PharmaTrain Assessment Report

Assessed Entity / Organisation: Name of Institution assessed	**Activity Type:** e.g. 1st Assessment / Confirmatory Assessment
Location and Address: Detailed (postal) Address City Country	**Date Report issued:** DD – MON – 20YY
Dates of Assessment: From / to, DD – MON - 20YY	**PharmaTrain Report Number:** ##
Lead-Assessor:	**Co-Assessors:**
Name of Course assessed:	

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Objective

This assessment was performed to evaluate the systems, processes, procedures and documentation at <Name of the Master Course, University, City, Country > to ensure compliance with PharmaTrain requirements and applicable quality/syllabus standards as a precondition for "PharmaTrain Centre Recognition"/ "PharmaTrain Centre of Excellence" award.

Scope

This assessment focused on <brief description of main scope and goals of the assessment, e.g. syllabus, learning outcomes, curriculum, faculty, processes, procedures, teaching methodology, quality standards of this course to assess its readiness for "PharmaTrain Centre Recognition"/ "PharmaTrain Centre of Excellence"> and was conducted in accordance with the relevant sections of PharmaTrain SOP 11.1.

Summary of Findings

During this assessment the below listed critical / major [1] deficiencies were observed. The institution was requested to submit <adequate Corrective Actions>. These were reviewed by the Assessors for adequacy in addressing the observed findings and became an integral part of this Assessment Report.

1. Finding # 1[2]
   Corrective Action #1

2. Finding # 2
   Corrective Action #2

Etc.

Final Recommendation to the PharmaTrain Executive Board

Based on the submitted written information, the Assessors' thorough review of the material and Corrective Actions provided and the interviews with key representatives of the course the assessors came to the conclusion that <Name of the Master Course, University, City, Country > fulfills the PharmaTrain standards and quality requirements and therefore recommend to the PharmaTrain Executive Board to award "PharmaTrain Centre Recognition"/"PharmaTrain Centre of Excellence" to <Name of the Master Course, University, City, Country >.

By signing this document the Lead Assessor and both Co-Assessors endorse this Assessment Report and approve its distribution:

Name Lead Assessor — On: DD MONTH 20YY
Title Lead Assessor
Affiliation Lead Assessor

Name Lead Assessor — On: DD MONTH 20YY
Title Lead Assessor
Affiliation Lead Assessor

Name Lead Assessor — On: DD MONTH 20YY
Title Lead Assessor
Affiliation Lead Assessor

[1] Definitions are provided in Annex 1.
[2] List findings / observations in decreasing order of severity, i.e. critical > major. Minor findings / observations are generally not listed in the summary page.

Course Description

Course Organisation:

(give a short description of)

- History of the course
- Academic and legal provisions for the course environment
- Governance, organisational structure and administration
- Maximum and minimum number of students
- Course language and duration
- Faculty
- Financial management

(example – to be expanded /changed according to the course's organisation:)

The <Name of the Master Course, University, City, Country > has been established in 1996 as an initiative of experts in the national pharmaceutical industry who identified the need for post-graduate education in pharmaceutical medicine. The course is established in form of the "form of legal entity", (responsible for organization/performance of the course and student affairs), an institution of the University of ….. This includes the liability coverage by the University. The Scientific Course Committee (responsible for curriculum, examination, QA, award of titles), is a body of the Faculty of Medicine and consists of x members: y professors from the faculty of medicine and z head lecturers. The Scientific Course Committee has a Quality Board, a Student Selection Committee, and an Examination Committee.

The course is provided in English to a maximum of xx and a minimum of yy students per course. The course is offered *(e.g.)* every two years, starts always in *(month)* and lasts for vv months including master thesis and final examination.

The faculty consists of ca. zz Head Lecturers, responsible for individual Modules, Senior Lecturers and Lecturers and has been very steady over the years. There are vv to xx lecturers involved in a Module. The vast majority of the speakers and chairs come from "the Pharmaceutical Industry/CRO/consultant sector/competent authorities/NGOs". The faculty members receive "fees/travel cost reimburse-ment/nothing". The course is supposed to be "self-sustainable/financially supported by…". Profits from the course are used to ….., losses are covered by….."

Course Content:

(give a short description of)

- Structure ("Base course plus extension modules" or "Integrated course")
- Number of ECTS
- Number and titles of modules
- Syllabus compliance
- Learning Outcomes compliance
- Teaching methodology
- *Additional course offerings (for "Centre of Excellence" recognition)*

(example – to be expanded /changed according to the course's content:)

The course follows the "base-course-plus-extension-modules structure / integrated course structure", based on xx ECTS and contains x modules (or other structure), provided within "time period":

Titles of the Modules (e.g.):

1. General introduction to the health system and the pharmaceutical industry
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.

