Cooperative European Medicines Development Course (CEMDC)

Student Information

Student selection and enrolment; Tuition fees and reductions;

The Examination procedure

Version 2 (February 2, 2013.)

TABLE OF CONTENTS

1. Student selection and enrollment
2. Student engagement; overall education plan
3. Tuition fee and other expenses
4. Fellowship and tuition fee reduction
5. The examination procedure
6. Certificates provided by the CEMDC
7. Student representatives; management of complaints

1. Student selection and enrollment

The target student population is professionals with medical, pharmaceutical, or MSc (or equivalent) degrees in natural and life sciences. An adequate knowledge of English is necessary in order to follow the lectures, participate in the discussions and complete the various forms of assessments. For admission, students must submit a copy of their graduate and/or post-graduate degrees, a certificate or any other document proving their knowledge of English, and a CV describing their professional experience if available directly to the office of the Study Director. Students will be selected for enrollment by the Study Director, based on the submitted documents, without any direct entrance examination. If deemed necessary, the Study Director may request further information, or even a direct discussion with the candidate. In case of problematic applications, the Study Director may seek advice and decision from the Governing Board.

All students are centrally registered for the course by the Coordinating University. Information on course participation and student performance is maintained at the Coordinating University, which issues the various levels of certificates together with English Diploma Supplements.

Personal data of students will be handled confidentially with respect to personal integrity and in line with the Hungarian laws on data protection.

2. Student engagement; overall education plan

The CEMDC uses the harmonized syllabus and the modular curricular contents developed by PharmaTrain, having 6 base modules, and 6 advanced modules which can be selected from the harmonized pool of mandatory extension and electives modules. The learning outcomes were strictly defined by the PhT harmonization procedure and have to be applied unchanged by all course programs, since these form the basis for achieving similar educational outcomes by the different courses. All educational activities must be directed toward achieving the specified outcomes.

- The **Base Course** contains 6 modules. It offers a broad and comprehensive overview of drug development science and covers all the topics of the harmonized educational syllabus

- The **Advanced Master Level Course** contains additional 6 advanced modules some of which are mandatory extension modules while others are freely selectable elective modules. The educational aim is to deepen selected topics of drug development science and provide additional competence skills for the students. The elective modules can be selected by the students from a pool of quality controlled elective modules available through the IMI-PhT cooperation.

All educational activities will be directed toward achieving the specified outcomes. Students might finish the course after the 6 basic modules. For a master level degree additional 6 advanced modules must be finished and a thesis has to written and defended. The complete master-level course of the CEMDC is composed of 12 modules.

The European Credit Transfer System (ECTS) requires minimum 25 hours of learning time for each ECTS point; accordingly, one module consists minimally of 125 hours.Twenty per cent of this time has to be devoted to face-to-face teaching. Considerable time should be spent by the students reading the recommended literature, preparing themselves for the case presentations and consultations, studying the lecture materials and working on the assignments. Additional working time will be spent on E-learning programs. Some E-programs are already available, while many more are under development and will be gradually incorporated into the program.

A PharmaTrain Module (minimally of 5 ECTS) is built up as follows:

- Usual duration of face-to-face teaching at a university centre: 4 days (minimally 30 hours)
- Preparatory work and E-learning preparation (minimally 35 hours)
- Post-teaching work: research, reading, assignments (minimally60 hours)
- Each module is finished with an assessment

The face-to-face teaching will be preferentially given in four day-long sessions six times per year, but other schedules may be defined as applicable. The suggested schedule for a module is:

- Wednesday: arrival
- Thursday, Friday and Saturday: teaching the entire day
- Sunday morning: summing up and MCQ examination;
- Sunday afternoon: departure

This schedule is meant to reduce the number of working days that students must be away from their place of employment. The face-to-face sessions of the modules may be held in the same country, or in different countries; however, 50% of the modules must be organized at the Coordinating University. The teaching program will consist of face-to-face delivery of lectures and case discussions. According to experience from other courses, these face-to-face sessions are essential for the students to internalize the subjects during joint problem solving and discussions.

The Base Course provides an overall survey of the entire field of drug development; therefore it is recommended that students complete the Base Course without taking prolonged breaks, if feasible. Each module is accredited minimally for 5 ECTS which can be summed for a master level degree within 5 years.

Possibility for individualized program following only selected modules

In addition to the students registered for the overall course, it is possible for additional students to attend selected modules, by paying a tuition fee determined for that single module. When choosing to participate in selected modules, the extension and elective modules delivered in the advanced program are generally recommended.

3. Tuition fee and other expenses

The tuition fee is divided into the following items:

- Base modules
- Advanced modules
- Individual modules if the student wants to participate only at selected modules
- Joint examination at the end of the Base Course
- Consultation and defense of a thesis for the master level

The tuition fees for the above items will be defined at the start of each new course by the GOBO, taking into consideration the actual financial environment.

Students can only be enrolled once at least 50% of the total tuition fee has been paid. The other 50% must be paid at the beginning of the next semester. In case an individual student

interrupts or terminates the study program or fails the examination three times, the CEMDC is not obligated to refund the tuition fee.

