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Klingelbergstrasse 50, CH-4056 Basel

Tel. -41-(0) 61 267 15 00

Fax -41-(0) 61 267 15 16

INSTITUTE OF PHARMACEUTICAL TECHNOLOGY UNIVERSITY OF BASEL



Newly installed sterile line facility for "hands-on training" of industrial pharmacists in the Industrial Pharmacy Lab of the Institute of Pharmaceutical Technology (supported by Novartis Pharma).

INSTITUTE STAFF

Hans Leuenberger, PhD
Professor of Pharmaceutical
Technology

Georgios Imanidis, PhD
Private Docent of Pharmaceutical
Technology

Gabriele Betz, PhD
Head Industrial Pharmacy Laboratory

Christina Erb
Secretariate

Sonja Reutlinger
Laboratory assistant

Stefan Winzap
Technical and administrative assistant

EXTERNAL DOCENTS

Daniëlle Giron, PhD, Private Docent (PD),
Novartis Pharma, Basel

Theodor Güntert, PhD, Professor of
Biopharmaceutics, Roche, Basel

Peter van Hoogevest, PhD, Private
Docent (PD) Phares Ltd, Muttentz

Stephan Marrer, PhD, Private Docent
(PD), Roche, Basel

Michel Ulmschneider, PhD, Private Docent
(PD), Roche, Basel

Ottheinrich Eichhorst, PhD, Liestal

Klaus Eichler, TTC (Technology Training
Center, Binzen BRD

Bernd Herzog, PhD, Ciba SC,
Grenzach, BRD

Claudia Reinke, PhD, MedSciences, Basel

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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. (See the different organizational charts in the attachment). The Center of Pharmaceutical Sciences Basel-Zürich fits well into the concept to establish and strengthen the cooperation between Swiss Universities.

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 as well as of the equipment manufacturer Glatt. Thus 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.
MAXIM: “Science fascinates us as the key for Technologies changing the world” (freely adapted from I.Asimov). Pharmacists have excellent job-opportunities in the pharmaceutical industry (see the web page of the Swiss Society of Industrial Pharmacists www.gsia.ch).

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. Postgraduate Teaching

D.2.1 Postgraduate education program (NDS) in cooperation with the Center of Pharmaceutical Sciences, Basel – Zürich.

After the successful implementation in 2003 (see annual report 2003) the 6-day course on “Strategies and Trends in Pharmaceutical Development and Production” was offered again and took place on Sept. 29/30, Oct 6/7 and Oct. 13/14. The course was organised in the frame of the postgraduate education program (NDS) of the Center of Pharmaceutical Sciences Basel-Zürich, the Institute of Pharmaceutical Technology and the Chair “Galenic Sciences” (Prof. H.P. Merkle, ETH Z) together with representatives from the pharmaceutical industry. The majority of the speakers/lecturers were experts from industry. The PhD students paid a moderate fee compared to participants from industry similar to the already established course on “Quality Assurance” offered by the Center. PD Dr. G. Imanidis of the University of Basel, together with Regula Furegati and Dr. Angela Küng Krähenmann, center employees, coordinate these activities.

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

➤ **Teaching:** Recently, a new Department of Technology of Chemical-Pharmaceutical and Cosmetic Products at the Mendeleev's University of Chemical Technology of Russia (MUCTR) was founded. The co-operation Basel-Moscow has the aim to exchange expertise and to step towards the creation of a Faculty of Pharmacy at MUCTR. The program has as a goal to give Russian specialists the opportunity to strengthen the knowledge in Pharmaceutical Technology: The CD-Rom Physpharm with mathematical model equation has been successfully translated into Russian by Maxim Puchkov (MUCTR) and is part of the student education at MUCTR and at the University of Basel.

Teaching Presentation; Glatt equipment: The company Glatt, Binzen, Germany is a global leader in process equipment for life sciences. The equipment and the technologies, such as fluid bed, granulating, coating, drying etc. are presented in a power point presentation and translated into Russian by Denis Shishulin, MUCTR. The teaching presentation is part of the student education in the field of modern technological equipment of pharmaceutical plants at MUCTR.

➤ **Development of an Expert System for Capsules and Tablets:** The primary goal of this expert system is to create a pharmaceutical formulation database for the development and manufacturing of solid dosage forms. In addition, statistical experimental design studies and the application of artificial neuronal networks [ANN] are used for the optimisation of Pharmaceutical Dosage Forms. The idea is to use this system as a support for decision-making and as a tool in laboratory training and for development optimisation.

➤ **Computational Science Project:** Mathematical modelling using data on Spray-Freeze Drying and data, which will be provided by the new prototype of this equipment at Glatt, Binzen in connection with the PhD-project of Matthias Plitzko on the "Preparation of Nanocomposites" in collaboration with the NCCR Nanocenter in Basel (Prof. Güntherodt, group "Nanoscience in Medicine" of Prof. U. Aebi, Biocenter of the University of Basel).

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 representing the majority of prescribed medications, presently and most likely also in the future, are no exception as the science and technology of powders are still in the state of infancy. Research in the field of dosage forms, 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).

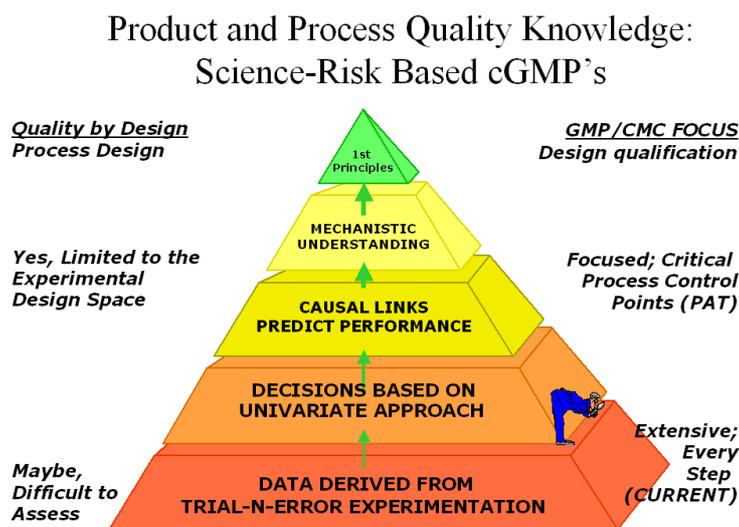


Figure E. 2.1 Science Pyramid
(Presentation A. Hussain,
Feb. 16, 2004,
Pharmacenter Basel)

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

E. 3. Research Areas

E.3.1 Main Areas

Research in Powder Technology

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

New Process Technologies

- Vacuum Fluidised Bed System
- Spray Freeze Drying at Atmospheric Pressure
- Scale-up in the 4th Dimension (Moist Agglomeration and Drying Process)
- Supercritical CO₂ 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; (PD 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

- 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)

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. 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 1999-2003

1999

Effect of Concentration and Degree of Saturation of Topical Fluocinonide Formulations on In Vitro Membrane Transport and In Vivo Bioavailability on Human Skin. Publication, in english. Fabian Schwarb, Georgios Imanidis, E.W. Smith, J.M. Haigh, Christian Surber, *Pharm.Res.* 16, 1999, 909-915. ISSN 0724-8741.

Effect of Separation Characteristics between Salbutamol sulfate (SS) Particles and Model Carrier Excipients on Dry Powder for Inhalation. Publication, in japanese. Kotaro Iida, Hans Leuenberger, Lise-Marie Fueg, Rudi Müller-Walz, Kazumi Danjo, *YaZa* 119 (10), 1999, 752-762. ISSN 0031-6903.

Effect of the Amphoteric Properties of Salbutamol on its Release Rate through a Polypropylene Control Membrane. Publication, in english. Roger Imboden, Georgios Imanidis, *Eur.J.Pharm.Biopharm.* 47, 1999, 161-167. ISSN 0939-6411.

