Implementation of Shared Quality Standards for PharmaTrain Recognised Education and Training Programmes

This SOP refers to Chapter 9 of the Manual (V2.0): PharmaTrain Centre and Course Recognition, Appendix 13.8.1 to PharmaTrain Manual

Revision History of SOP 1

Version No:	Revision No:	Description of changes
1.0, May 31, 2011		
1.1, March 25, 2014	No 1	Adaptation for the final version of PharmaTrain Manual V2.0
1.2, July 04, 2017	No 2	Major revision: Adaptation to the new recognition procedure of PharmaTrain Centres and Courses by PharmaTrain Federation asbl

Approved by the PharmaTrain Federation asbl ExCo

Name:	Signature:	Date:
1. PharmaTrain Coordinator Ingrid Klingmann		April 2, 2014
2. PharmaTrain Federation asbl President Ingrid Klingmann		July 6, 2017
3. PharmaTrain Federation asbl Vice-President Gerfried Nell		July 6, 2017
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5. PharmaTrain Federation asbl Treasurer Heinrich Klech		July 6, 2017
6. PharmaTrain Federation asbl Secretary Peter Stonier		July 6, 2017

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2 History

PharmaTrain Federation is the not-for-profit organisation established during the IMI PharmaTrain project to enable sustainability of the project's outcomes following the end of its 5-year term in 2014. The IMI project's consortium members agreed that all outcomes of the project will be owned by PharmaTrain Federation. After the end of the project in 2014 all assets and members of the Federation under Swiss law were transferred to the PharmaTrain Federation asbl under Belgium law to ensure the Federation's ongoing support and funding opportunities under EU conditions. The PharmaTrain objectives of further developing and promoting shared quality standards in medicines development education and training remained unchanged.

3 Purpose

This Standard Operating Procedure (SOP) describes the Shared Quality Standards Implementation, Evaluation and Recognition Process (SQS-IP) for all education and training centres and courses covering all or at least one topic of the PharmaTrain Syllabus in Pharmaceutical Medicine / Medicines Development. Successful assessment can lead to three (3) potential outcomes:

- the **PharmaTrain Centre of Excellence Recognition**
- the **PharmaTrain Centre Recognition**
- the **PharmaTrain Course Recognition**

In addition to assessing and recognising educational programmes in all aspects of medicines development, a **regular Re-assessment process** – every three (3) years for 'PharmaTrain Centre' and 'PharmaTrain Centre of Excellence' recognition and every year for 'PharmaTrain Course' recognition – is an integral part of the maintenance of the PharmaTrain Shared Quality Standards.

4 Cross Project Course Quality Criteria

Course quality is based on the IMI Cross Project Shared Course Quality Criteria which were accepted by all four IMI Education and Training projects, EMTRAIN, PharmaTrain, SafeSciMet and EU2P. These criteria are summed up in the common term 'Shared Quality Standards' and have been published (**Klech H**, Brooksbank C, Price S, Verpillat P, Bühler FR, Dubois D, Haider N, Johnson C, Lindén HH, Payton T, Renn O & See W. **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*).

Principles of PharmaTrain Shared Quality Standards:

- Trainees are supported to acquire the necessary knowledge and skills
- Course structures encourage knowledge exchange and multi-disciplinarity
- Teaching methods are appropriate to the goals of the course
- Transparency is observed regarding potential conflicts of interest
- Equality and diversity principles apply throughout.

Academic and non-academic PharmaTrain Course providers must fulfil the 'PharmaTrain Shared Quality Standards' as a prerequisite for 'PharmaTrain Course', 'PharmaTrain Centre' or a 'PharmaTrain Centre of Excellence' recognition.

The nine (9) 'PharmaTrain Shared Quality Standards' for centres and courses are:

1. Recognised University accreditation or a system for approving, monitoring and reviewing the training offered.
2. Regular review of the QA / QC process and demonstration that the training is further developed in light of this review.
3. Quality assurance of teaching staff.
4. A system for collecting, assessing and addressing feedback from learners, teachers, technical & administrative staff, and programme / course / module leaders.
5. Availability of appropriate and regularly-reviewed reference material (e.g. published articles, links, book chapters, scripts).
6. Defined & transparent admission criteria.
7. A predefined set of teaching objectives, leading to defined Learning / Training Outcomes.

