



Standards for Course Recognition and SMD Certification

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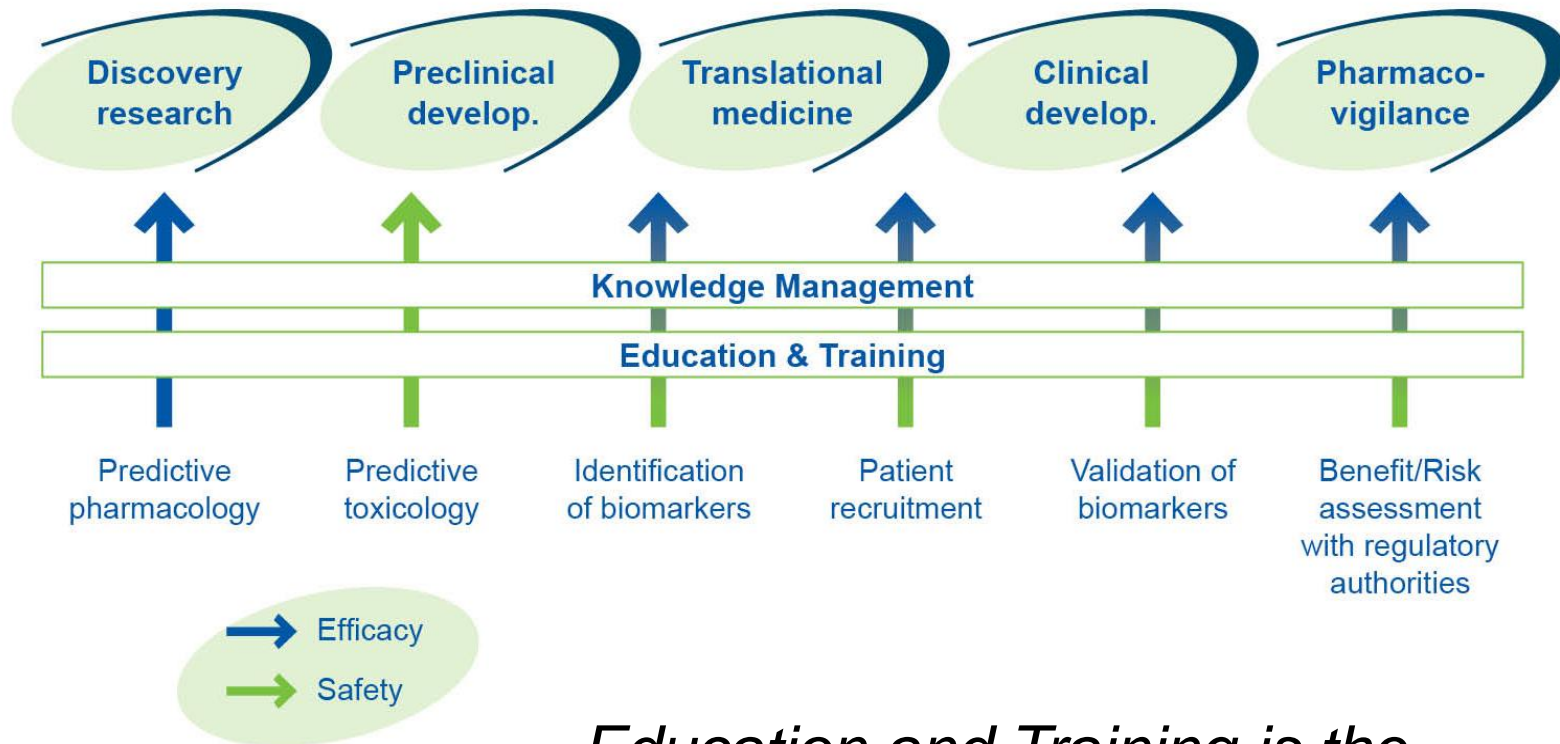
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Innovative Medicines Initiative



Strategic Research Agenda



Education and Training is the foundation for the entire value chain



IMI Education and Training Projects



European Medicines Research Training Network



Pharmaceutical Medicine Training Programmes



European Modular Education and Training Programme
in Safety Sciences for Medicines



IMI Education Training Programmes



- 5-year projects – establishing flexible, modular courses
- Mutual recognition of modules enhances mobility
- Multiple levels from single modules to Masters/PhD
- Shared quality standards and course recognition
- Initiatives to date:
 - Pharmaceutical Medicine/Medicines Development
 - Advanced Safety Sciences for Medicines
 - Pharmacovigilance and Pharmacoepidemiology
 - An Extensive Course Catalogue
 - European Framework towards Continuing Professional Development (CPD)
 - Training, education and information of patients and the public



PharmaTrain Consortium

- EFCPM = European Federation of Courses in Pharmaceutical Medicine (nearly all European universities offering PM Diploma or Master Courses)
- IFAPP
- Additional universities like Copenhagen, Freiburg, Strasbourg, etc.
- Learned societies like EUFEPS, Faculty of Pharmaceutical Medicine, EFGCP, DIA, EORTC, etc.
- 15 pharma companies

