Appendix 13.8 to
PharmaTrain Manual

Quality System

PharmaTrain

This is the PharmaTrain Quality System Version 1.0 (April 2014).

In the PharmaTrain Quality System and in all related PharmaTrain documents the terms “Medicines Development” and “Pharmaceutical Medicine” are used synonymously.

Content

1. Introduction and Overview

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1.1. Introduction

Quality is defined as a certain set of properties of a product. In this context products are defined as the deliverables of PharmaTrain (e.g. Learning Outcomes in Medicines Development, see List of products). The purpose of this Quality System is to describe the products of PharmaTrain and the quality review procedures these products have to undergo. It includes all factors which may have an impact on the quality of the products of PharmaTrain and outlines the measures which are implemented in order to guarantee the quality of those products. The Executive Board of PharmaTrain expects all members of PharmaTrain and external consultants to work according to these rules.

The Quality System describes the following processes and principles:

1.1.1. Definition of the criteria of the product to be created
1.1.2. Definition of process of ongoing development of these criteria and consequently the products
1.1.3. Definition of creation team and processes
1.1.4. Definition of how deviations are detected and person in charge of evaluation
1.1.5. Definition of person responsible for proposing and implementing corrective procedures
1.1.6. Definition of how the success of corrective measures is evaluated

Since PharmaTrain is an organization setting up the quality standards which are used to evaluate, recognize and certify certain activities or individuals, and defines the procedures how this should be done, it is mandatory to establish a hierarchy of quality management procedures.

The primary process is to define and maintain the quality of the PharmaTrain products. These products are listed under point 1.5 (List of PharmaTrain Deliverables) in this chapter. Examples of these products are the curriculum of Medicines Development, competencies of Specialists in Medicines Development, and the e-Quality Handbook guide. The primary task of this Quality System is to describe the criteria on which the creation of these products are based, and how their quality is assured and maintained.

The products of PharmaTrain, e.g. the course recognition criteria and procedures (PharmaTrain Manual, Appendices 13.8.1., 13.8.2., 13.8.3.), are then applied to perform a quality check of the products delivered by applicants for the PharmaTrain recognition. This is defined as the secondary process of quality assurance. However, this is not a quality measure of PharmaTrain itself but an evaluation whether other products, e.g. a course in Medicines Development, are complying with PharmaTrain quality standards. All documents related to this secondary process, i.e. the PharmaTrain Products, are part of the PharmaTrain Manual and will be referenced in the Quality System.

Chapter 1, Introduction and Overview of the Quality System, outlines the general features of the QMS in PharmaTrain and describes the PharmaTrain goals and the organizational set up to achieve these goals. It describes the products created and general aspects of responsibility, documentation and resources. In the following chapters the quality assurance of the PharmaTrain products are outlined.

1.2. General principles of the Quality System PharmaTrain

The Quality System is based on a set of standards which was outlined by the Cross Project Task Force on Course quality (1). This task force was set up by the four E&T projects of the Innovative Medicines Initiative [IMI]-(IMI EMTRAIN, IMI Eu2P, IMI PharmaTrain, IMI SafeSciMet). The quality standards set up by this group align with pan-European initiatives to harmonize course quality standards, both in higher education (the European Standards and Guidelines for Quality Assurance in the European Higher Education Area, 2), and in vocational education and training (European Quality Assurance Reference Framework to promote and monitor continuous improvement of national systems of vocational education and training, 3). The programmes developed by the four IMI E&T projects all follow the Bologna process (4)

These shared IMI quality standards are based on six principles:

1.2.1. Trainees are supported to acquire the necessary knowledge and skills
1.2.2. Course structures encourage exchange and multidisciplinary approaches. This principle is meant to stimulate geographical, and inter-sectorial mobility (e.g. between industry and academia), and encourages a translational approach e.g. applying skills learned in drug discovery to drug development or regulatory affairs
1.2.3. Facilities, infrastructure, leadership, and competences of the course providers are adequate to deliver the approved curriculum
1.2.4. Training is offered on the basis of equality principles. These principles endorse non-discrimination regardless of gender, racial or ethnic origin, religion or belief, disability, age or sexual orientation
1.2.5. Teaching methods are appropriate to the goals of the course
1.2.6. Transparency regarding potential conflicts of interest.