8. Adequate facilities, infrastructure, leadership and competences are available for the support of students' education and training (E & T).
9. Assessment of the students' achievement in accordance with the agreed Learning / Training Outcomes of the E&T offered.

5 Language Requirements for PharmaTrain Recognised Courses

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

1. All materials / documents which are required for the evaluation of the courses must normally be available in English.
2. Presentation slides should be in English, except when referring to national laws.
3. Dissertations, theses, MCQs and all SOPs should be available in English for evaluation purposes.
4. The decision for the teaching language will be at the discretion of the lecturers, depending on the composition of the audience.
5. In courses which are more local in nature (e.g. CLIC, level 1 or 2), local languages may be used for examinations and MCQs.
6. Websites promoting courses should be at least bilingual (English plus local languages).

6 Award Classification, Definitions and Requirements

Award Classification

- Recognition as PharmaTrain Centre
- Recognition as PharmaTrain Centre of Excellence
- Recognition as PharmaTrain Course

These awards are not an accreditation; this remains prerogative of national universities and agencies.

Definitions and Requirements

Principles:

a. In the following table 'Full' PharmaTrain Syllabus means all 14 Sections of the Syllabus are covered; 'Section/s' means one or more of the 14 sections are covered; 'Topic/s' means one or more sub-Sections of the Syllabus are covered.

b. PharmaTrain Centre Level Title depends on the E&T offering:
   i. Pharmaceutical Medicine Domains
   ii. Outcome / Qualification
   iii. Syllabus Section / Topic Coverage.

c. PharmaTrain Centre Recognition awards are for a 3-year term after which they must be renewed.

d. PharmaTrain Courses or modules as CPD Recognitions to be evaluated annually.

Table 1: Pharmaceutical Medicine / Medicines Development Science Domains in the PharmaTrain Recognition Process

Pharmaceutical Medicine / Medicines Development Science Domains	Syllabus Coverage	PharmaTrain Recognition Level	PharmaTrain Recognition Level Title
Pharmaceutical Medicine / Medicines Development Science MSc (without) and Diploma (with) additional course or Module	Full	1	PharmaTrain Centre of Excellence
Medicines Regulation	Section/s	2	PharmaTrain Centre
Drug Safety, PV & Risk Management	Section/s	2	PharmaTrain Centre
Non-Clinical Development Early Clinical Development Clinical Pharmacology CRO, CRU (Early Phase)	Section/s	2	PharmaTrain Centre
Clinical Development (Phase 2-4) Clinical Trials CRO, CRU (Late Phase)	Section/s	2	PharmaTrain Centre
Healthcare Marketplace Medical affairs. Ethics & Law Stats & Data Management	Section/s	2	PharmaTrain Centre
CLIC & Other PTF, IMI programme	Section/s	2	PharmaTrain Centre
Other topics	Section/s	2	PharmaTrain Centre

Table 2: Outcome/ Qualification of Centre and Course Assessment

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 (any title)	Section/s or Topic/s	2	PharmaTrain Centre
Inhouse Certificate Training Course	Topic/s	3	PharmaTrain Course

Course / Centre Recognition follows a pyramidal or consecutive process:

‘PharmaTrain Course’
All courses go through a PharmaTrain course recognition process. If they cover at least one PharmaTrain Syllabus Topic and fulfil the PharmaTrain Quality Criteria the applicant is awarded a:-

‘PharmaTrain Course’ recognition.

‘PharmaTrain Centre’
If the course is in addition a diploma or master course (any title) and covers all or at least one PharmaTrain Syllabus Topic, or a course provider offers a large range of courses that jointly cover many PharmaTrain Syllabus Topics, and fulfils PharmaTrain Quality Criteria the applicant is awarded a:-

‘PharmaTrain Centre’ recognition.

‘PharmaTrain Centre of Excellence’
a. If the course is a higher qualification course in Pharmaceutical Medicine / Medicines Development Science (PhD, MSc, SMD, PMST) irrespective of amount of syllabus covered and fulfils the PharmaTrain Quality Criteria the applicant is awarded a:-

‘PharmaTrain Centre of Excellence’ recognition.

b. If the course is a Diploma course in Pharmaceutical Medicine / Medicines Development Science and covers the full PharmaTrain Syllabus, fulfils the PharmaTrain Quality Criteria, AND there is an additional course or module covering at least one topic of the PharmaTrain Syllabus the applicant is awarded a:-

'PharmaTrain Centre of Excellence' recognition.