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

- Prof. Theodor Güntert, PhD, having important responsibilities in his job at Roche Basel is lecturing Biopharmaceutical and Pharmacokinetic topics and is supervising a tutorial with practical applications of Pharmacokinetic data.
- PD Daniëlle Giron, PhD, is expert and head of the Thermoanalytic laboratory at Novartis Pharma Ltd. Her contribution teaching thermoanalytical topics is highly appreciated. Her publications are listed in the attachment.
- PD Peter van Hoogevest, PhD, is an expert in the formulation and the manufacture of liposomes. He is COO of Phares Drug Development Ltd., Muttentz, a company specialised in liposomal technologies and applications. He is teaching liposomal related topics (including practical training) at the Institute of Pharmaceutical Technology.
- PD Stephan Marrer, PhD, from F. Hoffmann-La Roche AG, is teaching Quality Assurance topics and is tutor in the seminar for Pharmaceutical Technology.
- Ottheinrich Eichhorst, PhD, has completed his study as a Pharmacist in 1999 and started to collaborate in 2000 with the Institute of Pharmaceutical Technology.
- 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.
- Claudia Reinke, PhD, has a degree in biology (PhD) and pharmacy (diploma). She owns the company MedSciences, Basel.
- 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 Rűf Stiftung Basel, Switzerland.
NETS Special Award sponsored by Gebert Rűf Stiftung Basel, Switzerland.

F. 2. G. Imanidis

Georgios Imanidis, June 8, in Serres, Greece

born 1958

EDUCATION

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

PROFESSIONAL APPOINTMENTS

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

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), Referee for different journals, Member of peer review committees: ETHZ (1993), University of Groningen and Utrecht (1997), Publications: more than 180, 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 [Fédération Internationale 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

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

Novartis Animal Health Ltd, Basel

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

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 2004

H. 1. Special Events 2004

H.1.1 Development of the MSc curriculum with the major “industrial pharmacy”

The department of pharmaceutical sciences has decided 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 FHBB (University of Applied Sciences Basel-City and Country UASBCC), 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 Pharm.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. It is planned that the MSc study at the University of Basel will start in autumn 2006 and the Master of Pharm.Engineer in autumn 2008. The University of Applied Sciences of Basel-City and Basel-Country has adopted as its focus “Life Sciences” and is now part of the University of Applied Sciences Northwestern Switzerland (FH-NWCH).

H.1.2 Donations for the Industrial Pharmacy Lab (IPL) at the Mülhauserstrasse 49/50, 4056 Basel.

In 2003 the Presster™ equipment (Donation: Pfizer Ltd.) for scale-up experiments in the area of tableting had to be revised in the USA. The carefully validated equipment could be successfully used for our research projects. Due to a donation made by Korsch (Berlin, Germany) an instrumented high-speed tableting machine could be added to our equipment. Last but not least a sterile line for ampoule filling could be installed which permits a “hands-on” training of students in this area. The installation was possible through the support of Novartis Pharma. A first “hands-on” training course could be successfully organized together with the International Association for Pharmaceutical Science and Technology PDA in November 2004. It is the idea to use in future intensively the IPL as an ideal platform for the education of industrial pharmacists and pharmaceutical engineers. After completion of the task described in H.1.1 a presentation of the curricula is planned at the IPL with a demonstration of the facilities of the IPL which will permit to show to the public and celebrate the most recent application of the sterile line.

H.1.3 NETS award



Dr. Gabriele Betz, head of the Industrial Pharmacy Lab, has received in 2004 the prestigious NETS award. The NETS program is an initiative of the Gebert Rüt Foundation, a young Swiss science foundation focussed upon innovation. NETS is dedicated to promoting new science and technology entrepreneurs in Switzerland.



Each year a group of promising young scientists and business people who are affiliated with Swiss Universities, Federal Institutes of Technology, and Universities of Applied Science are given the opportunity to learn about new chances and methods for starting a successful business. The NETS Program aims to promote cooperation and synergies on a nation wide level in order to establish an effective network of training, exchange of information, and knowledge transfer support.

NETS is an ongoing contribution to helping and encouraging young entrepreneurs.

The NETS Jury selected 18 young scientists and technologists from various Swiss universities to follow the specially designed NETS Entrepreneurship Development Program 2004. The Award Ceremony took place at Lausanne Palace on September 10, 2004.

“The key of the spirit of competition of our country is its extraordinary effort for education, research and development”. François L’Eplattenier, President of Novartis Venture Fund.

Gabriele Betz is a pharmacist and working at the University of Basel, where she is heading the Industrial Pharmacy Lab of the Institute of Pharmaceutical Technology. The Industrial Pharmacy Lab is an interface between University and the Pharmaceutical Industry and is intended to become a semi-public Institute for Industrial Pharmacy. Gabriele Betz studied pharmacy at the Albert-Ludwig-University in Freiburg/Breisgau, Germany. After she had completed her studies, she moved to Switzerland and joined the Institute of Pharmaceutical Technology of Prof. Hans Leuenberger, where she performed her Ph.D.-thesis in the field of Transdermal Heparin Application using Liposomal Preparations. In 2001, Prof. Hans Leuenberger has offered her a postdoc position with the aim to implement research and teaching in solid dosage form design, scale up, and manufacturing science in the rooms of a former bakery. One year later, in 2002, the opening of the Industrial Pharmacy Lab in an appropriately adapted infrastructure was celebrated.

H.1.4 CAETS Award

May 27, 2004, in recognition of his outstanding service Prof. Leuenberger was conferred a Certificate of Appreciation by the International Council of Academies of Engineering and Technological Sciences, Inc.



H.1.5 Award dedicated to our partner institution at MUCTR Russia

With this bronze medal the Mendeleev University of Chemical Technology of Russia was awarded for the development of web-portal “Pharmacy-online”. The portal was developed during joint project between Institute of Pharmaceutical Technology (University of Basel) and Mendeleev University of Chemical Technology of Russia. The project was sponsored by Swiss National Science Foundation

At the IV MOSCOW INTERNATIONAL SALON OF INNOVATIONS AND INVESTMENTS (February 25-28, 2004 Moscow, All Russian Exhibition Centre), our partner institution at MUCTR Russia got awarded with the bronze medal and diploma for the development of the portal of distance and multimedia education “Pharmaceutics-online”. Some information concerning this event (SCOPEs Project No 7IP of the Swiss National Science Foundation for the promotion of scientific research).

Goals of the Salon - to assist inventors, developers and manufacturers of high technology products in presenting inventions and innovative projects in order to promote promising technologies and products on the domestic and international markets, in establishing mutually beneficial business contacts, to attract the attention of potential investors and customers to competitive innovations, to encourage business innovation activities, determine capabilities for effective use of intellectual resources, science and technology, production and staff potential of research institutions and industrial enterprises.



The 4th Moscow international salon of innovations and investments welcomes participation of Russian and foreign research organizations and industrial enterprises, small and medium sized companies, inventors, sponsors of innovation projects, members of the business community interested in obtaining a mutually beneficial result from marketing competitive research-intensive products and innovative technologies as well as members of financial and consulting structures, whose activities involve participation in financing, implementation and backing of innovative research-intensive projects.



By decision of the International Jury, the most promising innovations will be awarded with Grand-prix, medals and diplomas of the Salon Organizational committee, decorations and special prizes of the Russian and international organizations.

H.1.6 Opening of the Russian-Swiss Center for Education and Technology Transfer in the area of pharmaceutical and biological Technology.

The idea put forward by our partner institution at MUCTR, to create a Russian Swiss Center for Education in Pharmaceutical Sciences and for Technology Transfer in Pharma- and Biotechnology, was

opened in the presence of the Swiss Ambassador and the rector of MUCTR, Prof. Pavel Sarkisov on Nov. 24, 2004. The creation of this center is a result of the cooperation between the Institute of Pharmaceutical Technology of the University of Basel and the Cybernetics Department of D. Mendeleev University of Chemical Technology of Russia. The head of the Basel Institute of Pharmaceutical Technology is proposed to become an honorary director of this center assisting the executive director in the organisation of symposia and special events.