On the basis of these six principles, shared standards for course quality are developed:

(1) A formalized and transparent quality assurance/quality control policy that includes the following:
a. University accreditation (or equivalent) for approving, monitoring and reviewing the training offered
b. A system of quality assurance of the teaching staff
c. Regular review of the quality assurance /quality control process and demonstration that the training is further developed taking into account review findings

(2) A set of documented criteria for individual modules, courses or course programmes that include the following:
a. Defined and transparent admission criteria
b. A defined set of teaching objectives, with defined learning outcomes
c. The facilities, infrastructure, leadership, and competences available for the support of student learning should be adequate, appropriate and up to date for the training offered
d. Assessment of the students' achievement in accordance with the agreed learning outcomes of the training is offered
e. A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers

1.3. Description of PharmaTrain

The legal basis of PharmaTrain is the IMI structure within the 7th Framework of the European Commission based on the concept of public/private partnership. PharmaTrain is one of the educational projects. It started in 2009 and was planned for 5 years.

The organization of PharmaTrain is tailored in order to achieve the goals mentioned (see PharmaTrain Manual 3.1.). One of the goals of PharmaTrain is to implement quality standards for postgraduate education and training in Medicines Development. Training Centres, which offer Diploma Courses, Master Programmes and CPD Modules under the PharmaTrain project, share the PharmaTrain standards and are subject to its quality assessments.

The Target Product Profile of the 5-Year Programme is (Full Project Proposal, FPP, section 2.1):

Please note that PharmaTrain now uses the terms “Medicines Development” and “Pharmaceutical Medicine” synonymously.

- To foster the overall understanding and competence of professionals for the successful execution of integrated development and life-cycle managements of medicines, as examined following education and on-the-job training.
- To improve clinical research and drug development in Europe through training methods and programme content.
- To introduce, validate and sustain a dynamic learning and teaching process which defines and incorporates new training needs.
- To offer the possibility of high level career development in training courses blended with on-line programmes.
- To develop and implement modular training programmes using the drafted EFCPM (European Federation of Courses in Pharmaceutical Medicine, now PharmaTrain Federation) Syllabus for a number of University-based Base (Diploma) Courses (University Professional, 30-60 ECTS) and Master-level (‘Master of Advanced Studies’ (MDDS, MSc, 60-90 ECTS) as well as for other specialists including clinical investigators and those involved in clinical research practice - particularly study coordinators, data monitors and study nurses in Clinical Trial Units as well as Master level programmes e.g. for regulatory sciences.
- To identify needs and to build and implement new postgraduate Base (Diploma) Courses and Master-level training programmes in Medicines Development in Europe.
- To create a website containing information on all training-related activities in Pharmaceutical Medicine/Medicines Development in Europe with their curricula, structures, learning outcomes and qualifications.
- To produce and promote interactive e-learning programmes,
- To set, maintain and constantly improve the standards and quality management of training schemes and practices for pharmaceutical professionals at the competitively participating University PharmaTrain Centres of Excellence, which are developed during and accredited by the IMI-programme.
- To develop ‘Pharmaceutical Medicine as a European medical specialty. Pharmaceutical Medicine / Medicines Development as a specialty will continue to have a special commitment to the medicines development, regulation and safety processes.

- To help future medical doctors and related specialists in pharmaceutical medicine and drug development research in their careers, and to embed understanding of the relevance of pharmaceutical medicine and drug development in healthcare delivery.

For further information refer to FPP, section 2.1.

In order to achieve these goals an organizational structure as outlined in Fig. 6 of the FPP has been created. The Executive Board is the main decision-making body for the overall management of PharmaTrain. It is the initial arbitration board for any dispute amongst public and private participants that may emerge throughout the execution of the project. Decisions are taken by simple majority votes. Voting by proxy is possible (FFP 4.1.1.). For final arbitration and possible mediation an ombudsman, from outside the PharmaTrain, may be sought.

The ExBo can create Work Packages with appointed leaders for specific topics whose proposals and results are submitted to the ExBo for approval. The Work Packages may propose to create task forces for specific assignments which are usually limited in time.

The present membership of the ExBo is shown on the PharmaTrain website under Executive Board.