Global University Membership Network 2014

University of Newcastle
Trinity College, Dublin
Hibernia College, Dublin

Cardiff University, UK
Kings' College, London
Semmelweis-University
Budapest & CEMDC
University of Milano-
Bicocca
Catholic University of
Rome

University of Copenhagen
 University Hospital of Freiburg i.Br.
 University of Strasbourg
University of Basel
Université Libre de Bruxelles

University of Duisburg-
Essen
University Claude Bernard
Lyon
University of Lausanne
Moscow University

University of Aveiro, Portugal
University of Barcelona

UCSF San Francisco
and at Washington DC
São Paulo
Buenos Aires
Mexico

Peking University
University of Osaka
Yonsei University, Seoul
University of Fudan, Shanghai
University of New South Wales, Sidney
Manipal University, Jaipur

University of Vienna
University of Tel Aviv
University of Belgrade
University of Stellenbosch

Remarks

- Red** Centres of Excellence (12)
- Bold** European University Core Partners (23)
CEMDC Universities (+11)
- Membership based on a Memorandum of Understanding (7)
- Italic** Centres with documented interest

PharmaTrain's Pharmaceutical Medicine Work Plan

Step 1:

To establish a Europe-wide network of university course providers in Pharmaceutical Medicine and global “Affiliate” course providers

Step 2:

To develop shared standards for Diploma/Master courses involving a common syllabus, learning outcomes, curriculum, examination process, assessed quality standards leading to “PharmaTrain Centre Recognition”

Step 3:

To develop a modular platform of modular courses, elective modules, eLearning modules, suitable for mutual recognition and CPD for cognitive competence development

Step 4:

To establish a concept for job-based competence development leading to professional certification of “SMD”

IMI PharmaTrain Project Objectives

- ★ To provide a comprehensive solution to training needs in all topics of pharmaceutical medicine / medicines development sciences for all professionals involved
- ★ To create (new) and integrate existing multi-modular programmes of advanced studies in pharmaceutical medicine / medicines development sciences leading to a postgraduate Diploma or Master of Science, based on the Bologna credit and title system with 30, respectively 60+ ECTS credits
- ★ To establish and offer a global post-graduate course recognition system
- ★ To establish the concept for on-the-job based competence development, leading to a “Specialist in Medicines Development” for physicians and non-physicians

PharmaTrain Federation's Global Role

Creation of a global quality environment in Pharmaceutical Medicine / Medicines Development Sciences through

- ★ Development and implementation of reliable standards for high-quality post-graduate education and training in all disciplines in Medicines Development

Training centres and course providers who offer Diploma Courses, Master Programmes as well as CPD Modules and individual training courses, quality assessed and recognised by PharmaTrain Federation, support and are part of the global course quality environment defined and promoted by PharmaTrain Federation and IFAPP

- ★ Development and implementation of the post-graduate Specialist in Medicines Development (SMD) certification.

SMD is a competency-based, workplace-centred 4-year education & training certification programme in Medicines Development developed and implemented by PharmaTrain and IFAPP

PharmaTrain Course Recognition Awards

Outcome / Qualification	Syllabus Coverage	PharmaTrain Recognition Level	PharmaTrain Recognition Level Title
PhD MSc SMD PMST (incl: Pharmaceutical Medicine; Medicines Development Science; Related to PM)	N/A	1	PharmaTrain Centre of Excellence
Diploma in Pharmaceutical Medicine / Medicines Development Science PLUS Another Course / Module covering at least 1 Topic of PharmaTrain Syllabus	Full	2	PharmaTrain Centre of Excellence
Diploma or Master Course (any title) or 10+ Training Courses covering different topics	Section/s or Topic/s	2	PharmaTrain Centre
Individual Modules or Training Courses of at least 8 hours	Topic/s	3	PharmaTrain Course

From Syllabus (Vs 2.0) Topics to Modular Content Learning Outcomes and Competencies

Covering the entire medicines development process



160 topics



13 Syllabus Sections



6-12 module programmes (taught at master level)



6-10 Learning outcomes per module towards
Diploma/Master degree/Certificate
towards a set of cognitive competencies required
for Specialist title (vocational)



PharmaTrain Quality Criteria for Course Recognition

A formalised and transparent QA/QC policy

- 1 University accreditation OR a suitable system for approving, monitoring and reviewing the training offered
- 2 A system for ensuring quality of teaching staff
- 3 Regular review of the QA/QC processes

A set of documented criteria for individual modules, courses or course programmes

- 4 Defined and transparent admission criteria
- 5 A predefined set of teaching objectives, leading to defined learning outcomes
- 6 Adequate facilities, infrastructure, leadership and competences
- 7 Assessment of the trainees' achievement according to the learning outcomes
- 8 A system for collecting, assessing and addressing feedback
- 9 Adequate reference materials

PharmaTrain Quality Criteria for Course Recognition

Language requirements

English, as the global language of science, should be used for all PharmaTrain recognized courses, with exceptions listed below:

- ★ All materials / documents which are required for the evaluation of the courses must normally be available in English.
- ★ Presentation slides should be in English, except when referring to national laws.
- ★ Dissertations, theses, MCQs and all SOPs should be available in English for evaluation purposes.
- ★ The decision for the teaching language will be at the discretion of the lecturers, depending on the composition of the audience.
- ★ In courses which are more local in nature (e.g. Investigator training), local languages may be used for examinations and MCQs.
- ★ Websites promoting courses should be at least bilingual (English plus local languages).