H.1.7 Agreement with the École des Mines Albi-Carmaux

Due to the agreement which was signed by the responsible person at the École des Mines d'Albi and by the rectorate of the University of Basel, students, which have completed the pharmacy degree at the University of Basel (diploma or MSc equivalent) can enrol in a two year study at the Grande École des Mines d'Albi and can obtain a diploma as an engineer, of this prestigious Technical University having a high reputation in the EU.

H.1.8 Collaboration with Bosnalijek

The head of the Institute was invited to visit Bosnalijek Company in Sarajevo, Bosnia & Herzegovina. This visit was suggested by a long term collaborator of the Institute, Dr. S.E. Kocova El-Arini, who had an assignment by UNIDO (United Nations Industrial Development Organization) to give support for the reconstruction of the pharmaceutical company Bosnalijek after the war in Bosnia.



From left to right: Prof. Dr. H. Leuenberger,
Prof. Dr. Zijad Pašić, Minister of Education,
Arslanagić Edin, CEO Bosnalijek Company

During this visit it was planned to sign a Letter of Intent by the CEO of the Bosnalijek Company in his office, for a closer cooperation between this company and the Institute to foster the relationship and to give a support concerning the training of pharmacists in the area of Pharmaceutical Technology in the frame-work of the actual PhD-program of the Institute at the University of Basel.

The head of the Institute of Pharmaceutical Technology was impressed that the Minister of Education of Bosnia & Herzegovina, Prof. Zijad Pašić considered this cooperation to be of such a high importance and of high priority that the CEO and the author of this report was invited to the ministry where the letter of intent was signed (see photo). The Bosnalijek Company is ready to give a financial support for three PhD students from Sarajevo to do a PhD thesis at the Institute of Pharmaceutical Technology of the University of Basel. Bosnalijek Company is an important employer for this country.

H.1.9 Construction of a new web-site

Thanks to the work of Dr. Maxim Puchkov a new and improved website of the Institute of Pharmaceutical Technology could be established (www.pharmtech.ch), which offers a lot of advantages.

H.1.10 Technology Transfer

Principal partner in a contract with DiPierro Ventures, Inc., New York, to develop a device for time controlled drug delivery includes a consortium of industrial partners. The project is coordinated by the Office of Technology Transfer (WTT) of the University of Basel. New patent applications have been filed in collaboration with PD Dr. Georgios Imanidis.

H. 2. Diploma Studies

In the year 2004 9 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 2004

Student	Topic	Supervisor/Location
Grauwiler Sandra	Formulierungsintegrierte, komplexe Mikroemulsionssysteme als transdermale Penetrationsenhancer des hydrophilen Modellwirkstoffes Nicotinsäure	Heiko Nalenz, PD Dr. G. Imanidis Institute of Pharmaceutical Technology, University of Basel,
Honegger Myriam	Investigation of matrix systems from network-forming starch	Dr. Gabriele Betz Institute of Pharmaceutical Technology, University of Basel,
Mazzola Stefano Enzo	Entwicklung und Optimierung einer in vitro-Dissolutionsmethode einer innovativen Veterinär-Arzneiform	Kathrin Schalper, Ph.D., Prof. H. Leuenberger Novartis Animal Health, Basel,
Meier Brigitte	Anwendung von Neuronalen Netzwerken bei der Inprozesskontrolle von Wirbelschichtgranulation	Maxim Puchkov, Gabriele Betz, Ottheinrich Eichhorst Institute of Pharmaceutical Technology, University of Basel,
Michel Bettina Rebecca	Absorption von Saquinavir im Caco-2 und HDM-Modell: Quantifizierung von passiven und aktiven Transportprozessen in wässrigen und liposomalen Medien	Dr. S. Kapitza, PD Dr. G. Imanidis, PD Dr. P. van Hoogevest Institute of Pharmaceutical Technology, University of Basel,
Nellen Micha Dominique	Identifizierung natürlicher Substanzen mit antiinflammatorischer Wirkung auf gastrointestinale Zellen	Dr. J. Schwager DSM Nutritional Products, Kaiseraugst,
Ottiker-Bader Evelyne	Klinische Studie zur Quantifizierung von Triamcinolonacetonid im Stratum corneum	Carolina Pellanda, Verena Figueiredo, Prof. Dr. Christian Surber Institute of Pharmaceutical Technology, University of Basel,
Schaad Eliane Helen	Transdermale Aufnahme eines Pflanzenextraktes	Dr. Karin Berger Büter , PD Dr. Imanidis Georgios Institute of Pharmaceutical Technology, University of Basel,

Wyss Kaspar	Einfluss von Adjuvantien auf die Eigenschaften von Caco-2 Zellmembranen - Fluoreszenzdepolarisationsmessungen	Susanne Reitbauer, PD Dr. G. Imanidis Institute of Pharmaceutical Technology, University of Basel
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H.2.2 Visiting Diploma Student

Maaranto Helena Trainee from University of Kuopio	In vitro Study of Pig Skin Permeation and Metabolism of Nitroglycerin with a Patch and a Solution in Combination with Nicotine	PD Dr. G. Imanidis Institute of Pharmaceutical Technology, University of Basel,
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H. 3. Completion of the SCOPES 2000-2003 project in cooperation with MUCTR

H.3.1 Teaching/New Learning Technologies:

New education and multimedia courses for the Department of Pharmaceutical and Cosmetic Technology (MUCTR) were developed and introduced into curriculum.

Multimedia web-based education environment (web-portals) for the students of MUCTR and Institute of Pharmaceutical Technology, University of Basel was created, conceptually new model of education process, based on multimedia and web-based technologies in both Universities was introduced.

Five textbooks were published (two of them are in print now) and can be used for education of the students and PhD students.

Ph.D. student Denis Shishulin defended his thesis "Information-program environment for development of new technologies and drug dosage forms production flowsheet".

H.3.2 Research activity:

The following software was developed:

Multimedia- and web-based education environment (web-portals).

Intelligent system and rule-based expert system shell (CLIPS).

Decision-making support system for dosage form design is under developing.

Innovation technology and equipment for freeze drying in fluid bed at atmospheric pressure is developing.

The work "In vivo comparison of various liposomal formulations for cosmetic application" was completed and presented on the 5th Central European Symposium on Pharmaceutical Technology and Biotechnology, Ljubljana, Slovenia, September 2003.

As a consequence of the fruitful cooperation and the excellent results, there is a common desire to continue the project and to expand the activities especially in the field of Computational Science and Freeze-drying activity.

H. 4. Research

H.4.1 Publications 2004

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. Pharm. Res. submitted (2004).

Atmospheric Spray Freeze Drying with fluidized bed of Mannitol. 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.

Detection of percolation phenomena in binary polar liquids by broadband dielectric spectroscopy. Publication, in english. Hernandez Perni Maria Engracia, Stengele Andrea, Leuenberger Hans, Special issue of *Int.Journal of Pharmaceutics*, (in press).

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).

In vivo comparison of various liposomal formulations for cosmetic application. Gabriele Betz, Angela Aeppli, Nathalia Menshutina, Hans Leuenberger, submitted to *International Journal of Pharmaceutics*.

Modelling of the spray-freeze drying process. Proceedings, in english. Leuenberger Hans, Pitzko 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 in the field of chemical technology and pharmaceutics. Applied software. N.V. Menshutina, H. Leuenberger, S.V. Goncharova, D.V. Shishulin, E.O. Lebedev, A.E. Korneeva. Textbook, 2003, 92 pp. (in print).

Physics of Particulate Matter. Pharmaceutical Powder Technology Handbook. H. Leuenberger and N. Menshutina, 2003, 120 pp. (In print).

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.

Towards a better understanding of the parameter E_i/E in the characterization of polar liquids. Publication, in english. Hernandez Perni Maria Engracia, Stengele Andrea, Leuenberger Hans, Special issue of Int.Journal of Pharmaceutics, (in press).