1.4. Abbreviations and definitions

CPD	Continuing Professional Development
CLIC	Clinical Trial Investigators Certificate
DCTP	Diploma for Clinical Trial Professionals
DMD	Diploma in Medicines Development
ECRIN	European Clinical Research Infrastructures Network
EMTRAIN	European Medicines Research Training Network
Eu2P	The European Programme in Pharmacovigilance and Pharmacoepidemiology
ExBo	Executive Board
F2F	Face to face
FPP	Full Project Proposal
HSeT	Health Science e Training (Foundation at the University of Lausanne, Switzerland)
IMI E&T	Innovative Medicines Initiative Education and Training
MCQ	Multiple Choice Question
MMD	Master of Medicines Development
MRA	Master of Regulatory Affairs
Quality System	Quality System PharmaTrain
QMS	Quality Management System
SafeSciMet	European Modular Education and Training Programme in Safety Sciences for Medicines
SMD	Specialist in Medicines Development
SMDWG	Specialist in Medicines Development Working Group
SPM	Specialist in Pharmaceutical Medicine
SOP	Standard Operating Procedure
WP	Work Package

1.5. PharmaTrain results

All products and procedures of PharmaTrain are subject to a rigorous quality management system:

- **Diploma in Medicines Development, DIMD**
- **Master of Medicines Development, MMD**
- **Master of Regulatory Affairs, MRA**
- **Continuing Professional Development, CPD Platform**
- **Complementary Modular e-Library**
- **Clinical Investigators Certificate, CLIC**
- **Diploma for Clinical Trial Professionals, DCTP**
- **Specialist in Medicines Development, SMD**

1.6. Responsibilities

The ExBo takes ultimate responsibility for the implementation, execution and ongoing adaptation of the Quality System PharmaTrain. Any member of PharmaTrain may propose changes in the Quality System. The ExBo may request WP8 to formulate a proposal for a change in the Quality System which has to be submitted to the ExBo, which makes the final decision on the proposal.

The ExBo decides whether certain procedures should be described as SOPs. It should then delegate the task of drafting these SOPs to the appropriate personnel inside or outside PharmaTrain, and grant final approvals.

The ExBo will initiate a review of the entire Quality System every three years. It may delegate this task to WP8 and request for a report on this subject.

1.7. Documentation

Documentation is an essential feature of a QMS. It is the responsibility of the managing unit (WP2) to keep track of the overall system of documentation. The preferred location of the essential documents is the PharmaTrain dedicated Website. WP2 will ensure that the latest versions of the documents are available to the members of PharmaTrain.

WP2 should design a system of documentation which allows for easy availability of the previous versions of all quality related documents, and of a historic archive of preceding versions together with the rationale for amendments. The SOPs should be written using specific templates, stating who has drafted the document, who has reviewed it and when it has been approved and put into effect, as well as the pertinent dates of these procedures together with the signatures of the colleagues involved. The ExBo is responsible for approval and implementation. The coordinator or the co-coordinator may sign on behalf of the ExBo.

1.8. Resources

The ExBo is responsible for providing the appropriate resources in order to set up and maintain the QMS.

2. Course Content Development

2.1. Quality principles

2.1. 1. Introduction

PharmaTrain devotes itself to setting appropriate standards in education and training in Medicines Development within the project. It provides assessment of the adherence to these standards by defining procedures which will allow for checking of compliance by course providers and individuals. The first step is to define the content of the PharmaTrain approved courses.

2.1.2. Definitions

The development of course content starts from defining the syllabus. The **syllabus** is a list of topics comprising a subject, discipline or specialty filed.

The syllabus serves as basis of the development of a curriculum. The **curriculum** is the guideline to transfer the content of the syllabus into modular structure and is a statement of the aims and objectives, content, experiences, outcomes and processes of a programme, including a description of the structure and expected methods of learning, teaching, feedback and supervision. The curriculum sets out what knowledge, skills, attitudes and behaviours the trainee will achieve.

Learning Outcomes are statements of what a trainee is expected to know, understand and/or be able to demonstrate after completion of a process of learning. Learning outcomes are the guiding principles for the development of the curriculum and each module, thus enabling potential mutual recognition between different institutions across Europe. They have been defined using Bloom's taxonomy (see Appendix 13.1. PharmaTrain Manual). Learning outcomes are an integral part of the curriculum. They are mapped to the syllabus.