PharmaTrain Centre Assessment Process

Recognition request by the centre

Preparation of documents and questionnaires

Nomination of 3 assessors

Preparation of the assessment visit

Assessment on-site

(1-2 assessors; 1-2 days, 1-2 remote assessors)

Assessment report with recommendation

Approval by the Executive Board PTF



PharmaTrain Course Assessment Process

Recognition request by the course provider
Preparation of documents and questionnaires

Nomination of 2 assessors
Preparation of the assessment visit

Assessment of submitted material by Lead Assessor
(discussion of outcome with second assessor)

Assessment report with recommendation
Approval by the Executive Board PTF



PharmaTrain Centre and Course Assessment Process

The Application Package Consists of:

- ★ Completed PharmaTrain Assessment Questionnaire;
- ★ CVs of the course director and key faculty members;
- ★ Detailed course programme including the agendas of the training day(s);
- ★ Course Manual / Documentation including syllabus, learning outcomes, selected presentation material, topics for exercises, and, if available, course works and assignments;
- ★ Description of the examination process and conditions with examples of questions / MCQs;
- ★ Documentation on student selection and feedback process.
- ★ In case of Higher Education academic title provisions examples of students' theses should be provided.

PharmaTrain Centre and Course Re-assessment Process

- ★ PharmaTrain Centre and Centre of Excellence recognition valid for 3 years
- ★ PharmaTrain Course recognition valid for 1 year
- ★ The re-assessment focuses on changes to the content and / or structure of the assessed courses as well as the infrastructure of the Centre as far as they affect the PharmaTrain Quality Criteria. The assessors also check whether necessary changes due to the development of the medicines development sciences have been adopted (e.g., updates of the Syllabus)
- ★ The Re-assessment package is identical to the original assessment package highlighting the changes
- ★ PharmaTrain Centres and Centres of Excellence are re-assessed by one on-site Lead Assessor and 2 remote assessors
- ★ PharmaTrain Courses are re-assessed by 1 assessor

Specialist in Medicines Development

- ★ The Specialist in Medicines Development (SMD) is a competency-based, workplace-centred 4-year education & training certification programme in Medicines Development, comprising a knowledge base covering the PharmaTrain Syllabus for Medicines Development, delivered & assessed through modular curricula, & the acquisition & demonstration of competencies for medicines development across 7 Domains of the competency curriculum
- ★ Physician & scientist participants in this mentored programme acquire knowledge & competencies within a framework of assessment, appraisal & annual review of progress & achievement
- ★ On completion, participants achieve SMD certification from the Global PharmaTrain Certification Board (gPCB) (Members from PharmaTrain and IFAPP)
- ★ SMD is renewable after participation in a 5-year CPD programme



SMD Concept

SMD award preconditions:

- ★ Completed Diploma or Master course in Pharmaceutical Medicine / Medicines Development (or Equivalent) from a PharmaTrain recognised course or a course approved by the gPCB
- ★ Competencies acquired in workplaces approved for SMD (Pharma Company, CRO, Competent Authority, Academia), supported by Mentor at workplace, supervised and appraised by PharmaTrain Regional Specialist Advisor
- ★ Demonstrated performance in at least 3 Domains of competence curriculum & evidence for assessed cognitive competency acquired in additional Modules or Courses to cover the remaining of the 7 Domains
- ★ Commitment to CPD with 250 working hours demonstrated learning in a 5-year period
- ★ gPCB decides on the award based on candidate's training record, Mentor Report, annual appraisals

The SMD Programme in Italy and Japan: Progress Made

- ★ PharmaTrain Federation received a very limited IMI Extension Programme Grant for 2 years to support the practical implementation of the SMD concept in Italy.
- ★ JAPhMed participated in the initiative without any financial support
- ★ Actual status:
 - ✓ Italy: the programme is formally implemented and the first candidates are currently recruited
 - ✓ Japan: the programme is formally implemented and the first candidate received the SMD Certificate at the Award Ceremony in Tokyo, September 2018, after successful completion of the programme
- ★ We look for further countries willing to introduce the SMD programme. The infrastructure on PharmaTrain's and IFAPP's side is available.

PharmaTrain Federation and IFAPP in Global Collaboration

THANK

YOU

FOR

YOUR

ATTENTION