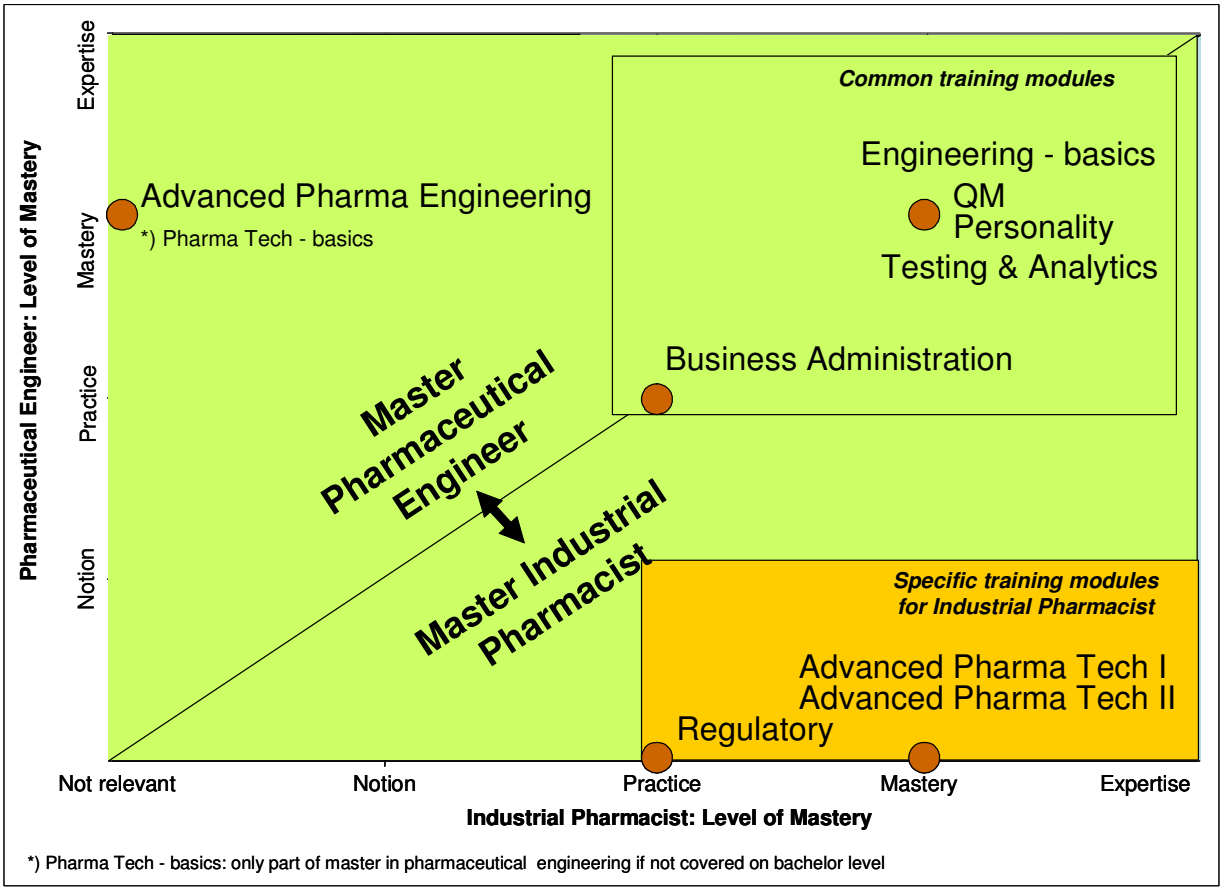
L. 2. Anhang 2: Masterkonzept und Synergien



Gemeinsame, aufeinander abgestimmte Masterarchitektur zwischen Uni Basel und FHBB / FHNW



Inhaltliche Synergien zwischen den Masters «Industrie-Pharmazeut» und «Pharma-Ingenieur»



Portfolio von gemeinsamen und spezifischen Ausbildungsmodulen für die beiden Masters