The modules "fully/mostly/partly" cover the PharmaTrain Syllabus. The modules "fully/mostly/partly" cover the PharmaTrain Syllabus. *(Deficiencies would qualify as "Findings" of minor, major or critical degree).*

Learning Outcomes are defined and cover those defined in the PharmaTrain Curriculum. The modules "fully/mostly/partly" cover the PharmaTrain Syllabus. *(Deficiencies would qualify as "Findings" of minor, major or critical degree).*

(Example for "Teaching Methodology"): While the students receive a comprehensive pre-reading package before each module, most of the teaching time is face-to-face over x days per module including one assignment to be worked on in teams, followed by individual homework. *(Describe level of eLearning and other teaching methodology aspects).*

(For "Centre of Excellence" recognition additional offerings need to be provided):
There are additional course offerings provided by <Name of the Master Course, University, City, Country > *(e.g.):*
– Elective Module 1 (x days) (Title)
– Elective Module 2 (x days), (Title) etc.
And *(optional, e.g.)*:
– GCP training (1 day)
– Site management for CRAs and study teams (1 day)
– Training in medical device studies for investigators and study teams (1 day)

Student Selection Process:

(give a short description of)

- Students' required educational background
- Level of required practical experience
- Other selection criteria
- Selection process

(example – to be expanded /changed according to the course's selection process:)

Students must have completed a university degree, should come from different backgrounds, have practical experience but can achieve that also during the course duration, go through an interview process and need to demonstrate their English skills. Applicants are ranked and the top 25 are selected (sex usually approx. 50/50). There is a guidance document for the selection process.

Examination Process:

(give a short description of)

- Examinations
- Home works
- Assignments

(example – to be expanded /changed according to the course's examination process:)

Beside assignments based on industry-provided case studies during the lecture cycle, students have to deliver home works and pass written tests at the end of each Module. After submission of the Master Thesis students have to pass an oral examination over 1 hour.

Quality Management:

(give a short description of how the 9 PharmaTrain quality criteria are fulfilled. Refer to the course's Quality Manual/Section in the Course Manual. Deficiencies would qualify as "Findings" of minor, major or critical degree)

The 9 PharmaTrain quality criteria are well fulfilled:

A formalized and transparent QA/QC policy

1. University accreditation OR a suitable system for approving, monitoring and reviewing the training offered.
   (Example): The course is Bologna-accredited by AQAS/ENQA, Bologna-re-accredited by AQAS/ENQA and accredited by IFAPP.

2. A system for quality assurance of teaching staff.
   (Example): There is a quality management system in place including SOPs for all relevant processes

3. Regular review of the QA/QC process.
   (Example): There is a regular QA/QC review and adaptation process in place to ensure ongoing quality improvement.

A set of documented criteria for individual modules, courses or course programmes

4. Defined and transparent admission criteria.
   (Example): There are well defined and transparent admission criteria as described above.

5. A predefined set of teaching objectives, leading to defined learning outcomes.
   (Example): There are predefined Teaching Objectives fulfilling the PharmaTrain syllabus and leading to defined Learning Outcomes which are in line with the PharmaTrain Learning Outcomes

6. Adequate facilities, infrastructure, leadership and competences.

(Example): The teaching takes place in modern, well-equipped and suitably sized lecture halls. Faculty, their expertise and course organization are suitable for optimal teaching and student learning as described above.

7. Assessment of the students' achievement according to the learning outcomes.

   (Example): Minimal requirements for acceptance of assignments and homework are defined and communicated to the students as well as the minimal requirements for passing the examination at the end of each Module and in the Final Examination.

8. A system for collecting, assessing and addressing feedback.

   (Example): A feedback system is in place containing a feedback questionnaire for students in each module on quality of teaching/faculty, facilities, organisation, food.

9. Adequate reference materials.

   (Example): The reference material is highly professional with extensive pre-reading literature and eLearning tools per Module.

Course quality principles
The course adheres to the following course quality principles:

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

e-Quality Management:

*(give a short description of how the **e-learning outcomes enabling and technical related criteria** are fulfilled.)*

A set of e-learning outcomes enabling criteria

1. Blended levels of interactivity (face to face and internet based) to be available:
   (Example): There are x% face to face and 100-X% interactive activities included for each e-course module

2. System in place for online practice exercises
   (Example): A system is in place for online practice exercise (critical appraisal of published paper, case studies, …). The system has the following main characteristics:……..

3. Archiving policy SOP to allow repetition (repeating multiple times) and spacing (spreading modules over time)
   (Example): *e*-Archive policy SOP is in place. Latest version of the archive policy document is :…. Revisions are planned every X years

4. System in place for obtaining feedback in conjunction with self-assessment questions (eg. Tutor availability)

(Example): Tutor availability SOP is in place, describing the tutor assignment, as well as procedures for checking availability of nominees and process for standing-in in case of non availability of the assigned nominee.