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

H.4.2 Doctorate Colloquia

27.04.2004	Krisanin Chansanroj	The application of hot melt technique to the controlled Release formulation
29.06.2004	Lars Rehorik	Process modelling as a tool to optimize quality by design in the pharmaceutical production.
27.07.2004	Michael Lanz	UICEL - a new cellulose-II based excipient - and its role as a disintegrant
21.09.2004	Invited Speaker, Dr. Ajaz Hussain, FDA	Process Analytical Technology
09.11.2004	Ursula Bausch	Protein degradation during filling processes
30.11.2004	Anja Guntermann	Evaluation of Presster compaction simulator capabilities

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

05.02.2004, Zürich	Pharma-Day Doktoranden	Hot melt coating technique for controlled release pellets.
16.02.2004, Basel	Visit at the Pharmacentre Dr. Ajaz S. Hussain, Status of FDA's PAT Initiative	Process Understanding and PAT: FDA Guidance Framework
16.02.2004, Basel, Valporsson Hedinn	Presentations in the framework of the visit of Dr. Ajaz S. Hussain, Deputy Director, CDER, FDA, Rockville, USA	Process Analytical Technology (PAT) as a Challenge in Pharmaceutical Production
16.02.2004, Basel, Russell Frauke	Presentations in the framework of the visit of Dr. Ajaz S. Hussain, Deputy Director, CDER, FDA, Rockville, USA	Dissolution Testing and Near-Infrared Spectroscopy: The Alternative Approach
16.02.2004, Basel, Lema Carmen	Presentations in the framework of the visit of Dr. Ajaz S. Hussain, Deputy Director, CDER, FDA, Rockville, USA	In-line Testing of Lyophilized End-Products
16.02.2004, Basel, Betz Gabriele	Presentations in the framework of the visit of Dr. Ajaz S. Hussain, Deputy Director, CDER, FDA, Rockville, USA	Power Consumption Measurement and Temperature Recording during Wet Granulation
16.02.to 18.02.2004, Basel, Imanidis Georg	Moderation of the interest group meeting at the PDA International Congress and Exhibition	Drug Delivery Devices
18.02.to 19.02.2004, Basel	(Process Analytical Technology) Initiative	From Pharmaceutical Art to Science: Process Optimization based on CAD/ANN and its role in FDA's PAT
19.02.2004, Basel, Betz Gabriele	Workshop at IPL organized by Pharmatrans Sanaq AG	Direct compression & Roller compaction. Efficient & Cost effective?
15.03.to 18.03.2004, Nürnberg, Betz Gabriele, Meyer Andrea, Puchkov Maxim, Leuenberger Hans	International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology	Investigation of granulation and comparison of tablet compaction properties of polymorphs of Mannitol after wet granulation with directcompressible Mannitol using a compaction simulator.

15.03.to 18.03.2004, Nürnberg, Trobradovic Haris, Betz Gabriele, Kocova Silvia, Hadžidedić Šeherzada, Leuenberger Hans	International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology	Differential scanning calorimetry as a tool for the prediction of the compatibility and stability of multicomponent drug systems
16.03.to 18.03.2004, Nürnberg, Leuenberger Hans, Plitzko Matthias, Puchkov Maxim	International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology	Modelling of the spray-freeze drying process
16.03.to 18.03.2004, Nürnberg, Leuenberger Hans, Plitzko Matthias, Puchkov Maxim	6 th International Congress for Particle Technology, PARTEC 2004	Keynote-Lecture; Nanocomposites by Spray Freeze Drying
22.03.2004, Seville, University of Seville Leuenberger Hans	Participating at the PhD-Defence of Antonia Miranda Lora	Estudio de los Puntos críticos para la optimización de matrices hidrófilas de liberación controlada. Aplicación a una formulación con lobenzarit disódico
23.03.2004, Binzen/Lörrach Betz Gabriele on behalf of Leuenberger Hans	No.78 Technology Training Center (TTC)- Workshop High Shear Processing	Granulation end point detection
27.03.to 30.03.2004, Sarajevo Leuenberger Hans	Cooperation Conference with Bosnalijek, Pharmaceuticals and Chemicals Industry, in Bosnia & Herzegovina.	Letter of Intent signed for a close cooperation between Bosnalijek and IPT
26.04.2004, Basel Leuenberger Hans	PDA Central Europe Chapter Forum	The FDA PAT Initiative "From the Horse's Mouth" - Impact of PAT on Academia
27.04.to 29.04.2004, Binzen/Lörrach Leuenberger Hans	No. 79 Technology Training Center (TTC)- Workshop	Granulation and Tableting
28.04.2004, Basel, Prof. Moïse Azria	Vorträge am Pharmazentrum - Seminars on Drug Discovery & Development	Oral Delivery of Peptides: Dream of Reality?

11.05.to 12.05.2004, Brussels Leuenberger Hans	ISPE European Congress	PAT Seminar - Process Analytical Technology - Facilitating Manufacturing Excellence and Regulatory Compliance Seminar FDA's PAT initiative on teaching and research in academia
29.05.to 03.06.2004, Kyoto Leuenberger Hans	2nd Pharmaceutical Sciences World Congress The Global Translation of Science into Drug Development in Advancing Therapy	Pharmaceutical Process Optimization based on CAD/ANN and its role in FDA's PAT (Process Analytical Technology) Initiative
04.06.2004, Gifu Leuenberger Hans	Lecture for the Tokai Branch of the Pharmaceutical Society of Japan	Pharmaceutical Powder Technology - Art, Science, Process Technology
14.06.2004 Cambridge, MA, Gabriele Betz	Swiss House of Advanced Research (SHARE)	The Industrial Pharmacy Lab (Selected as the most promising project by the audience in the frame of the NETS program)
23.06.2004 Gabriele Betz	Babson College, William F. Glavin Center, Wellesley, MA.	Creation of an Independent Industrial Pharmacy Lab
01.07.to 03.07.2004 Tromsø, Norway, M. Sutter and G. Imanidis	Oral presentation at the Midnight Sun Meeting on Drug Transport and Drug Delivery, University of Tromsø, Norway	Correlation of Phospholipid Membrane Order and Dynamics Derived from Fluorescence Anisotropy with Solute Permeability
01.07.to 03.07.2004 Tromsø, Norway, D. Blaser, C. Bucher and G. Imanidis	Poster at the Midnight Sun Meeting on Drug Transport and Drug Delivery, University of Tromsø, Norway	Combined Active Efflux and Phase II Metabolism of Amentoflavone in Caco-2 Cell Monolayers
01.07.to 03.07.2004 Tromsø, Norway, S. Reitbauer, K. Wyss, C. Mettler and G. Imanidis	Poster at the Midnight Sun Meeting on Drug Transport and Drug Delivery, University of Tromsø, Norway	Assessing Adjuvant Affected Changes on the Plasma Membrane of Caco-2 Cell Monolayers with Fluorescence Depolarization Measurements
06.07.to 07.07.2004, Zürich, ETH Technology, Leuenberger Hans	Event in the field of Nano-Science Micro- and Nanotechnologies in Life-Sciences	Atmospheric Spray-Freeze Drying - a novel technique for manufacturing organic nanocomposite pellets as drug delivery systems
19.07.2004, University of London, The School of Pharmacy, Leuenberger Hans	Invited Member of the board, participating at the PhD-Defence of Kevin Sooban	Preliminary Report given by Hans Leuenberger (University of Basel, Switzerland) for the PhD Defence of the PhD Thesis (author: Kevin Sooben)