Competency is defined as the "observable ability of any professional, integrating multiple components such as knowledge, skills, values and attitudes". Competency-based education is founded on competencies, or predefined abilities, as outcomes of the curriculum. The competencies are based on a thorough review and analysis of the core competencies published by academic groups and professional associations related to Pharmaceutical Medicine and Clinical Research. By an iterative process 7 domains and 60 competencies in Medicines Development were identified and mapped against the PharmaTrain Learning Outcomes and Curriculum. The term domain can be thought of as a category which comprises a certain array of activities e.g. medicines regulation (for more details see section 5).

(For further details see PharmaTrain Manual, section 2)

2.1.3. Criteria

The content of the PharmaTrain Courses are selected based on:

1) Knowledge and skills considered essential by pharmaceutical industry, CROs, biotech companies, regulatory authorities and academic organizations involved in medicines development
2) Scientific relevance
3) Relevance of medical needs
4) Regulatory requirements
5) Modular structure of the course content, as defined by the Bologna principles will be followed (4)

The experts defining the course content should have a high level of knowledge and skills of best practice and guidelines in Pharmaceutical Medicine/Medicines Development. This knowledge should be current as verified by fulfilling national requirements for continuing education where applicable. Where there are no national requirements available, the decision should be taken based on the curriculum vitae and the professional achievements of the potential expert

2.1.4. Responsibilities

The ExBo PharmaTrain decides on the need to develop the content of a course and assigns this task to an appropriate individual or group of experts.

2.1.5. Procedures for content development

2.1.5.1. The ExBo PharmaTrain assigns the task of compilation of the content of courses to the respective WP in charge of the topic (for schedule of responsibilities see PharmaTrain Manual). The WP may set up specific task forces and also invite external experts with special experience.

2.1.5.2. The WP defines the content according to the criteria mentioned in 2.1.3. The WP has to achieve a consensus regarding the specific content and submit it to the ExBo for approval.

2.1.5.3. The ExBo reviews the proposed content and approval decision is made based on the criteria shown in 2.1.3. In case of non-approval the proposal is sent back to the WP assigned with the task for re-work.

2.1.5.4. After approval, the ExBo arranges for the inclusion into the PharmaTrain Manual as presented on the PharmaTrain Website

2.1.6. Continuous updating

Since the scientific methods, the medical needs, the regulation of medicines development and the needs of pharmaceutical industry change over time the content of the PharmaTrain approved courses has to be adapted accordingly. There are two procedures in place:

2.1.6.1. Any member of PharmaTrain may at any time request an update of the content of a specific course with a clear rationale. This request is brought to the attention of the PharmaTrain ExBo which refers the topic to the respective WP. The WP in charge considers the request and, as appropriate, presents a proposal regarding the particular topic to ExBo PharmaTrain which takes the final decision. If approved, the update is developed and implemented by the WP, and included under the respective subject in the PharmaTrain Manual.

2.1.6.2. At regular intervals, at minimum every three years, WP8 will initiate a full revision of all documents mentioned in 2.1.2, present the results to the PharmaTrain. ExBo which takes the final decision. The approved changes are implemented in the PharmaTrain Manual and shown on the website.

2.2. Specific course contents

2.2.1. Diploma or Master degree in Medicines Development

Scope: The Diploma and Master degree programmes in Medicines Development provide a training platform to enhance the knowledge, expertise and skills needed to perform modern discovery, development and regulation of medicinal products. Comprehensive instruction for integrating cutting-edge concepts and best practices will foster the availability and appropriate use of medicines for the benefit of patients and society.

Responsibilities: The PharmaTrain ExBo assigns the task of defining and of developing the content of **Syllabus, Curriculum, Learning Outcomes and Competencies** of courses designed to obtain a Diploma or Master degree in Medicines Development to WP 3 (Harmonization of Syllabus and Training Principles). The current membership of Work Package 3 is shown on the PharmaTrain website.

These four topics have been approved by PharmaTrain and are described in Section 2 of the PharmaTrain Manual and outlined in Appendices 12.1, 12.2, 12.3.

