#### PharmaTrain Check-list to prepare for re-assessment as a PharmaTrain Training Centre

Encl. 1

*The reassessment procedure builds on the findings and results of previous assessments. In most cases the focus of the assessors will be on significant changes in the overall content and performance of courses in comparison to previous assessments. The course directors/organisers therefore should highlight changes/amendements/deletions of content, syllabus items, structure, personal changes, changes for students assessments, quality changes, etc*

1. **General Information**

1.1 Date of first centre recognition \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of last re- assessment (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1.2 Title of Course (s):

1.3 (Main) University organising the Course (if applicable):

1.4 Address of Secretariat of Course

1.3.1 Telephone number:

1.3.2 Fax number:

1.3.3 E-mail address:

1.3.4 Website (if available):

1.5 Names of:

1.5 1 Course Director:

1.5.2 Course Coordinator:

1.5.3 Course Quality Officer:

1.5.4 Secretary/Assistant:

1.6 Type of Course and Degree (please mark right answer)

1.6.1 Base Diploma Course DiMD

yes  no Degree: Diploma in pharmaceutical medicine/diploma of university professional in pharmaceutical medicine

1.6.2 Extended Master Programme MMD

yes  no Degree:

1.6.3 Integrated Master Programme MMD

yes  no Degree:

1.6.4. **Other courses (please list) together with the main topics and its learning outcomes**

Course 1 …. Title

Main topics

Learning outcomes

Course 2 …. Title

Main topics

Learning outcomes

Course 3 **….** Title

Main topics

Learning outcomes

**Please use a full questionnaire/check list for each of your courses (just replicate the checklist)**

1.7 Year of Foundation of the Course:

1.8 Language of the Course:

**2. PharmaTrain QA Questionnaire/Check-list for Shared Quality Standards Assessment**

**2.1 Cross Project Shared Course Quality Standards  
(**please indicate what is in place)

|  |  |
| --- | --- |
| **A formalised and documented QA/QC policy that includes the following:** | % in place  (0-100%) |
| 2.1.1 University accreditation OR a suitable system for approving, monitoring and reviewing the training offered.  **Please specify institution or source** |  |
| 2.1.2 Quality assurance of teaching staff. |  |
| 2.1.3 Regular review of the QA/QC process and demonstration that the training is further developed in light of this review.  **2.1.4 Further specification, details and examples** |  |
| **A set of documented criteria for individual modules, courses or course programmes that include the following:** | % in place  (0-100%) |
| 2.1.5 Defined and transparent admission criteria. |  |
| 2.1.6 A predefined set of teaching objectives, leading to defined learning outcomes. |  |
| 2.1.7 The facilities, infrastructure, leadership and competences available for the support of student learning. |  |
| 2.1.8 Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered |  |
| 2.1.9 A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers. |  |
| 2.1.10 Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc.) |  |

**2.1.11 Further specification, details and examples**

**2.2 Modules**

2.2.1 Does the course programme cover (all or part of) items mentioned in the PharmaTrain Syllabus 2018?

**Please specify**

2.2.2 Is the PharmaTrain Modular Structure in place? comprising the 6 Modules of the Base Diploma Course ( only if applicable)

2.2.3 Are Learning Outcomes which refer to PharmaTrain Syllabus 2018 V1.0 in place?

2.2.4 Are modules distributed over 1, 2 or more years?

2.2.5. Specific module structure other than above

Please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.2.5 How many hours of teaching does the full course contain?

2.2.6 How is this distributed? **Give percentages**

Pre-F2F Module activity:

Didactic lectures:

Workshops:

Group discussions/Case Studies:

Post F2F Module assignments:

Other (please specify):

2.2.7 Is distance learning or homework scheduled in the course?

yes  no

2.2.8 Is the course taught (please mark right answer)

all in one place?

rotating to several places in the same city, in the same country or in different countries?

2.2.9 Assessed Assignments

Please state if / which assignments – which are also compulsory for the (Base) Diploma Course – are in place? (only applicable in case base modules are provided)

2.2.10 Are they assessed as part of each Module for the Certification (a document)?

yes  no

Please specify or give examples

**2.3 Time**

2.3.1 How many hours are spent on teaching of:

Introductory course? hours

Drug discovery and development planning? hours

Non-clinical testing? hours

Pharmaceutical development? hours

Early clinical development? hours

Clinical trials? hours

Regulatory affairs? hours

Drug safety and pharmacovigilance hours

Economics of healthcare? hours

**2.4 Teachers**

2.4.1 How many teachers are participating in the programme?

2.4.2 How many are from:

Academia?

Industry?

CROs?

Regulatory Authority?

Other organisations? (Please specify)

**2.5 Course material**

2.5.1 Is course material (please mark right answer)

Paper-based

E-learning tools

Both

**2.6 Students**

2.6.1 What has been the average number of students registering each year? (only applicable for centers providing PTF base modules)

the full Course?

individual Modules ?

the integrated examinations (if applicable)?

2.6.2 Which percentage of applications for participation to Courses/Modules have been accepted?

2.6.3 What are the requirements to register for the course and the examinations? (Please mark right answer):

Physicians only

Physicians and biomedical sciences degree only

Plus other scientists? (Please specify)

2.6.4 What is the average ratio of physicians versus non-physicians?

**2.7 Integrated Examination (only applicable in case true PTF modules are provided)**(Theoretical part for Specialist title to be combined with documentation of work experience)

2.7.1 Are examinations conducted (Please mark right answer)

Once a year

Twice a year

Other frequency (Please state)

2.7.2 Are the examinations (Please mark right answer)

Written only

Oral only

Both written and oral

2.7.3 Does the written examination include (Please mark right answers):

Multiple Choice Questions (MCQs):

yes  no

If yes, how many MCQs are asked at each session?

In the choices given is only one correct or several ones?

Only one  several

Short questions essays?

yes  no

Short dissertation?

yes  no

2.7.4 Who writes and updates the MCQs? A specific Committee?

2.7.5 What is the duration (in minutes or hours) of

The written examination?

The oral examination?

Is attendance to the courses compulsory for sitting the examination?

yes no

If yes, how much of the course must be completed (in percentage)?

Are there any assessments during the course?

yes  no

**2.8 Recognition**

2.8.1 Do you want your course recognised by (please mark the right answer)

Your National Health Authorities?  yes  no

Your National Academy of Medicine?  yes  no

Your Regulatory Authorities?  yes  no

Employers? yes  no

2.8.2 Is your course already recognised by any of these organisations or others? Please comment:

**2.9 Fees (in Euro)**

2.9.1 What is the fee to be paid for attendance to?

The full course?

Per module?

The integrated examination?

2.9.2 Is a fee requested when awarding a diploma, certificate, or award?

yes  no

**2.10 Marketing**

2.10.1 Do you communicate and promote your course by using the PharmaTrain Brand “Mastering Medicines Development”?

yes  no

2.10.2 Have you implemented the PharmaTrain Identifier on your website?

yes  no

*This Check-list has been conceived by Dominique Dubois, Pharmed Brussels and WP8 on QA, May 31, 2011, and adapted in September 2013., in 2016* ***and adapted by Heinrich Klech in 2022***