June 13, 2009
Stresa, italy

Charlotte Kloft

New Approaches in Pharmacy Education – German view

Charlotte Kloft
Martin-Luther-Universitaet Halle-Wittenberg
Institute of Pharmacy
Dept. Clinical Pharmacy
charlotte.kloft@pharmazie.uni-halle.de
www.klinische-pharmazie.eu
www.pharmacometrics.de

CLINICAL PHARMACY

7th Symposium on New Developments in Clinical Pharmacy and Clinical Pharmacology
Stresa, 13 June 2009

Current global status and views

nature publishing group
CLINICAL PHARMACOLOGY & THERAPEUTICS | VOLUME 82 NUMBER 1 | JULY 2007
EDUCATION
103

Time for Quantitative Clinical Pharmacology: A Proposal for a Pharmacometrics Curriculum

N Holford[1] and MO Karlsson[2]

PROPOSAL

A central theme of our proposal relates to the need to consider *time*. Time is an essential component of almost all descriptions of drug actions in clinical trials. We explore how much time is needed to learn pharmacometrics, and at what times it could fit into the undergraduate, postgraduate, and postdoctoral training sequence. Finally, we propose that the time is upon us for renewed efforts in pharmacometric training.

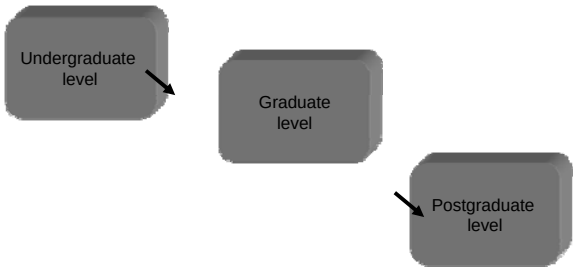
Pharmacometrics at FDA: Evolution and Impact on Decisions

JR Powell[1] and IVS Gobburu[2]

- *Training*: Currently, there are limited academic programs in the US and Europe training pharmacometricians. Many of the people performing this work have prior quantitative skills (e.g., pharmacokinetics, statistics, engineering) and are trained on the job. Within 5 years, there will be a demand for 25-50 trained pharmacometricians per year.

New Approaches in Pharmacy Education – German view

Pharmacometrics curriculum



www.pharmacometrics.de

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, italy

Charlotte Kloft

New Approaches in Pharmacy Education – German view

Motivation

- Pharmacometrics & computational disease modelling (PM & CDM)
  - **highly interdisciplinary field:** underlying biological/pharmaco-logical/pharmaceutical and disease mechanisms and the formal mathematical methods
  - gaining **increasing attraction**
- In Germany, qualifying in PM & CDM: **difficult to master for a PhD student** (interdisciplinary character, lack of a curriculum)
- At the same time: **high demand for thoroughly trained young scientists**
  ➔ boost field in academia as well as in pharmaceutical companies

www.pharmacometrics.de

New Approaches in Pharmacy Education – German view

A long way to go ...

2004/05:	First **ideas**
Sep 2006:	Concrete **initiative paper**
Jan-Dec 2007:	Negotiations about **Contract between 8 partners**
▪	How to deal with Results/IP and publications
▪	Location of PhD students
▪	Role and involvement of Industry Partners
Mar 2008:	**Start** of Graduate Research Training Program

www.pharmacometrics.de

Launch of a Graduate Research Training Program in Germany

"Pharmacometrics & Computational Disease Modelling" (PharMetrX)

Charlotte Kloft, Wilhelm Huisinga
(Chairs)

Martin-Luther-Universitaet Halle-Wittenberg,
Dept Clinical Pharmacy, Halle, Germany
Hamilton Institute/NUIM, Ireland & MATHEON/
Freie Universitaet Berlin, Germany

www.pharmacometrics.de

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, italy

Charlotte Kloft

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Partners and Boards

Steering Board

Academic Partners

- **Charlotte Kloft**, MLU Halle-Wittenberg
- **Wilhelm Huisinga**, Hamilton Institute/NUIM, MATHEON/FU Berlin

Industry Partners

- **Abbott** GmbH & Co. KG
- **Bayer Schering Pharma** AG
- **Bayer Technology Services** GmbH
- **Boehringer Ingelheim** Pharma GmbH & Co. KG
- **Merck** KGaA
- **Sanofi-Aventis** Deutschland GmbH

Extended Steering Board (2+2)

www.pharmacometrics.de

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Aims

- Train junior scientists in *Pharmacometrics & computational disease modelling (PM & CDM)*
- Convey method and software expertise
- Implement *PM & CDM* in the academic environment
- Promote *PM & CDM* within and outside academia and bridging the gap between academia and industry

www.pharmacometrics.de

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, italy

Charlotte Kloft

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Realisation

3 year PhD program:

1. Research Projects of PhD student
   - Generic/methodological topics
   - Motivated by theoretical or industrial considerations
2. Research Training: Module Curriculum
3. Mentoring by an Industry Partner

www.pharmacometrics.de

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Structured research training curriculum

1. Academic modules
   - 30 h en bloc (1 week)
   - subdivided into
     i) theoretical concepts & methods (2/3) and
     ii) practical hands-on exercises (1/3)
2. Industry modules
   - variable duration
   - at site/s of companies

www.pharmacometrics.de

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Se-mester	Research training modules			Research
1st	**A-module 1**: PK/PD modelling	**A-module 2:** PBPK modelling	**I-module 1:** Drug discovery/ development *(1 wk)*	**Continous work in research project for PhD thesis**
2nd	**A-module 3:** Population analysis	**A-module 4:** Systems Biology	**I-module 2:** Internship *(1+ wk)*	
3rd	**A-module 5**: Stats & data analysis			
4th		**A-module 7:** Pharmacology		
5th	**A-module 6:** Biometrics &Trial designs/simulation			
6th				

(a) during 1st - 4th semester at Host University

www.pharmacometrics.de

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, italy

Charlotte Kloft

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Structured research training curriculum

1. Academic modules
   - Introduce to the field: framework, theoretical concepts and methodology
   - Method and software expertise
   - Illustrative examples of relevance to drug development and use
2. Industry modules
   - Insight into the mission and tasks of pharmaceutical companies
   - Learn about fields of application of modelling approaches
   - Learn about the value chain of drug discovery and development

www.pharmacometrics.de

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Attractiveness to graduate students

The new program offers graduate students a

- unique opportunity to experience research in drug development and optimising drug therapy
- close link and strong interaction within academia and industry
- a competitive research fellowship

- Online-application process

www.pharmacometrics.de

Pharmacometrics & Computational Disease Modelling

Graduate Research Training Program

Key Characteristics of the PharMetrX Program

- Thematic orientation in a promising, expanding area
- **Trans-disciplinary** approach
- Close **partnership** and **strong link** with **Pharma Industry**

Outlook & Perspectives

- Continuous monitoring and evaluation process
- Integration and expansion of international **Faculty Network**
- **Integration** of new partners, **exchange** with and **linkage** to other programs (internationally)

www.pharmacometrics.de

7th Symposium
New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, italy

Charlotte Kloft

7th Symposium
New Developments in Clinical Pharmacy
and Clinical Pharmacology