2.2.2. Master of Regulatory Affairs

Scope: The development of an academic course leading to a Master of Regulatory Affairs (MRA) is one of the deliverables of PharmaTrain. In order to achieve this goal a MRA curriculum has been designed in accordance with the European Bologna agreement on mutual recognition amongst participating universities (University of Basel, University of Copenhagen, University of Hertfordshire and University of London King's College). Awarding of MRA is contingent upon achievement of 60 ECTS from 10 compulsory and 2 elective modules and the completion of a MSc dissertation. The objectives and the curriculum are shown in the PharmaTrain Manual under point 3.3 and in detail the curriculum and learning outcomes in Appendix 12.5.

Responsibilities: The programme of the MRA is developed by a committee whose members are listed on page 3 of Appendix 12.5 coordinated by representatives of the four universities (see page 3 Appendix 12.5). This curriculum has been approved by the PharmaTrain ExBo.

2.2.3. Clinical Investigators Certificate (CLIC and e-CLIC), Diploma for Clinical Trial Professionals

Scope: PharmaTrain is committed to improve Medicines Development. A crucial part of each medicines development programme is clinical research. Therefore it is of utmost importance to improve the education, training and career structure and opportunities for scientists involved in patient oriented research. The programme is described in a position paper: "A European Approach to Clinical Investigator Training" (PharmaTrain Manual, Appendix 12.6, V1.0). CLIC is based on a co-operation between PharmaTrain and ECRIN, and offers course content, learning outcomes, format, duration and procedures for course certification ("PharmaTrain stamp") as well as a format for examination and certification. It is planned to establish a network of academic course providers

who implement the CLIC programme as outlined (see PharmaTrain Manual, Appendix 12.6).
e-CLIC is an e-learning programme covering the content of CLIC based on a three level of competence structure similar to CLIC. The creation of this programme has been assigned by PharmaTrain ExBo to a joint committee of members of PharmaTrain and HSeT. e-CLIC can be accessed via the PharmaTrain website (e-directory).

The strategy for the investigatgor traing is based on the criteria outlined in 2.1.3, of the QMH.

Responsibilities: The PharmaTrain ExBo has assigned to the CLIC Advisory Board, respectively, the task of establishing the content, learning outcomes, format, duration of CLIC , the procedures for implementation of granting the “CLIC PharmaTrain recognition ” and for course providers the provision of CLIC certificates to trainees. The joint committee (PharmaTrain /HSeT) is responsible for the creation of e-CLIC. The PharmaTrain ExBo has to approve the results of both working parties. (see PharmaTrain Manual Appendix 12.6)

The content of the course leading to the Diploma for Clinical Trial Professionals (PharmaTrain Manual, Appendix. 12.7) has been developed according to the same criteria as mentioned in 2.1.3. QMH

3. Course delivery

3.1. Criteria

It is of utmost importance that delivery of courses follows the principles described in section (1), and the shared standards derived from them. Especially important aspects are:

- A formalized and transparent quality assurance policy
- Defined and transparent admission criteria of students
- A predefined set of learning outcomes based on the syllabus and curriculum
- The learning outcomes must be accompanied by appropriate assessment criteria in order to judge whether the expected learning outcomes have been achieved
- The teaching staff should have the ability and appropriate skills to teach the curriculum
- The teaching staff will transparently address potential conflicts of interest
- The facilities and infrastructure should be up to date
- A system for collecting, assessing and addressing feedback from students, teachers, and technical staff should be in place. Feedback should be collected with the aim of improving course quality
- Adherence to the content of the PharmaTrain approved and harmonized modules
- F2F teaching should be blended with e-learning

Responsibility and Process: The PharmaTrain ExBo has assigned the definition of quality criteria and the assessment of the course providers regarding quality assurance to WP8. WP 8 and WP2a have introduced a course and centre recognition process as described in Quality System chapter 6 and 8, see Appendix 13.5, 13.6).

3.2. E-Learning

3.2.1 Background

The principles are described under point 3.7 in the PharmaTrain Manual, see also Appendix 13.8.4.

3.2.2. Criteria

The criteria on which the selection of topics, material and authors is based are aligned to the PharmaTrain learning outcomes, respecting ethical principles in preclinical and clinical research, transparency of speaker's professional affiliation and address any conflict of interest, etc – see section Criteria 3.1 above.

