Education and Training of a Regulatory Science Workforce – European Initiatives

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Agenda

• Bologna Title and Credit System: Postgraduate Training

• Innovative Medicines Initiative IMI Training Excellence Programmes

• Pharmatrain European Training Platform in Pharmaceutical Medicine/Drug Development Sciences

• Specific Courses
Curricula within the Bologna System

University Training
Bachelor 180 ECTS
Master 90-120 ECTS

Diploma of Advanced Studies DAS
30 ECTS

Master of Advanced Studies MAS
60 - 90 ECTS

MD
MSc

PhD Programme

GRADUATE EDUCATION
POSTGRADUATE EDUCATION
Bologna Process

• June 1998: Declaration of Bologna Official process of harmonisation for higher education in Europe

• Pan-European comparable degrees: Bachelor and Master title

• ECTS: European Credit Transfer and Accumulation System
  Transparent comparison of content and level of education programmes

➤ Aim: to facilitate mobility and to collect ECTS credits at any European University
Bologna Process cont.

• Common quality assurance standards

• Lifelong learning:
  Linking undergraduate, graduate and postgraduate education and training
  plus CPD, Continuing Professional Development and working experience

➢ Collaboration of Academia (Training) and Industry, Authorities (Employers) => IMI
Innovative Medicines Initiative IMI

- Is a joint undertaking and a public private partnership between

  EU, European Commission
  European Universities & public organisations

  and

  EFPIA, European Federation of Pharmaceutical Industries Association

  partnering with

  Academia, Regulatory Agencies
Bottlenecks R&D Process

Discovery Research
Predictive pharmacology

Preclinical Develop.
Predictive toxicology

Translational Medicine
Identification of biomarkers

Clinical Develop.
Patient recruitment

Pharmacovigilance
Validation of biomarkers

Benefit/Risk assessment with regulatory authorities

Knowledge Management

Education & Training

Efficacy

Safety
Four Research Pillars of IMI

1. Improving the Predictivity of Safety Evaluation
2. Improving the Predictivity of Efficacy Evaluation
3. Closing the gap in Education and Training
4. Closing the gap in Knowledge Management
Education and Training Platform

Integrated drug development

Medicines Development

Quality
Non Clinical

Clinical
development
Investigators
Monitors
Regulatory
Four E &T Programmes

- European Medicines Research Training Network – EMTrain
- European Modular Education and Training Programme in Safety Sciences for Medicine – SafeSciMET
- Pharmaceutical Medicine Training Programme – PharmaTrain
- European programme of Pharmacovigilance and Pharmacoepidemiology – Eu2P
PharmaTrain

25 Partner Universities, 13 learned Societies and 15 EFPIA Companies coordinated by ECPM

Project started May 1, 2009
First steps
- Harmonise syllabus for training
- Harmonise teaching and examination standards
Postgraduate Three Tier Process

Base-Courses

Extension Modules

Work-Project
- Thesis (10 ECTS)
- Electives
- (Research) Project

Molecule to Marketplace

30 ECTS Knowledge
60 ECTS Expertise
90 ECTS Competence

CPD
Lifelong learning
Master in Regulatory Affairs

Pharmaceutical Regulatory Affairs

A new Master of Advanced Studies Programme developed by experts from industry, health authorities and Universities and jointly offered by Universities Basel, Copenhagen and London, King’s College Partners within IMI PharmaTrain
Modular Training Platform:

- ECPM Course
- Master Programme MDDS
- Continuing Education
  - choice of modules or courses according to training needs
  - e-learning (closed user group for participants)

At the University of Basel
In the past ten ECPM Course cycles a total of 1243 participants from 31 countries have been trained.

Including the current course cycle of 147 participants it will add up to 1390 integrated drug developer.

The ECPM faculty consists of about 130 members from different universities, representatives from the pharmaceutical industry and other European and overseas experts, including representatives from regulatory authorities.
Thank you

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