7 Procedure for PharmaTrain Centre and Course Recognition

To receive PharmaTrain awards, course providers, at their own discretion, call for assessment of their course or centre. They can also first call for coaching in order to set up their system in conformity with the PharmaTrain Manual Curriculum Standards and Programmes; this first helping hand does not have any elements of evaluation or assessment.

7.1 Call Process:

Coaching and Assessments are a **Call Process**. This means that the Centre Quality Officer, CQO **("local facilitator")** and / or the course director apply for assessment to the PharmaTrain Office. The PharmaTrain Office handles the interaction with the applicant until a complete submission package for assessment of the respective programme is available.

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.

7.2 'PharmaTrain Centre' and 'PharmaTrain Centre of Excellence' Assessment Process:

Once the completed assessment application package is submitted, the PharmaTrain Office and the Chair of the PharmaTrain Course Assessment Team appoint the three (3) members of the 'Assessment Panel' according to their expertise in the

respective scientific area, their language portfolio and availability. The Assessment Panel decides on their Lead Assessor and the Remote Assessor. Jointly, the submitted documentation is reviewed, formal checks of compliance with the PharmaTrain Syllabus in its current version, the Curriculum, Modularity, Learning Outcomes, assessed Assignments are made, omissions and / or insufficiencies are identified, the on-site course assessment strategy is defined, and a date for the 1-day assessment Visit to the course facilities by the two on-site assessors is agreed with the applicant.

The on-site Visit is expected to take a maximum of six (6) hours. It is appreciated if the on-site Visit can be organised in parallel with, i.e. during, already scheduled courses and teaching activities.

The on-site Visit contains a presentation from the course provider about the course and the centre's infrastructure and approach to training, and gives an opportunity for the two assessors to ask questions / clarify open issues from the pre-visit material reviews and from the on-site presentation.

The on-site assessors prepare the draft Assessment Report (Reporting Template Appendix 13.8.3.). Jointly, the three (3) members of the Assessment Panel discuss the results of the assessment and make an outcome proposal to the PharmaTrain Course Assessment Team. The recommendation from the PharmaTrain Course Assessment Team is approved by the PharmaTrain Executive Committee.

The possible outcomes are:

- Award granted
- Award granted upon conditions
- Award not granted

Depending on the assessed conditions presented in Table 2 the course provider can achieve:

- 'PharmaTrain Centre of Excellence' recognition
- 'PharmaTrain Centre' recognition
- 'PharmaTrain Course' recognition (if the conditions for 'Centre' recognition are not met)

The Final Assessment Report is signed by the Panel Lead Assessor and the PharmaTrain President, the Recognition Certificate by the Chair of the PharmaTrain Course Assessment Team and the PharmaTrain President.

As the final step, PharmaTrain Federation Office sends a letter to the course director in which the decision is communicated and the Certificate is attached.

7.3 'PharmaTrain Course' Assessment Process:

Once the completed assessment application package is submitted, the PharmaTrain Office and the Chair of the PharmaTrain Course Assessment Team appoint two (2) members of the PharmaTrain Course Assessment Team according to their expertise in the respective scientific area, their language portfolio and availability to form the Assessment Panel for this course. One of them is the Lead Assessor. He/she reviews the submitted material, compares it with the PharmaTrain quality and content requirements, identifies strengths, omissions and / or insufficiencies, and develops a recommendation. The two assessors discuss the findings and jointly formulate their recommendation to the PharmaTrain Course Assessment Team.

The 'PharmaTrain Course' Recognition is based upon:

a. fulfilment of the Shared Quality Standards, and
b. conformity of the submitted course Learning Outcomes with those of the PharmaTrain curriculum.

A 'PharmaTrain Course' should, as a minimum 'unit', cover one PharmaTrain Syllabus topic and be delivered as a 1-day course, i.e. 8 hours or equivalent (e.g., divided in 2 x 4-hour units). Additional units may be added.

The Lead Assessor prepares the draft Assessment Report (Reporting Template Appendix 13.8.4.), and makes an outcome proposal to the PharmaTrain Course Assessment Team. The recommendation from the PharmaTrain Course Assessment Team is approved by the PharmaTrain Executive Committee.