5. Standards for tutorial activities
   (Example): SOP is in place for responsibilities, organization and implementation of tutorial activities

e-Technical related quality principles

The e-course adheres to the following course quality principles:

a. Any module must be platform independent
b. Ease to use
c. Speed of access
d. Reliability
e. Security
f. Firewall policy
g. Fully featured real time virtual classroom

Assessment Activities

The findings and conclusions in this report are based upon the conduct and review of the following:

Personnel Interviewed:

(give a short description, e.g.)

- Dr. xyz, Course Director, Chairman Scientific Course Committee,
- Ms abc, Course Manager
- Prof. opq, Dean of the Medical Faculty
- Dr. mno, Global Head Clinical Operations, company, country
- Dr. aoe, Member of the Scientific Course Committee, Mentor of the Working Section curriculum development, Head Lecturer of one Module
- Dr. bcd, Lead Assessor, competent authority, country, Senior Lecturer in one Module

Processes and Deliverables Reviewed and Assessed:

(tick the assessed elements and describe detected deficiencies in the Findings section)

☐ Completed PharmaTrain Course Assessment Form
☐ Course Manual with Curriculum including Teaching Objectives and Learning Outcomes
☐ SOPs
☐ Introductory presentation at assessment visit on Course Structure and Quality Management
☐ Presentation at PharmaTrain General Assembly, Rome, September 2011
☐ Modular structure – PharmaTrain Syllabus Sections Mapping

- ☐ Students Feedback Form
- ☐ Examination Rules
- ☐ CVs (Scientific Course Committee, Examination Board, Quality Board)
- ☐ Listing of Master Thesis Topics
- ☐ Other documents

Facilities Visited:

(give a short description)

- ☐ Lecture hall
- ☐ Break-out room(s)
- ☐ Student restaurant/mensa/hospital restaurant
- ☐ Other facilities

Findings

(present in the order: critical, major, minor)

1. Descriptive name of the finding

Finding Classification: Minor, major or critical
(give a short description of the finding)

Corrective Actions:
(give a short description)

Responsible Person for Corrective Actions implementation:
(name and title of the responsible person)

Actions Implementation Dates:
(give a short description)

Lead Assessor's confirmation of implementation:
(give a short description and the date of verification)

2. Descriptive name of the finding

Finding Classification: Minor, major or critical
(give a short description of the finding)

Corrective Actions:
(give a short description)

Responsible Person for Corrective Actions implementation:
(name and title of the responsible person)

Actions Implementation Dates:
(give a short description)

Lead Assessor's confirmation of implementation:
(give a short description and the date of verification)

Conclusions

Based on the submitted written information, the Assessors' thorough review of the material and Corrective Actions provided and the interviews with key representatives of the course the assessors came to the conclusion that <Name of the Master Course, University, City, Country > fulfills the PharmaTrain standards and quality requirements and therefore recommend to the PharmaTrain Executive Board to award "PharmaTrain Centre Recognition"/"PharmaTrain Centre of Excellence" to <Name of the Master Course, University, City, Country >.

Annex 1

Findings / Observations Classification

Each finding / observation in this Report has been assigned a Classification Rating as defined below:

Critical - a departure from the PharmaTrain Syllabus or other applicable standards and/or procedural requirements has occurred with evidence of one or more of the following:

- The education purposes and goals, business processes and validity of degrees have been or are at a high risk of being compromised.
- The quality of the teaching and/or examinations is jeopardized and negatively affect the ultimate acceptability of the contents taught and the degree bestowed.
- The reputation of the PharmaTrain program or of the Institution assessed is put at risk.
- Multiple significant non-compliances occurred across areas of responsibility, indicating a systematic quality management system failure
- Inadequate, insufficient or untimely corrective actions have taken place regarding previously reported findings with an Impact Rating of 'Critical' and/or 'Major'.

Major – a departure from the PharmaTrain Syllabus or other applicable standards and/or procedural requirements has occurred with evidence of one or more of the following:

- The education purposes and goals, business processes and validity of degrees are at risk of being compromised.
- The quality of the teaching and/or examinations has been affected, however, without adversely affecting the ultimate acceptability of the contents taught and the degree bestowed.
- Non-compliances were noted across areas of responsibility, but with no indication of a systematic quality management system failure.
- The deficiency has not developed into a critical issue, but has a high potential to do so unless addressed adequately and in a timely manner.

Minor – a departure from the PharmaTrain Syllabus or other applicable standards and/or procedural requirements has occurred, however, the deficiency noted was found to have an inconsequential impact on education purposes and goals, business processes but still requires follow-up for resolution.