10.09.2004, Lausanne Palace, Gabriele Betz	NETS Award Ceremony, Lausanne. Selected as the NETS Special Award 2004.	We turn your active substance into a drug delivery system
12.09. to 15.09.2004, Istanbul K. Chansanroj , P. Praserthdam, G. Betz, H. Leuenberger, A. Mitrevej, N. Sinchaipanid	Posterpresentation at the 12 th International Pharmaceutical Technology Symposium	Thermal characterization of hydrogenated soybean oil as lipophilic glycerides used for the hot melt coated pellets
12.09.to 15.09.2004, Istanbul, Go Kimura , Gabriele Betz, Hans Leuenberger	Posterpresentation at the 12 th International Pharmaceutical Technology Symposium	Influence of loading volume of mefenamic acid on granule characteristic and compression behavior using a compaction simulator
21.09.2004, Basel, Prof. A.Hussain	Seminars on Drug Discovery & Development The Role of Knowledge in Product Development: Improving Knowledge Management in Pharmaceutical Sciences	The Journey from Corrective Actions – to - Continuous Improvement - to - Quality by Design: Achieving Right First Time, First Cycle Approval
26.09.to 29.09.2004 Monte Verità, Switzerland Imanidis Georg	Key Communication at the 8th International Conference on Pharmacy and Applied Physical Chemistry,	Phospholipid Membrane Properties Determining Drug Permeation
04.10.2004 Kuopio, Finland Imanidis Georg	Lecture at the Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Kuopio	Passive and Active Mechanisms of Drug Absorption. Quantitative Assessment of Determining Factors
06.10.to 07.10.2004, Basel, H.P. Merkle, H. Leuenberger, G.Imanidis R.Furegati	Continuing Education Course - Strategies and Trends in Pharmaceutical Development and Production	Strategies and Trends in Pharmaceutical Development and Production
07.10.2004, Basel, Gabriele Betz	Continuing Education Course 2004 Part II: Strategies and trends in pharmaceutical development and production	Scale-up of the tableting process with MCC Presster TM
11.10.2004, Casino Bern, Gabriele Betz	Swiss Science Forum, NETS Special Award Ceremony	We turn your active substance into a drug delivery system.

11.10.2004, Basel, Prof.Yoshiaki Kawashima, Gifu Pharmaceutical University, Japan	Seminars on Drug Discovery & Development	Dry Nano - Composite Particulate System for Pulmonary Delivery
13.10.to 14.10.2004, Albi CT Cedex Leuenberger Hans	Event of the École des Mines Albi- Carmaux Albi International Rencontres in Pharmaceutical Engineering 2004	Pharmaceutical process optimisation and its role in the FDA's Process Analytical Technology initiative
17.10.2004, Brussel Leuenberger Hans	EUFEPS Council Meeting and Open Forum	Panel Discussion on PAT and EU- research proposal
17.10.to 20.10.2004, Brussel, Leuenberger Hans	EUFEPS European Congress New Safe Medicines - Towards Mechanistic Prediction	Science behind PAT - from Art to Science – a challenge of PAT initiative
26.10.2004 to 27.10., Weimar Puchkov Maxim	Technology Training Center (TTC)- Workshop	Fluid bed process modelling
27.12.2004, Moscow, Puchkov Maxim	Lecture at the Mendeleyev University of Chemical Technology of Russia, in the frame of the Russian-Swiss Science Center	Application of computer aided systems in Industrial Pharmacy

H.4.4 Visiting scientists

April – May 2004	Cooperation with Mendeleyev University, Prof. N. Menshutina Visiting Scientist Anastasia Korneeva	Project “Modelling of atmospheric spray-freeze drying.”
July 2003 – June 2004	Cooperation with Mahidol University, Prof. Ampol, Visiting Scientist Krisanin Chansanroj	Project “The application of hot melt coating technique to the controlled release formulation.”
December 2004	Prof. Silvia Kocova El Arini	Project “Thermoanalysis”

H.4.5 List of PhD-Theses in Pharmaceutical Technology completed in 2004

PhD student	Title	Funding/Location
Gräflein Claudia	Parenterale Ernährung mit stabilitätsgeprüften, modularen Standardnährlösungen in der Neonatologie	Kantonsspital Aarau, Spitalapotheke
Schiffmann Axel	Modellierung und Formulierung von WIP (Washing In Place) - und CIP (Cleaning In Place) - Konzept für Wirbelschichtanlagen	Institute of Pharmaceutical Technology, University of Basel; Glatt GmbH Binzen
Kuny Tanja	Untersuchungen zur Trockenagglomeration von pharmazeutischen Wirk- und Hilfsstoffen	Institute of Pharmaceutical Technology, University of Basel
Altenbach Melanie	Transdermale Iontophorese von geladenen und ungeladenen Verbindungen: Einfluss der Molekülladung und der Moleküllipophilie auf den Transport durch menschliche Epidermis	Institute of Pharmaceutical Technology, University of Basel
Hernandez Perni Maria Engracia	A contribution to the Understanding of Percolation Phenomena in Binary Liquids	Institute of Pharmaceutical Technology, University of Basel

I. Outlook 2005

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. Requirement of adequate lab space

This problem is not new, as in 1982 the late minister of education, Arnold Schneider, briefed the author of this report just two weeks after being nominated as head of the Institute of Pharmaceutical Technology. His main message consisted in the fact that the Institute of Pharmacy located at that time in the historical down-town area, Totengässlein 3, where Paracelsus cured Johann Frobenius, should really move into a modern lab building. The author of this report took this suggestion serious and started together with his PhD students to plan lab space. The procedure took a long time. In 1992 the parliament of the city of Basel agreed to construct a new building for the natural science faculty. The plans of the buildings included five floors of research and training labs for pharmacist (ca. 2500m²).

The costs for the buildings were estimated to be 66.1 Million Swiss Francs, with a share of 22.1 Million to be paid by the Swiss confederation. In 1993 it became doubtful, whether the federal contribution of 22.1 Million will be granted by the federation, discussing the possibility to merge the Schools of Pharmacy of the german speaking part of Switzerland and to concentrate the education in Zürich.

Due to the lack of lab space in Basel and in Zürich it became evident that a physical merger was not possible to be realized in due time. Thus both partners decided to push forward a close cooperation between both schools leading to the creation of the Center of Pharmaceutical Sciences of the University of Basel and the ETH Zürich. The first contract was signed in 1995 between the rectorate of the University of Basel and the president of ETHZ. On that basis the financial federal contribution was granted and the new building which received the name “Pharmacenter” was completed in 2000. In 2005 the institutes of molecular pharmacy, pharmaceutical biology and pharmaceutical technology occupy three floors. Due to the heavy equipment of the Institute of Pharmaceutical Technology additional lab space could be rented outside the Pharmacenter at the Mülhauserstrasse 49/51, where the Industrial Pharmacy Lab was installed.

1.4. 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 and has been published on the website of the Institute of Pharmaceutical Technology (www.pharmtech.ch) as a preprint. The authors of this paper acknowledge the editor of the journal “Advanced Powder Technology” (Japan) and the publisher “Brill Academic Publishers Inc.” to have accepted the proposal of FDA to have this paper already publicly available before the publication date (February 2005).

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

1. 5. Future perspectives in education with introduction of new Master courses

The introduction of the new Master course MSc in Pharmaceutical Sciences Major “Industrial Pharmacy” at the University of Basel together with the Master course “Pharmaceutical Engineering” at the University of Applied Sciences of Northwest Switzerland in Muttenz will need a careful planning.

A working party with experts from all partners including the pharmaceutical industry is preparing on the basis of the job profiles “industrial pharmacy” and “pharmaceutical engineer” the necessary reference knowledge and competence profiles for the creation of the corresponding educational concept.