The possible outcomes are:

- Award granted
- Award granted upon conditions
- Award not granted

As presented in Table 2 the course provider can achieve

- 'PharmaTrain Course' recognition

The Final Assessment Report is signed by the Panel Lead Assessor and the PharmaTrain President, the Recognition Certificate by the Chair of the PharmaTrain Course Assessment Team and the PharmaTrain President.

As the final step, PharmaTrain Office sends a letter to the course director in which the decision is communicated and the Certificate is attached.

8 Re-assessment of PharmaTrain Awards

Re-assessment of the PharmaTrain award can occur for two (2) reasons:

a. Expansion of the course portfolio and therefore application for an award level increase
b. PharmaTrain awards are of limited duration (3 years for “Centre’ and “Centre of Excellence’ recognition, 1 year for ‘Course’ recognition) and require re-assessment to encourage and ensure ongoing quality improvement of education and training in pharmaceutical medicine / medicines development science.

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 ‘Cross Project Shared Quality Criteria’. The assessors will also check whether necessary changes due to the development of the medicines development sciences have been adopted (e.g., updates of the Syllabus).

8.1 Re-assessment of ‘PharmaTrain Centre’ and ‘PharmaTrain Centre of Excellence’ Recognition

PharmaTrain Office keeps track of the re-assessment schedule and reminds the ‘PharmaTrain Centres’ and ‘PharmaTrain Centres of Excellence’ of the timing of their upcoming re-assessment (usually 6 months prior to expiration of the award). The respective course director and the PharmaTrain Office arrange a suitable date for starting the re-assessment process.

In the request for re-assessment the course director specifies the changes that have occurred since the last assessment to all originally-submitted information and submits the new information.

Once the completed re-assessment application package is submitted, the PharmaTrain Office and the Chair of the PharmaTrain Course Assessment Team appoint the three (3) members of the Assessment Panel according to their expertise in the respective scientific area, their language portfolio and availability. The Assessment Panel decides on their Lead Assessor who will perform the on-site visit and on the two remote assessors. Jointly, the submitted documentation is reviewed, taking into account the PharmaTrain quality and content requirements and the former assessment results, strengths, omissions and / or insufficiencies are identified, the on-site course assessment strategy defined, and a date for the 1-day assessment visit to the course facilities by the Lead Assessor is agreed with the applicant.

The on-site Visit is expected to take a maximum of four (4) hours.
The on-site Visit contains a presentation from the course provider about the changes that have occurred, the Centre's current approach to training and an opportunity for the assessor to ask questions / clarify open issues from the pre-visit material review and the on-site presentation.

The Lead Assessor prepares the draft Re-assessment Report (Reporting Template Appendix 13.8.4.). Jointly, the three (3) panel assessors discuss the results of the re-assessment and make an outcome proposal to the PharmaTrain Course Assessment Team. The recommendation from the PharmaTrain Course Assessment Team is approved by the PharmaTrain Executive Committee.

The possible outcomes are:

- Award re-granted
- Award re-granted upon conditions
- Award not re-granted

Depending on the assessed conditions presented in Table 2 the course provider can achieve:

- 'PharmaTrain Centre of Excellence' recognition
- 'PharmaTrain Centre' recognition

The Final Re-assessment Report is signed by the panel Lead Assessor and the PharmaTrain President, the Recognition Certificate by the Chair of the PharmaTrain Course Assessment Team and the PharmaTrain President.

As the final step, PharmaTrain Office sends a letter to the course director in which the decision is communicated and the Certificate is attached.

Should the 'PharmaTrain Centre' announce or the re-assessment of the 'PharmaTrain Centre' reveal that the criteria for this award are no longer met, the course provider can apply for 'PharmaTrain Course' recognition for the respective course or another course.

8.2 Re-assessment of 'PharmaTrain Course' Recognition

PharmaTrain Office keeps track of the re-assessment schedule and reminds the 'PharmaTrain Course' provider of the timing of their upcoming re-assessment (usually 3 months prior to expiration of the award). The respective course director and the PharmaTrain Office arrange a suitable date for starting the Re-assessment process.

In the request for re-assessment, the course director specifies the changes that have occurred since the last assessment to all originally-submitted information and submits the new information.