In order to provide guidance for the production of e-Learning products a PharmaTrain E-Learning Products Development Guide has been compiled (see PharmaTrain Manual Appendix 13.2, V1.0).

Regarding specific quality standards a "Guideline for e-quality Standards and Processes" has been created which defines the quality criteria against which the products should be evaluated (Appendix 13.8.4).

3.2.3. Responsibilities

3.2.3.1. WP4 has been assigned the task to define the procedures described in the PharmaTrain E-Learning Products Development Guide of WP4 (for membership please see PharmaTrain website).

3.2.3.2. The PharmaTrain ExBo delegates the task of selecting appropriate topics, budgeting and planning and creation– mostly in cooperation with other institutions – and ensuring compliance with the PharmaTrain E-Learning Products Development Guide to WP4.

3.2.3.3. WP8 has been assigned the task to develop a specific e-Learning quality guide, the "Guideline for e-quality Standards and Processes". WP4 is responsible for compliance with this guideline.

3.2.3.4. The PharmaTrain ExBo makes the final decision on :

- Approval of the development of specific products for the PharmaTrain E-Learning section
- Approval of "Guideline for e-quality Standards and Processes"
- Selection of topic, coordinator and budget of the respective e-Learning modules
- Final approval of the e-Learning module

3.2.3.5. Continuous updating

For continuing updating the same rules apply as outlined under 2.1.6.

4. Examination and students assessment

4.1. Background

In chapter 4 of the PharmaTrain Manual the different types of examination and assessments are outlined.

4.2. Criteria

The general principles of assessing assignments and master theses are given in PharmaTrain Manual Chapter 4.

The main criteria to be followed by PharmaTrain regarding the quality of examinations are: being up to date, fit for purpose, robust, fair, and trusted to provide a consistent level of quality

According to these quality criteria standards for examinations are described in 'Good Examination Practices / PharmaTrain Manual, Appendix 13.3. The document defines the quality criteria regarding

- Selection of examiners
- Question setting
- Critical appraisal (e.g. appraising a published paper)
- Examination reliability

4.3. Responsibilities

PharmaTrain provides the principles for assessments and examinations only, since the details of each examination will be governed by the local university rules or national standards. The PharmaTrain ExBo assigns the task to define quality criteria for assessments and examinations to WP 7a, according to the criteria mentioned under section 4.2.

5. Centre and course recognition process

5.1. Assessment

The assessments of the courses are based on the Syllabus, Curriculum and Learning Outcomes described in section 1.1 of the Quality System PharmaTrain.

5.1.2. Criteria

The criteria are derived from the Shared Standards (see 1.2) and the Syllabus, Curriculum and Learning Outcomes described in chapter two of the PharmaTrain Manual as well as from Examinations Practices (chapter 4, PharmaTrain Manual).

5.1.3. Responsibilities

The PharmaTrain ExBo delegates WP8 with the responsibility to propose the criteria and procedures of the assessment of courses in Medicines Development.

5.1.4. Procedures

The principles of the assessment are given in chapter 6, 9 and 10 of the PharmaTrain Manual.

- Course Providers shall fulfil the Cross Project Course Quality Criteria. This is the prerequisite for all further QM and QA processes.
- Course Providers shall implement the PharmaTrain Syllabus, Curriculum incl. Modular Structure, Learning Outcomes and Assignments to become a PharmaTrain Centre. After having implemented these criteria Course Providers may call for Assessment 1.

- Providers of Master Programmes may apply to become a PharmaTrain Centre of Excellence. A Centre of Excellence must deliver a full master training programme as well as at least one additional relevant training activity.

5.1.5. Continuous update

WP8 and WP7a will check at regular intervals, at a minimum every three years, or on specific request of a member of PharmaTrain anytime (with clear rationale) whether the selection of criteria should be modified. It will submit the results of its considerations to the PharmaTrain ExBo which will take final decision. The approved changes will be implemented in the PharmaTrain Manual and shown on the PharmaTrain website.

5.2. Shared Standards

5.2.1. Scope

The aim of PharmaTrain is to certify academic courses in Pharmaceutical Medicine/Medicines Development for compliance with the standards set by PharmaTrain. Therefore PharmaTrain has developed a course approval procedure for these course providers.