1. 6. On-Going Research Activities

1.6.1 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
Daneshvari Dana	Dielectric Spectroscopy of binary hydrophilic solvent mixtures	Private source and Institute of Pharmaceutical Technology, University of Basel
Egger-Heigold Barbara	The effect of excipients commonly used for drug formulation on the blood distribution.	Novartis Pharma AG
Faatz Susan	Ländervergleich Irland-Schweiz betreffend der Rahmenbedingungen für die Pharmazeutische Industrie	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

Kimura Go	Effect of porosity on dissolution and tableting of granules containing Mefenamic acid	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
Lanz Michael	The behaviour of disordered particulate systems in case of dry and moist agglomeration processes	Swiss National Science Foundation, Bern, Grant No 20-58941.99; Institute of Pharmaceutical Technology; Basel
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
Meyer Thomas A.	The behaviour of disordered posticulate systems: flow properties and diffusive mixing	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
Plitzko Matthias	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
Reitbauer Susanne	Absorption paths of drugs through CaCo-2 cells	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
Sehic Selma	Effect of variability of primary materials on the performance of carbamazepine formulation	Industrial Pharmacy Lab, Bosnalijek, Bosnalijek, Pharmaceuticals and Chemicals Industry

Tassopoulos Tatiana	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
Thürlemann Charles	Development of a Biosensor-System for self-testing the intensity of anticoagulation by anticoagulated patients in capillary whole blood	Insel-Spital, Bern, Asulab, Marin/NE
Valporsson Hedinn	PAT and new Strategies in the pharmaceutical production and their economical impact	Novartis Pharma Stein AG, Stein
von Orelli Johannes	Expert Systems zur Entwicklung von Tabletten und Kapselformulierungen - Development of an expert system for solid dosage forms	Institute of Pharmaceutical Technology, University of Basel
Walter Marijke	Konzeption, Entwicklung und Realisierung eines vernetzten e-Lehr- und-Lernprogrammes der Pharm.Technologie	Private source

I.6.2 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)
Dr. Kapitza Susanne untill 30.9.2004	Solubilization of poorly water-soluble compounds	Institute of Pharmaceutical Technology, University of Basel

I. 7. Grants and Operating Budget

I.7.1 Contribution of the University (figures 2002 costs - 2003 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)

I.7.2 External funding administered by the University

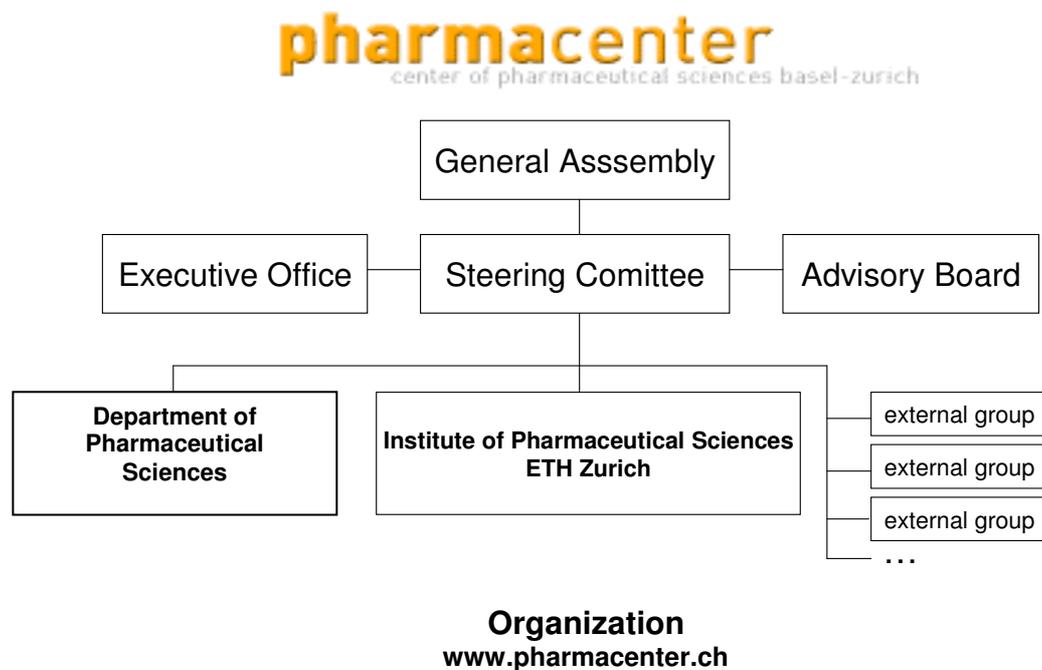
External funding administered by the University incl. Swiss National Science Foundation (SNF):
CHF 169 339 (2001-2003). CHF 175 000 (2003-2006).

I.7.3 Other third party money not administered by the University

Direct payments to PhD students **CHF 450 000 (estimate ± 20%)**
(individ. and SNF salaries):

ATTACHMENT

J. Organization charts



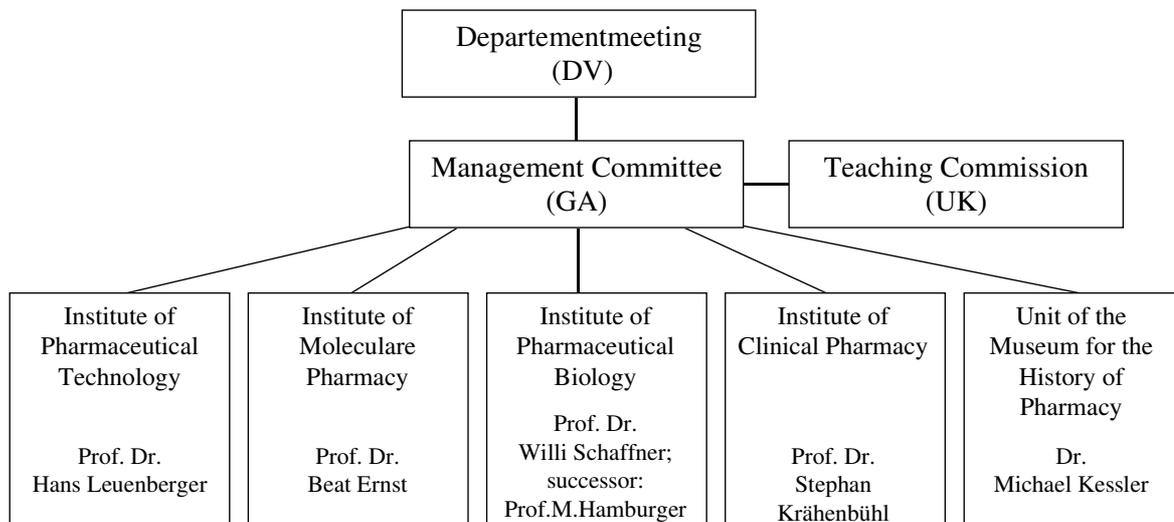
Steering Committee Members 2004

- G. Folkers, President; successor K.H. Altmann, President
- H. Wunderli (ETH)
- H. Leuenberger
- A. Eberle (external groups)