Once the completed re-assessment application package is submitted, the PharmaTrain Office and the Chair of the PharmaTrain Course Assessment Team appoint one (1) Assessor according to his/her expertise in the respective scientific area, his/her language portfolio and availability. The Assessor reviews the submitted documentation, compares it with the PharmaTrain quality and content requirements and the former assessment results, identifies strengths, potential omissions and / or insufficiencies and prepares a Re-assessment Report (Reporting Template Appendix 13.8.5.) with his/her outcome recommendation. The recommendation is shared with the Chair of the PharmaTrain Course Assessment Team and the Re-assessment Report is submitted to the PharmaTrain Executive Committee for approval.

The possible outcomes are:

- Award re-granted
- Award re-granted upon conditions
- Award not re-granted

The course provider can achieve again:

- 'PharmaTrain Course' recognition

The Final Re-assessment Report is signed by the Assessor and the PharmaTrain President, the Recognition Certificate by the Chair of the PharmaTrain Course Assessment Team and the PharmaTrain President.

As the final step, PharmaTrain Office sends a letter to the course director in which the decision is communicated and the Certificate is attached.

Should the course provider substantially increase his portfolio of training courses covering many different PharmaTrain Syllabus topics the course provider can apply for 'PharmaTrain Centre' recognition.

9 Responsibilities

- Centre Quality Officer (CQO - Local Facilitator)
  - Owner and responsible for the local quality process
  - Local facilitator of the coaching / assessment process

- PharmaTrain Course Assessment Panel (Evaluator team)

  is composed of three (3) assessors from the PharmaTrain Course Assessment Team. They are assigned to the assessment according to their scientific area of expertise, language portfolio and availability. Two (2) assessors will visit the site for a first 'PharmaTrain Centre" assessment; one (1) assessor will visit for a re-assessment of a 'PharmaTrain Centre', with remaining two (2) assessors serving as remote assessors in the case of a re-assessment. Their joint task is to:

  – accompany and evaluate the Centres through the coaching and assessment process;
  – conduct coaching advice, 'PharmaTrain Centre' and 'Centre of Excellence' assessment visits and later Re-assessment visits;
  – prepare a visit report containing discussion of the findings, outcome of the assessment visit and suggestions for improvement where appropriate.

- Training Centre
  – develop and maintain QC checks for 'PharmaTrain Centre' or 'PharmaTrain Centre of Excellence' activities, share these with the Quality Assurance Officer and review input and feedback from the latter;
  – develop the quality assurance strategy and plan for the PharmaTrain course, respectively Centre assessment;
  – collect the evaluation and reporting of outcomes of Student's Feedback Forms;
  – prepare and distribute the Centre Feedback Reports and implement any resulting follow-up actions;
  – establish required local Quality Control Guidelines (SOPs) by tailoring the PharmaTrain template to local needs;
  – ensure Corrective and Preventive Actions (CAPAs) resulting from assessment activities which are addressed in a timely manner.

- PharmaTrain Course Assessment Team
  – maintain the PharmaTrain templates for the Assessment Questionnaires, the Students' Feedback Forms, the Final Assessment and the Final Re-assessment Reports and the PharmaTrain Quality Assurance documentation;
  – perform a review, critical assessment and thorough analysis of all Final Assessment and Re-assessment Reports;
  – prepare and share trend analysis of all Final Assessment and Re-assessment Reports to identify common areas of improvement as well as of reports on examination sessions and provide guidance on possible improvements;

- develop and maintain together with the Centre Quality Officer a suite of QC checks and ensure these are shared with all PharmaTrain Centres;
- track completion of CAPAs resulting from assessment activities;
- ensure sharing of learnings from the above activities with all PharmaTrain Centres;
- monitor compliance of PharmaTrain Centres with rules and requirements of Re-assessment and Examinations.

Related appendices:
Appendix 13.8.2, Checklist V1.0
Appendix 13.8.3, Final Report 'Centre' Recognition template, V1.1
Appendix 13.8.4, Final Report 'Course' Recognition template, V1.1
Appendix 13.8.5, Final Report 'Centre' Re-assessment recognition template, V1.1
Appendix 13.8.6, Final Report 'Course' Re-assessment recognition template, V1.1

This PharmaTrain SOP 1 V1.3 has been conceived by Gerfried Nell, Peter Stonier, Sam Salek, Heinrich Klech, and Ingrid Klingmann, PharmaTrain Federation asbl, July 04, 2017 and is at the same time appendix 13.8.1 of the PharmaTrain Manual V2.0.