5.2.2. Criteria

The criteria on which the procedures for evaluation of academic courses in Medicines Development are based are given in 5.1.2. The procedure should ensure that the assessment reliably checks the compliance of course content, course delivery and examination criteria with these standards.

5.2.3. Responsibilities

The PharmaTrain ExBo delegates WP8 with developing a course approval procedure.

5.2.4. Procedures

WP8 has drafted a proposal for the course approval procedure for endorsement by the PharmaTrain ExBo. This procedure is based on the documents cited in section 5.1.2. After approval of the procedures they are included in chapters 8 and 9 of the PharmaTrain Manual together with Appendix 13.8.1. (SOP 1: Implementation of shared standards), Appendix 13.8.2. (Checklist), Appendix 13.8.3 (Reporting template). These documents are on display on the PharmaTrain website.

5.2.5. Continuous update

Since the requirements for course quality may change over time, procedures for continuous revision of the approval procedure also have to be in place. The same procedures as outlined under section 2.1 are currently in place. The responsible body for proposal to the PharmaTrain ExBo is WP 8.

5.3. Approval of PharmaTrain Centres/Courses

5.3.1. Scope

This describes how the course assessment procedure will be performed

5.3.2. Criteria

The selection of the assessors is described in the PharmaTrain Manual (chapter 9). The task is to follow the course approval procedure in a fair and collegial manner.

5.3.3. Responsibilities

WP8 is responsible for organizing the recognition process from selection of the assessors to the submission of the report to the ExBo. WP2 is responsible for publishing the result of the granted acknowledgment on the PharmaTrain website.

5.3.4. Procedures

The assessors evaluate the course according to SOP 1 using the provided checklist (Appendix 13.8.2.). The result of their evaluation is submitted in writing to the PharmaTrain ExBo. The assessors submit their report including a recommendation regarding course acknowledgement. The ExBo will confirm final approval.

5.3.5. Reassessment

The recognition of courses should be re-evaluated every 5 years at a minimum. The procedures and final decision making are the same as previously described for the initial evaluation.

6. Specialist in Medicines Development

The PharmaTrain Specialist in Medicines Development (SMD) Award

6.1. Background

The overarching goal of PharmaTrain is to increase the competence of all professionals engaged in medicines development by improving existing education and training, and by the introduction of a Europe-wide platform of recognized education and training, and continuing professional development, meeting shared quality standards and with flexibility of conduct and mutual recognition of outcomes across the region. In order that the acquisition of the relevant competencies will be acknowledged and recognized, an award of PharmaTrain Specialist in Medicines Development (SMD) is to be introduced (see chapter 5 in PharmaTrain Manual).

6.2. Scope

This programme is aimed at colleagues with both medical and scientific (non-medical) educational background.

For non-medical colleagues, there exists no system for professional acknowledgment based on competencies in Europe. PharmaTrain offers procedures for recognition of competency-based Education & Training (PharmaTrain SMD Award).

For colleagues with a medical educational background seeking recognition as a Specialist in Pharmaceutical Medicine, a post-graduate competency-based programme has been introduced in Switzerland, UK and Ireland, leading to a Certificate of Completion of Training (CCT) or equivalent. Whilst PharmaTrain acknowledges the specialist

recognition established for medical colleagues in these countries, it will be up to other national medical and health authorities to establish pharmaceutical medicine as a medical specialty in their countries.
PharmaTrain will offer procedures for recognition of competency-based Education & Training incl. the work place (PharmaTrain SMD Certification) to allow for this to be initiated.

6.3. Criteria

The PharmaTrain Specialist in Medicines Development (SMD) Award and its recognition is based on competencies for Specialists in Medicines Development (PharmaTrain Manual, Appendix 12.8, 13.4)

6.4. Procedures

The procedures for education, certification and CPD for PharmaTrain Specialists in Medicines Development are outlined in the documents:

SMD Procedural Document, (see Appendix to PharmaTrain Manual, 12.8)
SMD Competencies Curriculum, (see Appendix to PharmaTrain Manual, 13.4)
SMD Governance document – A Guide to SMD Training (in preparation)

6.5. Responsibilities

The PharmaTrain ExBo has assigned the task of drafting the criteria and procedures for acknowledgement as PharmaTrain Specialist in Medicines Development to WP3, WP 7a and WP8, through a joint Working Group (SMDWG).

