SOP 1 Version No: 1.1	April 2, 2014 Revision No: 1

Assessment Process of Shared Quality Standards for IMI PharmaTrain Training Programmes

This SOP refers to Chapter 9 of the Manual (V2.0): PharmaTrain Centre Recognition

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

Approved by the PharmaTrain ExBo

Name:	Signature:	Date:
1. PharmaTrain Coordinator or Co-Coordinator		April 2, 2014
2.		
3.		

Purpose

These Standard Operating Procedures (SOP) describe the Shared Quality Standards Implementation and Evaluation Process (SQS-IP) for all IMI PharmaTrain education and training providing centres. It is a three step procedure (Fig. 2):

- Peer Coaching Site Visit
- the **PharmaTrain Centre Recognition** (Award 1). Most importantly, with this Award they are eligible for additional contribution via student's sponsorship in-kind by private industry partners as well as the PharmaTrain Student Support Fund.

– Recognised training centres can then apply for the Award 2 **PharmaTrain Centre of Excellence** if the Centre provides additional training programmes, in particular Clinical Investigator Course, CLIC.

In addition to approving, monitoring and reviewing programmes, a **regular Re-Assessment process** –every 3 years – is an integral part of the sustained longer-term implementation.

Course Quality is based on the IMI E&T Cross Project Quality Criteria, which are a pre-requisite for achieving the PharmaTrain recognition:

