

PharmaTrain QA Questionnaire/Check-list for QA Teams and Training Centres

1. General Information

1.1 Title of Course: _____

1.2 (Main) University organising the Course: _____

1.3 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): _____

1.4 Names of:

1.4.1 Course Director: _____

1.4.2 Course Coordinator: _____

1.4.3 Course Quality Officer: _____

1.4.4 Secretary/Assistant: _____

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

1.5.1 Base Diploma Course DiMD

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

1.5.2 Extended Master Programme MMD

yes no Degree:

1.5.3 Integrated Master Programme MMD

yes no Degree:

1.6 Year of Foundation of the Course: _____

1.7 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. _____
- 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. _____

A set of documented criteria for individual modules, courses or course programmes that include the following: % in place (0-100%)

- 2.1.4 Defined and transparent admission criteria. _____
- 2.1.5 A predefined set of teaching objectives, leading to defined learning outcomes. _____
- 2.1.6 The facilities, infrastructure, leadership and competences available for the support of student learning. _____
- 2.1.7 Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered _____
- 2.1.8 A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers. _____
- 2.1.9 Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc.) _____

2.2 Modules
 (2.2.1-2.2.3 requires 100% adherence)

- 2.2.1 Does the programme cover all items mentioned in the PharmaTrain Syllabus 2010? _____
- 2.2.2 Is the PharmaTrain Modular Structure in place? (comprising the 6 Modules of the Base Diploma Course) _____
- 2.2.3 Are Learning Outcomes which refer to PharmaTrain Syllabus 2010 V1.0 in place? _____
- 2.2.4 Are the modules distributed over 1, 2 or more years? _____

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

2.2.6 How is this distributed?

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?

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

yes no

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?
the full Course? _____
individual Modules ? _____
the integrated examinations? _____
- 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

(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.