Executive Office

- H.P. Wessels, Managing Director

Organization Department of Pharmaceutical Sciences



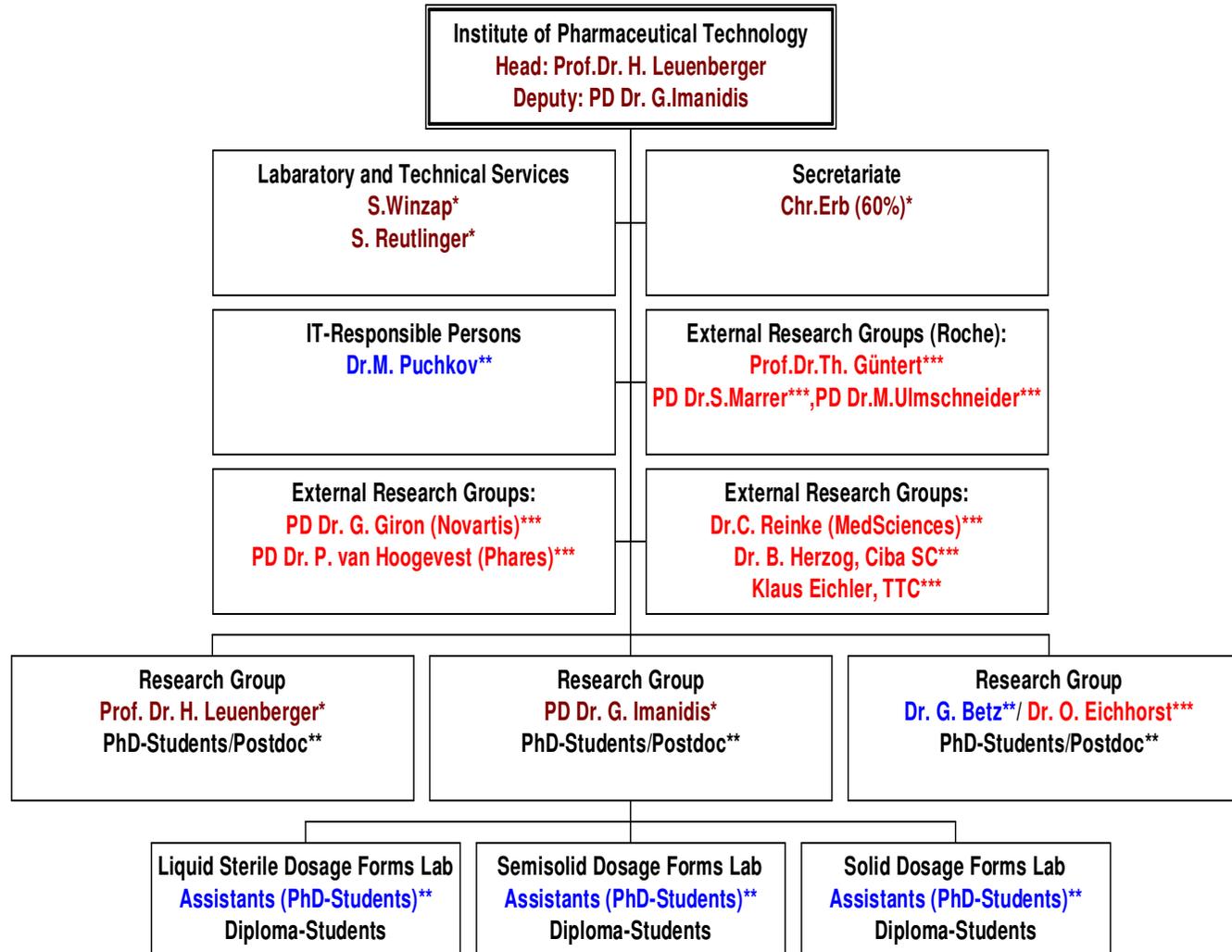
Management Committee 2004

- H. Leuenberger (Vorsitz)
- G. Imanidis
- B. Ernst
- A.B. Utelli
- W. Schaffner / successor: M. Hamburger
- J. Krähenbühl

Teaching Commission

- B. Ernst (Vorsitz)

Organisational Chart Institute of Pharmaceutical Technology



*Employees of the University

**PhD/Postdoc students

***External docents

non-permanent positions, support by
University, SNF, private grants etc.

not employees of the University

K. Reports / Contributions from External Docents

K. 1. K. Eichler

K.1.1 Activities

5. Jan	Grindelwald	New trends in the pharmaceutical industry
25. Mai	FMC Technology Symposium: Brüssel	
17. Juni	Cybernetical Congress der Mendeleyev Universität; Moskau	The future of processe modelling
18. Juni	BASF Symposium; Moskau	Qualitative evaluation of the top- bottom and tangential spray coating processes
24, September	Session Chairman beim 11. International Symposium on Microencapsulation, Basque University, Dept. of Pharmaceutical Technology, Vitoria, Spain.	Topic: Industrial Microencapsulation
29. September	Syntapharm Technology Symposium; Budapest	Qualitative evaluation of the top- bottom and tangential spray coating processes
10. Dezember	SciTech Center Mumbai, singular guest lecture; Mumbai	From Art to Science

K. 2. PD Dr. D. Giron

K.2.1 Activities

- **Participation** to the educative MSC Project: Kooperation UNI BS und FHBB im Bereich Life Sciences. September-December 2004

Symposium organization/scientific committee

- As Scientific comittee member, PhandTA8, eurostar-science, Ascona, September 2004
- As President of STK: joint meeting with EMPA, Dübendorf, 11 .11.04
- As Science and Technology member at Novartis: S&T day at Novartis, 26.11.04. Basel

Lectures

May 2003	STK-AFCAT Meeting	S. Garnier, M. Mutz and D. Giron, Study of crystallization of drug substances under solvent vapour atmospheres by microcalorimetry
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February 2004	Symposium Polymorphism in Crystals, invited lecture, American Chemical Society, ASCProspectives, Tampa, USA	Thermodynamic and kinetic aspects of solid phase transitions in pharmaceutical development
February 2004	Invited lecture, TA user meeting, San Antonio, USA	Combined thermoanalytical methods in pharmacy
March 2004	Invited lecture, Swiss Symposium on crystallization and precipitation, SCCP2004, ETH Zürich	Use of combined techniques for the determination of thermodynamic relationships between phases in pharmaceutical development
March 2004 (accepted for publication)	Invited lecture, LogP2004, The 3rd Lipophilicity Symposium, Zürich	Physicochemical characterisation of the solid state in drug development
June 2004	Invited lecture, Mettler TA user-meeting, Frankfurt	Anwendung von kombinierten thermoanalytischen Methoden-Von der Entwicklung bis zur Registrierung
September 2004	Key lecture, PhandTA8, Ascona	D.Giron, S. Monnier, M. Mutz and F. Stowasser “ Challenging analytical development for polyphasic new entities, case studies
October 2004	Invited lecture, TA User meeting, Turnhout, Belgium	Application of Thermal Analysis and Combined techniques in Pharmaceutical Development
October 2004,	Key lecture, Polymorphism&crystallization, IQPC conference, Frankfurt	Thermodynamic and kinetic factors to be considered in chemical development

Workshops, lectures at university

Januar 2004	Wahlpraktikum Pharma Institut, , Basel	Thermische Analyse
June 2004	Pharmaceutical University of Nancy	Le rôle de l'analytique dans le développement pharmaceutique des nouvelles substances actives
30.09, 6.10, 14.10 2004	Continuing Education Course organised by the Pharmaceutical Institutes Uni Basel-Uni Zurich. Lecture and Exercices	«Strategies and trends in pharmaceutical development and production », “Analytical development for active ingredients, salt form, polymorphism, stability, impurities”.
2.12.04	Chemical and Physical Institut (CPE), Lyon, Formation continue	Analyse thermique appliquée à la pharmacie

K.2.2 Publications

- D. Giron, M. Mutz and S. Garnier“*Solid state of pharmaceutical compounds*”, J. Therm. Anal. Calorim., (2004), 77, 709-747

Posters

- The uptake of solvents into drugs and their influence on the stability of polymorphs Sebastian Kaerger, Frank Stowasser, Stephanie Monnier, Michael Mutz, Danielle Giron, PhandT8, September 2004, Ascona
- Problems encountered in case of compounds having a low enantiotropic transition S. Monnier, T. Buser, P. Piechon, M. Bellus, D. Giron, PhandTA8, September 2004

Dissertation

Invited member of Jury (Examinateur) for the Ph D of A. Grandeury at the university of Rouen, 21 December 2004 about the crystallization mechanisms of supramolecular compounds.

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.

Dissertations

Completed Dissertation

- Susan Grange, University Basel Pharmacokinetic-pharmacodynamic modeling as a tool to extrapolate dose-effect relationships from animal to man. (Beginning 1996; End May 2004)
- Shiva Neysari, University Basel Characterization of the functional coupling and binding mode of Neuropeptide-Tyrosine (NPY) Y2 and Y5 receptors: Implications for their functional role (Beginning 2000; End June 2004)

K.3.1 Invited Speaker

Februar 19-20, 2004	APV Kurs 201, Basel	Arzneistoff-Disposition-Verteilung, Elimination
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K.3.2 External Courses

- Faculty Member in Workshop in Basic Pharmacokinetics, Dept. of Pharmacy, Univ. Manchester: Arosa July, 11 – 16, 2004