The PharmaTrain ExBo has to approve the results and outcomes of the SMDWG.

(It is possible that other IMI E&T projects and other organisations will join with PharmaTrain in this endeavour to introduce a competency-based professional certification.)

6.6. Continuous development:

Proposals for changes of the criteria and procedures for acknowledging PharmaTrain Specialists in Medicines Development may be put forward to the PharmaTrain ExBo by members of PharmaTrain anytime, with a clear rationale. These proposals are referred to WP3/WP7a/WP8 for evaluation. The proposal of WP3/WP7a/WP8 is then brought to the attention of the PharmaTrain ExBo which takes a decision.

At least every three years the PharmaTrain ExBo will request WP3/WP7a/WP8 for a thorough review of the respective criteria and procedures. WP3/WP7a/WP8 reports back to the PharmaTrain ExBo which will take decision on whether to approve the proposals.

7. CPD Platform

7.1. Background

Providing qualified educational offers for continuing professional development is one of the key commitments of PharmaTrain. Therefore, PharmaTrain has a procedure in place to evaluate and continuously monitor appropriate courses. This is achieved by the PharmaTrain integrated CPD Platform. The platform is described in chapter 6 of the PharmaTrain Manual.

7.2. Scope

In addition to the modules provided by partners in PharmaTrain, course providers of postgraduate training courses listed in the 'on-course' database maintained by EMTRAIN (www.on-course.eu), (see Appendices 13.5 and 13.6 to the PharmaTrain Manual) may apply for recognition - the "PharmaTrain flag". PharmaTrain together with EMTRAIN have provided appropriate tools on www.on-course.eu to allow short course and all CPD providers to initiate a review process by the PharmaTrain CPD assessment panel.

7.3. Criteria

The assessment panel will review all important elements utilizing the 9 IMI quality criteria and any additional information, to determine if the content of the offered modules complies with the PharmaTrain learning outcomes and shared standards.

7.4. Responsibilities

The ExBo PharmaTrain has delegated the granting of the PharmaTrain Recognition ("PharmaTrain flag") to a PharmaTrain CPD Platform Assessment Panel. This is a Cross Project Task Force comprising members of PharmaTrain WP1, WP2, WP3, WP4 and EMTRAIN with the task to evaluate if the PharmaTrain quality criteria have been met.

7.5. Procedures

The decision is taken by the panel based on the information collected by means of the PharmaTrain Flagging Request form (Appendix 13.6). The panel decides by majority voting of the members. The panel uses a collaborative website tool upon which the full information from the course providers can be uploaded. The course provider will receive a vote by the panel within a 6 weeks' timeframe. In case of a positive vote a PharmaTrain administrator will allow the flagging of the short course/CPD in 'on-course' database. Continuous updating of criteria and procedures will follow the rules outlined in 2.1.6.

7.6. Continuous Update

The PharmaTrain flag can be maintained for a period of 24 months. After that time the course provider has to resubmit the request.

8. References

1) Klech H, Brooksbank C, Price S et al.:
European initiative towards quality standards in education and training for discovery, development and use of medicines
European Journal of Pharmaceutical Sciences 2012; 45: 515 – 520

2) European Association for Quality Assurance in Higher Education, 2009. Standards and Guidelines for Quality Assurance in the European Higher Education Area

3) The European Parliament and the Council of the European Union, 2009
Recommendation of the European Parliament and of the Council on the Establishment of an European Credit System for Vocational Education and Training (ECVET)
Official Journal of the European Union, C155/11

4) Bologna process, Budapest- Vienna Declaration
http://www.ehea.info/news-details.aspx?ArticleId=59

5) Silva H, Stonier P, Buhler F et al.: Core competencies for pharmaceutical physicians and drug development scientists
Frontiers in Pharmacology 2013; 4: 1 – 8

9. Appendices

13.8.1. SOP for Implementation of Shared Standards
13.8.2. Checklist
13.8.3. Reporting Template
13.8.4. Guideline e-Quality Standards V 1.0
13.3. Good Examination Practices
13.5 CPD Recognition Process
13.6. PharmaTrain Flagging Request Form