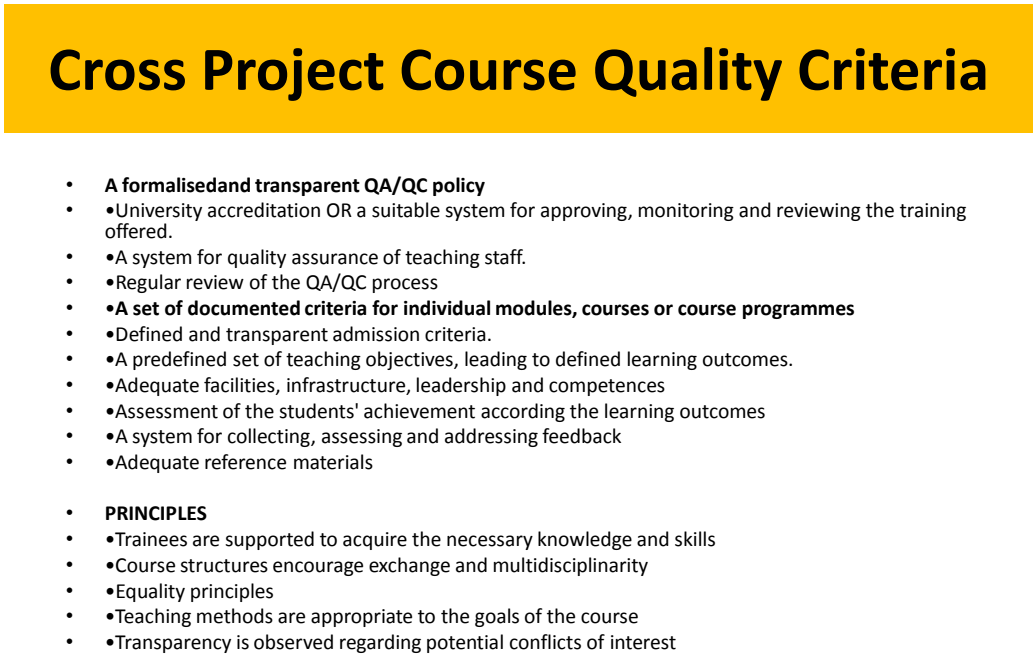

Fig 1: IMI E&T Quality Criteria

Procedure for PharmaTrain Course Recognition

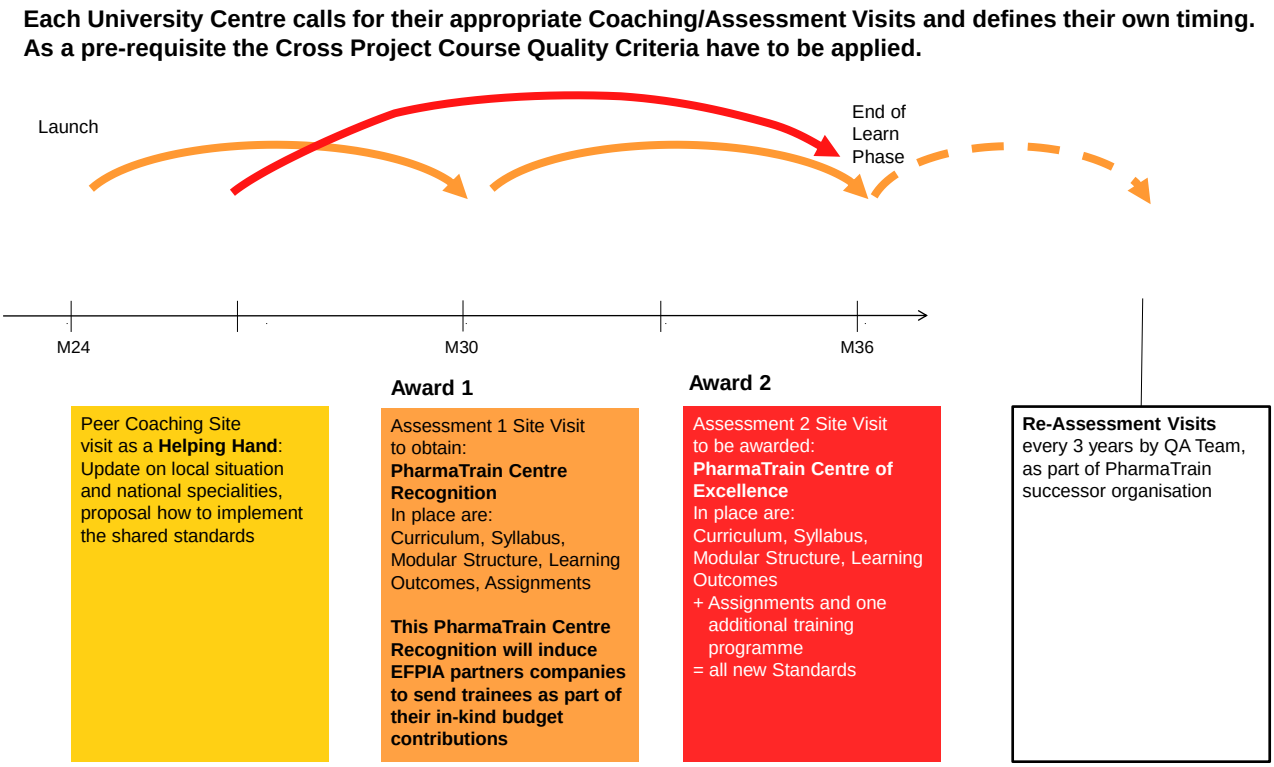

Fig 2: Procedure of PharmaTrain Course Recognition

- To receive PharmaTrain awards, course providers shall call at their own description for coaching and assessments. Teams put together of three assessors representing PharmaTrain ExBo, WP8 and IFAPP national Member Associations of IFAPP (nMAs) will assess course providers on-site
- As a prerequisite~~,~~ Course Providers shall fulfill the Cross Project Shared Course Quality Standards were accepted by all four IMI E&T project EMTRAIN, EU2P, PharmaTrain and SafeSciMet (see Fig 1. and PharmaTrain Manual, Chapter 10. PharmaTrain Centre Recognition Evaluation Process).
- PharmaTrain will give two ~~A~~awards as an acknowledgement for a PharmaTrain Centre Recognition (Award 1) and PharmaTrain Centre of Excellence (Award 2), respectively. These awards are not an accreditation, this remains in the hands of national universities and agencies.

The implementation of the early assessment process during the duration of the PharmaTrain project comprises a maximum of three visits corresponding to the incremental quality levels towards the PharmaTrain Centre of Excellence Award. Course

providers are invited to directly call for Assessment 1 and skip the peer coaching. The coaching "visit" may be managed via telephone and written advice. For Assessment 1 and 2, an on-site visit is requested whenever possible at the time of a centre's training module:

- **Peer Coaching Contact/Site visit:** The first level is a Coaching Process, which helps the participating centre to set up the system in conformity with the Pharma-Train Manual Curriculum Standards and Programmes. This first helping hand does not have any elements of evaluation or assessment.
- **Assessment 1 Site Visit:** The second level, the PharmaTrain Centre Recognition **(Award 1),** contains formal checks of compliance with the PharmaTrain Syllabus 2010, modularity, Learning Outcomes as well as assessed assignments. Satisfactory centres are awarded the PharmaTrain Centre Recognition and, most importantly, are eligible for additional in-kind contribution via industry (private partners) student's sponsorship.
- **Assessment 2 Site Visit:** A third quality level is the PharmaTrain Centre of Excellence **(Award 2),** and contains additional formal checks of Assignments and one additional training programme, as well as the implementation of Examination Standards.

