

Course Evaluation System

PharmaTrain

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1. Classification of Courses:

1.1 Recognition as 'PharmaTrain Centre' or 'PharmaTrain Centre of Excellence'

1.2. Recognition as 'PharmaTrain Course'

2. Awards; Definitions and Requirements:

Principles:

- a. In the following table 'Full' PharmaTrain Syllabus means all 14 Sections are covered; 'Section/s' means one or more of the 14 sections are covered; 'Topic/s' means one or more sub-Sections 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 accreditation awards are for a 3-year term after which they must be renewed.

PHARMACEUTICAL MEDICINE / MEDICINES DEVELOPMENT SCIENCE DOMAINS	SYLLABUS COVERAGE	PHARMATRAN CENTRE LEVEL	PHARMATRAN CENTRE LEVEL TITLE
Pharmaceutical Medicine / Medicines Development Science MSc (without) and Diploma (with) additional course or Module	Full	1	PHARMATRAN CENTRE OF EXCELLENCE
Medicines Regulation	Section/s	2	PHARMATRAN CENTRE
Drug Safety, PV & Risk Management	Section/s	2	PHARMATRAN CENTRE
Non-Clinical Development Early Clinical Development Clinical Pharmacology CRO, CRU (Early Phase)	Section/s	2	PHARMATRAN CENTRE
Clinical Development (Phase 2-4) Clinical Trials CRO, CRU (Late Phase)	Section/s	2	PHARMATRAN CENTRE
Healthcare Marketplace Medical affairs Ethics & Law Stats & Data Management	Section/s	2	PHARMATRAN CENTRE
CLIC & Other PTF, IMI programme	Section/s	2	PHARMATRAN CENTRE
Other topics	Section/s	2	PHARMATRAN CENTRE

OUTCOME / QUALIFICATION	SYLLABUS COVERAGE	PHARMATRAIN CENTRE LEVEL	PHARMATRAIN CENTRE 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
Certificate Individual Course or Module	Topic/s	3	PHARMATRAIN COURSE

Course / centre recognition follows a pyramidal or consecutive process:

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.

If the course is in addition a diploma or master course (any title) and covers all or at least one PharmaTrain Syllabus Topic and fulfils PharmaTrain Quality Criteria the applicant is awarded a:-

'PharmaTrain Centre' Recognition.

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.

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.

3. SOPs for Course evaluation:

The SOP 1 describes the procedures for evaluation and recognition of PharmaTrain Courses and Centres (see Appendix 1)

4. Fees (EURO):

This fee structure proposal has been developed taking into account three of the fundamental principles of the PharmaTrain Federation as follows:

- Fairness
- Safeguarding quality standards as a non-commercial, not-for-profit organisation
- Transparency

1. For courses to be evaluated to obtain recognition as a 'PharmaTrain Centre' or 'PharmaTrain Centre of Excellence' at the level of a Diploma or Master degree, PhD, MD PMST the fee for the evaluation will amount to 4.000,- . In case of an upgrade of 'PharmaTrain Centre' to 'PharmaTrain Centre of Excellence' a fee of 1.500,- will be collected.

The cost of reassessment visits for 'PharmaTrain Centres' and 'PharmaTrain Centres of Excellence' will be 1.500,-

In the special case of a 'PharmaTrain Centre' providing a larger number of courses the fee for evaluating up to 10 courses will be 3.000,- or calculated on the basis of units as outlined for 'PharmaTrain Courses' (see below) whatever is lower. For more than 10 courses either 4.000,- will be requested or again an amount based on the units delivered. The fee for reassessment will be 1.500,-.

2. 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. Additional units may be added.

For the minimum unit the fee will be fixed as 200 € for public and 500 € for private (commercial) course providers.

In the case of additional 1-day units, 130 € will be charged for each additional unit for public providers. Commercial providers will be requested to pay 325 € for each additional 1-day unit for the following four (4) units and then 130 € per unit.

Any other variation to the above and requests for concessions will be assessed on an individual basis taking into account the merits of the respective case.

For course re-evaluation, on an annual basis, it is the responsibility of the course provider to demonstrate that the PharmaTrain quality standards have been sustained since the last assessment and how the minor and major changes to the programme have been dealt with to ensure smooth transition. The fees applicable to such a re-evaluation exercise will be the same as for the first evaluation.

Evaluation of 'PharmaTrain course(s)' and payment of due fees constitutes a Membership of the course provider in PharmaTrain Federation, valid for one year, which can be continued by re-evaluation on an annual basis.

If as part of the assessment of 'PharmaTrain Courses' travel costs are accrued all the associated expenses and the necessary arrangements should be met by the applicant.

5. Language Requirements for PharmaTrain Recognised Courses

English, as the global language of science, should be used for all 'PharmaTrain Courses', with exceptions mentioned below:

1. All course materials which are required for the evaluation of the courses must 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. Certificates:

6.1: Certificate for 'PharmaTrain Course' Recognition

The PharmaTrain Federation asbl, Brussels, is proud to announce that AGAH e.V.'s provision and conduct of their course

Introductory Course in Exploratory Medicines Development

is in full compliance with the PharmaTrain guidelines for short courses and accredited with 3 ECTS.
Thus, the PharmaTrain Federation Board is glad to provide to

AGAH e.V., Germany

AWARD OF

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
COURSE RECOGNITION

Brussels, 15 February 2017 President Treasurer

6.2: 'Centre of Excellence' Recognition

The PharmaTrain Federation asbl, Brussels, is proud to announce that CenTrial GmbH's and Donau-Universität Krems' provision and conduct of their courses

University Course Master of Science (MSc) Clinical Research and All Other Courses Offered by CenTrial GmbH

are in full compliance with the PharmaTrain guidelines for post-graduate education in topics of pharmaceutical medicine/medicines development. Thus, the PharmaTrain Federation Board is glad to provide to

CenTrial GmbH, Germany, and Donau-Universität Krems, Austria

AWARD OF

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Brussels, 25 February 2017 President Treasurer