L. 3. Anhang 3: Architektur der Ausbildungsmodule

Unified Reference Knowledge List				
Date: 14/04/2005				
The first 9 modules are directly related to the two Masters "Industrial Pharmacist" and "Pharmaceutical Engineer". Among them, four modules will be common to both Masters. The last three modules will be part of the related Bachelors. They are considered as prerequisites for the Masters.				
Responsible of document: Ernst Hungerbühler, Hans Leuenberger				
No	**Module**	**Acronym**	**No**	**Sub-Module (English = Reference Version)**
1 IP	Advanced Pharm.Technology I: Formulation Research & Development (Stufe 3)	Advanced Pharma Tech I	1.1	Formulation Strategy: Route of Administration, Preformulation, Stability & Shelf Life, Compatibility, Tox incl. studies, compound properties (e.g. polymorphism, salt form), BioAvail./BioEquivalence
			1.2	Biodiagnostics, Biofeedback Controlled Systems
			1.3	Innovative Formulation + Process Technologies/ Drug Delivery Systems, Medical Devices;
			1.4	Particle Design & Powder Technology
2 IP	Advanced Pharm.Technology II: Manufacturing Sciences (Stufe 3)	Advanced Pharma Tech II	2.1	Process Development, Optimization (Robustness), PAT
			2.2	Scale up, Validation and TechTransfer
			2.3	Minimization of cycle time, technical life cycle management, cost effective manufacturing
			2.4	Dimensional analysis/similarity
			2.5	Supply Chain Management: Logistics&Sourcing, In-/Out sourcing, Lean Production
3 x	Business Administration and Marketing (Stufe 2)	Business Administration	3.1	Introduction business administration; key financial terms (balance sheets, NPVs,…); Branding; Life Cycle Management; Purchasing
4 x	Personality (Stufe 2)	Personality	4.1	Personality Development/Intercultural skills, Holistic approach, leadership, Project management (Basics), Entrepreneurship, Teamwork. Decision making (such as Kepner Tregoe technique) communication skills and presentation.
5 x	Pharmaceutical Engineering I (Basics) (Stufe 3)	Pharma Engineering - basics	5.1	Infrastructure: Clean and Sterile Rooms, Zone Concepts incl. Safety/environmental protection, Risk assessment, Utilities, Material Flow, Cost Management, Equipment and technologies
			5.2	Process Equipment (incl.Controls, System Integration & Containment, Maintenance, WIP/"CIP", Cost Management).
			5.3	Basic mechanical & thermal process technology and equipment design.
6 x	Quality Management II & Inspection Management (Stufe 3)	QM	6.1	GMP/ISO (incl.deviation management/OOS) Systems Engineering (Process documentation) with exercises, legal aspects (pharma law, industrial law, labour law).
			6.2	Qualification/Validation, Calibration incl. CSV
			6.3	Documentation, Archiving and Traceability
7 IP	Regulatory Requirements / Intell. Property /Patents (Stufe 2)	Regulatory	7.1	The regulatory Process (IND, NDA, ANDA, DMF, CTA,…) and related Guidelines, Change control/SUPAC, Printed matters, ICH, Risk&Chance Management (e.g. Pharmacovigilance, complaints, processes)
			7.2	Patents/IP, Licensing Issues (in/Out), Basic contract matters, Drug Law
8 x	Testing & Analytics (Stufe 3)	Testing & Analytics	8.1	Analytical Development: Strategy, Methods, Valid. (Excipients, API & drug product)
			8.2	Phys. and Chem. Methods: Theory
			8.3	Phys. and Chem. Methods: Practical Applications
			8.4	Analytics of Biomolecules (DNA, Proteins,..)
			8.5	Pharmacopoieal Analytics (advanced analytics)
			8.6	Analytical Troubleshooting, OOS
9 PE	Pharmaceutical Engin. II (Advanced) (Stufe 3)	Advanced Pharma Engineering	9.1	factory/plant concepts (material, personal flow, disposal concept)
			9.2	production planning and scheduling
			9.3	economical aspects
			9.4	maintenance concepts
			9.5	pharma media preparation
			9.6	energy supply, building maintanance
			9.7	project management (advanced) with case studies
10	Part of Bachelor: Life Sciences Technologies (LST), Basics	LST - basics	10.1	basics of mechanical and thermical process engineering
			10.2	fluid dynamics
			10.3	process control technology / process control engineering
			10.4	Monitoring and control of processes, electrical and pneumatic engineering
			10.5	informatics
			10.6	industrial measuring techniques
			10.7	chemistry, biochemistry, biotechnology for engineers
			10.8	basics of Analytics (incl. laboratory course)
			10.9	material science
			10.10	microbiology (incl. laboratory course)
			10.11	technical english
11	Basics in Pharma technology (Part of Bachelor BSc in pharm.Sciences Uni BS)	Pharma Tech - basics	11.1	pharmaceutical technology I-III (incl. lab courses)
			11.2	Biopharmacy incl. Pharmakokinetics
12	Pharmaceutical Process Technologies (Part of LST Bachelor FHBB, pharma technics - specialities)	Pharma Process tech	12.1	pharmaceutical, mechanical process technology
			12.2	pharmaceutical thermical process technology
			12.3	pharmaceutical processes, pharmaceutical engines (incl. laboratory courses)
			12.4	packing materials
			12.5	packing machine
			12.6	bottling/filling machines