The assessment visit/meeting process

- Call process:
  Coaching and Assessments are a **Call Process**. This means that the Center Quality Officer, CQO **("local facilitator ")** and / or the course director call the PharmaTrain QA Team **("the evaluator team")**. Date and time schedule:
  The CQO and the course director will schedule with the QA Team 1-day meeting at the course facilities. The meeting is expected to take a maximum of 6 hours. It is appreciated to schedule a site visit in parallel i.e. during already scheduled courses and teaching activities.
- Documents to be delivered prior to the site visit:
  The course director will provide the evaluating QA Team with the **course documentation,** including the course programme, at least 1 month before the meeting so that they can review these documents and get prepared in advance **(Check-list,** see Appendix 13.8.2 to the Manual).
  The CQO and QA Team should compare the course documentation with the IMI PharmaTrain Syllabus 2010 and identify omissions and/or insufficiencies. This preparation prior to the visit will facilitate the review and accelerate the evaluation process during the visit.
- During the visit:
  The QA Team, the local CQO, and the Course Director should all participate at the assessment meeting and the relevant material concerning the course in question should be ready for further clarification and detailed evaluation.

- After the visit:
  The QA Team will provide a written report ((Reporting Template Appendix 13.8.3.) on the visit to the site commenting on the strengths and weaknesses of the course and making either a proposal concerning the improvements needed before the Assessment Visits or recommending an award right away. Awards will be granted by the PharmaTrain QA Office (leader WP8 until April 2014).

The result of the Assessment 1 and 2 visits will fall into one of the three categories: Award granted, Award granted upon conditions, Award not granted

Responsibilities

- CQO Centre Quality Officer (Local Facilitator)
  - Owner and responsible for the local quality process
  - Local facilitator of the coaching/assessment process
- Quality Assurance Team (Evaluator team)
  Teams are composed of three Assessors: a member of the PharmaTrain Executive Board, a member of the PharmaTrain Quality Assurance Team and a representative of a national member association of IFAPP (nMA Quality Specialist) to:
  - accompany and evaluate the Centres through the three-step implementation
  - conduct coaching advice, Award 1 and Award 2 visits and later Re-Assessment Visits
  - prepare visit report containing discussion of the findings, outcome of the coaching/assessment visit and suggestions for improvement, if and as appropriate
  - send letter to Course Director in which the decision is communicated
- (University) Training Centre
  - develop and maintain QC checks for centre PharmaTrain 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 programmes and Centres
  - collect the evaluation and reporting of outcomes of Student's Feedback Forms
  - prepare and distribute of the Centre Feedback Reports and action 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 coaching and assessment activities which are addressed in a timely manner
- PharmaTrain Central Quality Assurance Office
  - maintain the PharmaTrain templates for the Students' Feedback Forms, Centre Feedback Reports and the Quality Control Guidelines.
  - perform a review, critical assessment and thorough analysis of all Centre Feedback Reports
  - prepare and share trend analysis of all Centre Feedback Reports to identify common areas of improvement

- review Coaching and Assessment Reports as well as 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 coaching and assessment activities
- ensure sharing of learning's from the above activities with all PharmaTrain Centres
- monitor compliance of PharmaTrain Centres with rules and requirements of Accreditation and Examinations

Related appendices:
Appendix 13.8.2, Checklist V1.0
Appendix 13.8.3, Reporting template, V1.1
Appendix 13.8.4, Guideline for e-quality standards, V1.1

This PharmaTrain SOP 1 V1.1 has been conceived by Dominique Dubois, Pharmed Brussels, and WP8 on QA, March 24, 2014 and is at the same time appendix 13.8.1 of the PharmaTrain Manual V2.0.