K.3.3 Research 2004

- 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

- “Physical Properties of Organic Particulate UV-Absorbers Used in Sunscreens: I. Determination of Particle Size with Fibre-Optic Quasi-Elastic Light Scattering (FOQELS), Disc Centrifugation, and Laser Diffraction”, B. Herzog, A. Katzenstein, K. Quass, A. Stehlin, H. Luther, J. Colloid Interface Sci., **271**, 136 – 144 (2004)
- “Prediction of Sun Protection Factors and UVA Parameters by Using a Calibrated Step Film Model”, B. Herzog, S. Mongiat, K. Quass, C. Deshayes, J. Pharm. Sc. **93**, 1780 – 1795 (2004)
- “Physical Properties of Organic Particulate UV-Absorbers Used in Sunscreens: II. UV-Attenuating Efficiency as Function of Particle Size”, B. Herzog, K. Quass, E. Schmidt, S. Müller, H. Luther, J. Colloid Interface Sci., **276**, 354 - 363 (2004)
- “New UV Absorbers for Cosmetic Sunscreens – A Breakthrough for the Photoprotection of Human Skin”, B. Herzog, D. Hüglin, E. Borsos, A. Stehlin, H. Luther, Chimia **58**, 554 – 559 (2004)
- “Models for prediction of sun protection factors and UVA parameters as screening tools in the development of sunscreen formulations”, B. Herzog, Proc. 23rd IFSCC Congress, Orlando 2004
- “A new method to determine the particle size of microfine organic sunscreen actives”, S. Müller, B. Herzog T. Ehlis, Proc. 23rd IFSCC Congress, Orlando 2004
- “Microfine organic particles – a new class of UV absorbers”, Stefan Müller, Marcel Schnyder, Werner Baschong, Bernd Herzog, Uli Osterwalder, Proc. SCCJ, Tokyo 2004

K.4.2 Vorträge:

June 2004	Pharmaceutical University of Nancy	Le rôle de l'analytique dans le développement pharmaceutique des nouvelles substances actives
2004 U. Osterwalder, S. Mongiat, B. Herzog	AAD Washington (poster)	In vitro and in vivo assessment of UVA protection of sunscreens with traditional actives ZnO, Avobenzone, and new UV absorbers MBBT and BEMT
2004 Sao Paulo, Brasil U. Osterwalder and B. Herzog	Condgresso Nacional de Cosmetologia, (oral presentation)	Photostable broad-spectrum protection – discussion of the current in vivo and in vitro assessment tools

2004 Orlando B. Herzog	23 rd IFSCC Congress (poster)	Models for prediction of sun protection factors and UVA parameters as screening tools in the development of sunscreen formulations
2004 Orlando S. Müller B. Herzog T. Ehlis	23 rd IFSCC Congress (poster)	A new method to determine the particle size of microfine organic sunscreen actives
22.7.-24.7. 2004 Zurich, U. Osterwalder, B. Herzog, W. Baschong	Skin Cancer Zurich Skin Cancer Congress, (oral presentation)	New sunscreen actives for broad-spectrum UV protection
25.10.2004 Japan, S. Müller, M. Schnyder, W. Baschong, B. Herzog, U. Osterwalder	Society of Cosmetic Chemists in Japan SCCJ. Annual Meeting (oral presentation)	Microfine organic particles – a new class of UV absorbers
2004 Tokyo, Stefan Müller, Marcel Schnyder, Werner Baschong, Bernd Herzog, Uli Osterwalder	SCCJ, Tokyo (oral presentation)	Microfine organic particles – a new class of UV absorbers

K.4.3 Ehrung

Auszeichnung mit dem Sandmeyer-Preis der Schweizer Chemischen Gesellschaft im März 2004 für Beiträge zur Entwicklung neuer UV-Absorber für den kosmetischen Sonnenschutz.

K. 5. PD Dr. Peter van Hoogevest

K.5.1 Activities

Lectures

September 3 and 4 , 2004	at the Lehrstuhl für Pharmazeutische Technologie of the Friedrich-Schiller- Universität Jena at Jena, FRG	Status liposomaler Produkte Anno 2004
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K.5.2 Publication 2004

- H. Tiemessen, P. van Hoogevest, M. L.S. Leigh, Characteristics of a novel phospholipid-based depot injectable technology for poorly water-soluble drugs, Eur. J. Pharm. Biopharm. 58 (2004) 587–593

K. 6. PD Dr. Stephan Marrer

K.6.1 Contributions to research and teaching

PD Stephan Marrer, PhD, responsible for Strategy and Asset Management at F. Hoffmann-La Roche Ltd, Basel, was teaching Quality Management topics. 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

Russell	Frauke	Near-infrared Transmission Spectroscopy – a fast and non-destructive method for dissolution testing of solid dosage forms	F. Hoffmann-La Roche Ltd
Rehorik	Lars	Process modelling as a tool to indicate quality aspects in the pharmaceutical production	F. Hoffmann-La Roche Ltd

K. 7. PD Dr. Michel Ulmschneider

K.7.1 Activities

Oral Communications

February 2004	Doktorandenkolloquium Uni Basel, Basel	F. Russel, Dissolution testing and near-infrared spectroscopy: an alternative approach
March 2004	AAPS Workshop on Dissolution, Washington D.C.	F. Russel, Dissolution testing by means of NIR transmittance spectroscopy
October 2004	EUFEPS Conference 2004, Brussels	M. Ulmschneider, Applications in drug product development
November 2004	IIR Conference on Process Analytical Technologies, Dublin	M. Ulmschneider, Industry case study two. Process understanding, the ethos of PAT
November 2004	Barnett International Conference on Bioavailability/Bioequivalence/Dissolution, Brüssel	F. Russel, NIR spectroscopy of intact tablets: an alternative to the USP method?
Dezember 2004	APV-Dissolution-Workshop für Fortgeschrittene, Nürnberg	F. Russel, Zerstörungsfreie Bestimmung der Dissolution mittels NIR Spektroskopie

Posters

- Genetic algorithms for wavelength selection. F. Russell, Y. Roggo, M. Ulmschneider, H. Leuenberger. Pharmaday 2004. Basel (January 2004).
- Méthodes chimiométriques pour l'imagerie infrarouge. Y. Roggo, P. Chalus, C. Roeseler, M. Ulmschneider. Forum Labo 2004. Paris (March 2004).
- Importance de la préparation des échantillons pour le dosage de principe actifs dans des comprimés par spectroscopie proche infrarouge. P. Chalus, Y. Roggo, C. Roeseler, M. Ulmschneider. Forum Labo 2004. Paris (March 2004).
- Determination of active content in intact tablets by near infrared spectroscopy: chemometric optimization of the method. P. Chalus, Y. Roggo, M. Ulmschneider. Chemometrics in Analytical Chemistry 2004. Lisbon (September 2004).
- Chemometric and spectral imaging for quality control of pharmaceutical products. Y. Roggo, P. Chalus, C. Roeseler, M. Ulmschneider. Chemometrics in Analytical Chemistry 2004. Lisbon (2004).
- Influence of sample preparation on dosage of active content in tablets with near infrared spectroscopy. P. Chalus, Y. Roggo, C. Roeseler, M. Ulmschneider. Chemometrics in Analytical Chemistry 2004. Lisbon (2004).
- Dissolution testing by NIR spectroscopy: a comparison between diffuse reflectance and transmittance measurements. F. Russell, M. Ulmschneider, H. Leuenberger, EUFEPS2004, Brüssel (October 2004)

- Détermination de la teneur en principe actif dans des comprimés à faible dosage par spectroscopie proche infrarouge. P. Chalus, Y. Roggo, C. Roeseler, M. Ulmschneider. Symposium jeunes chimistes. Dijon (October 2004).
- Infrared imaging and chemometrics for qualitative analysis of pharmaceutical solid forms. Y. Roggo, A. Edmond, P. Chalus, M. Ulmschneider. Chimiométrie 2004. Paris (December 2004).

K.7.2 Publications

Peer Review Articles

- Chimiométrie appliquée à la spectroscopie proche infrarouge: methodes pour l'analyse quantitative. Y. Roggo, A. Edmond, M. Ulmschneider. Spectra Analyse, 33, 18-22, 2004.
- Near infrared spectroscopy for qualitative comparison of pharmaceutical batches. Y. Roggo, C. Roeseler, M. Ulmschneider. Journal of Pharmaceutical and Biomedical Analysis, 36, 777-786, 2004.

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.



Basel, February, 2005

Prof. Dr. H. Leuenberger