L. 4. Anhang 4: Berufsprofile

L.4.1 Industrie-Pharmazie

Mission	The industrial pharmacist is in charge of handling multi-disciplinary tasks such as dosage form design, pharmaceutical processes, analytical methods, biopharmaceutical, quality, patent and regulatory aspects of the development and manufacturing of innovative medicinal products in order to successfully introduce them on the market in an efficient way covering a broad range of job opportunities (see figure below).

Key activities	1	To translate pharmaceutical knowledge into a practical solution (drug formulation) satisfying therapeutic goal (administration modality), and needs of the market (innovation).
	2	Develop and evaluate robust processes/methods (formulation, analytical, administrative) for new formulation and transfer them to the production (from small to large scale production).
	3	Manufacture clinical service forms/market forms with the required quality, timeline and cost effectiveness in order to satisfy the client needs.
	4	Use validated analytical methods allowing monitoring the manufactures, clinical or market forms.
	5	Evaluate and purchase instruments, equipment and material in order to be able to fulfil the processes and economical goals.
	6	To get alignment of the team members on formulation strategies and to inform decision makers in order to mobilise required resources.
	7	To compare different scenarios (SWOT) for formulation development and production through registration.

PHARMAZEUTISCHE FORSCHUNG UND ENTWICKLUNG ~ 19 %

ZULASSUNG, REGISTRIERUNG VON NEUEN PRODUKTEN ~ 14 %

QUALITÄTSSICHERUNG, QUALITÄTSKONTROLLE ~ 11 %

INFORMATION, DOKUMENTATION, ARZNEIMITTELSICHERHEIT, COMPETITIVE INTELLIGENCE ~ 6 %

GRUNDLAGENFORSCHUNG, WIRKSTOFFFINDUNG ~ 1 %

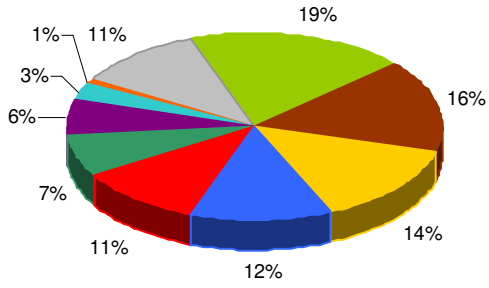
PHARMAZEUTISCHE PRODUKTION ~ 16 %

MARKETING UND VERKAUF, BUSINESS DEVELOPMENT ~ 12 %

ANALYTISCHE FORSCHUNG UND ENTWICKLUNG ~ 7 %

KLINISCHE FORSCHUNG, LOGISTIK VON KLINISCHEN PRÜFMUSTERN ~ 3 %

ANDERE ~ 11 %



Source: GSIA, Schweiz. Ges. der Industrieapotheker www.gsia.ch

L.4.2 Pharma-Ingenieur

Mission	The pharmaceutical engineer must be able to convert pharmaceutical processes into technical installations and to operate them in a sustainable way.	
Key activities	1	Apply the planning methodology (documentation, processes, legislation) by understanding the project management processes, the pharmaceutical procedures/medication science and general engineer knowledge with respect to quality management rules (GMP, GLP).
	2	Design, implement, qualify, operate, optimise and maintain facility infrastructure such as clean room, GMP, energy- and means preparation according to the company and authorities requirements.
	3	Apply the functionality (production process, infrastructure, safety) and the organisation of the pharmaceutical company (production of pharmaceutical products) according to the company guideline.
	4	Evaluate, implement and optimise the installations (interpretation, acquisition, putting into service, maintenance, technical support, supervision of the business) leaning on a deep understanding of the production processes (including the cleaning process) and according to the indications given be the industrial pharmacist.
	5	Lead the team to reach the objectives of the unit acting in accordance with the company culture/values and implementing decisions in a consequent, objective oriented and communicative way (including language competences).

ACKNOWLEDGEMENTS

All the persons especially the external docents and the companies/institutions, who have supported research and teaching at the Institute of Pharmaceutical Technology are officially acknowledged.

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Basel, February, 2006

Prof. Dr. H. Leuenberger