In addition to the tuition fee, students are responsible for covering the cost of their travel and local accommodation, and the teaching materials. The organizers should provide students with free coffee and lunches during the lecture days. In addition the organizers are encouraged to advise students on accommodation for a relatively modest price.

Students shall undertake to personally ensure their social and health insurance and protection under a civil liability insurance policy of their choice for the entire duration of their education. The CEMDC is not liable for any damages the student might experience or any damage caused by that student to a third party during the course.

4. Fellowship and tuition fee reduction

Student may apply to various organizations, including their employers, for fellowships to finance their education. Pharmaceutical companies and CROs are encouraged to cover all or part of the costs for the professional education of their employees. There is a limited sum within the Students Support Fund to support participants of the various IMI-PhT harmonized courses (http://collab.pharmatrain.eu) for the duration of the IMI-PhT grant (until 2014).

CEMDC support: If the budget permits, the GOBO may decide upon the extent of tuition fee reduction for individuals, as well as the conditions for selecting students to obtain support. When applying to receive a tuition fee reduction, students should explain their need for support by providing controllable relevant personal and financial details, including educational and working experience, which can be controlled by the Study Director.

5. The assessment procedure

The conditions to participate at the integrated assessment for receiving a diploma are the following:

- Presence at 80% of the face-to-face teaching programs (In case of justified absence the face-to-face work may be compensated by an additional written essay concerning the content of the module)
- Successful completion of required preparatory work for the module(s)
- Timely submission of the assignment(s)
- The learning outcomes of each module will be evaluated separately based on 20-25 multiple choice questions (MCQs), 2 written assignments (800-1200 words) per module and scoring pre-module preparation and evaluation of the students' work performance at the face-to-face activities. The MCQs should cover mostly the material of the preparatory work, , but additionally also the content of the lectures presented. Both types of assessments have to be passed by the students. (See

attachments: Assignment Evalaution Scheme; Multiple choice questions /MCQs/: guidance notes for candidates; pp 18-22)

A failed examination at the end of the module can be corrected once by writing an additional assignments covering the learning outcomes of the module provided the assignments are accepted by the two Module Leaders.

***Examination* at the end of the Base Course:** In addition to the examinations at the end of each module, an integrated assessment will be carried out covering the entire syllabus following the completion of the 6 basic modules. This approach is considered necessary for supporting the students in obtaining an overview of the entire material covered in the syllabus. The examination at the end of the base course will consist of a minimum of 80 MCQs and short written answers.

Transparent examination is the required basis for mutual recognition of the degrees given by the courses which use the same harmonized examination process. The MCQs will contain some joint questions from the IMI-PhT pool to support transparency. Moreover the MCQs will be evaluated by a computer based statistical evaluation process accepted by the IMI-PhT courses.

The achievements of the students will be graded according to a 5-point scaling system:

- Excellent (5)
- Good (4)
- Moderate (3)
- Acceptable (2)
- Failed (1)

Failed (1) means that the student did not pass.

The achievements corresponding to these levels are defined by the GOBO.

Students who fail the integrated Base Course examination can repeat the examination at the next Base Course examination of the CEMDC or at Base Course examinations provided by other IMI-PhT courses. Failing two times results in the obligatory termination of the course.

6. Certificates provided by the CEMDC

The added value of the course given jointly by several universities in English language is the multi-national certificate scientifically accredited by the PhT organization which is a guarantee of its broad international acceptance. The certificates are given by the coordinating Semmelweis University on behalf of the associated universities.

- ***Module certificate (MC).*** A stand-alone document certifying the successful completion of the module, including the examamination. the module certificate will be

issued by the respective Module-Organizing University and will be accepted by the Coordinating University.

- ***Diploma in Medicines Development (DMD) / Pharmaceutical Medicine.*** This certificate, provided at the end of the Base Course, is based on an integrated assessment covering the entire syllabus following the completion of the 6 basic modules.
- ***Master-Level Degree in Medicines Development (MLDMD) / Pharmaceutical Medicine*** This certificate is issued following completion of the entire master-level program containing both the Base and Advanced Courses, and after a thesis has been submitted and successfully defended.

The diploma and master-level degree will be issued by the Coordinating University on behalf of the Participating Universities. The Participating Universities' intention is to create a multilaterally signed joint degree in the future, once the legal environment within the EU permits its realization.

If considered advantageous, the joint program may be submitted for additional national accreditation by the Partner Universities and can be used to provide national certificates

7. Student representatives; management of complaints

The students should select two representatives for the entire duration of the course at the beginning of the education. They should represent the opinion and communicate the suggestions or complaints of the students. Their primary contact person is the Study Director.

In case of suggestions or complaints they should follow the three-level path outlined below:

- 1st instance: Module Leaders
- 2nd instance: Study Director
- 3rd instance: Governing Board

The representatives of the respective instances have to give a written report of the evaluation of the complaints both to those who filed the complaint and to the GOBO.

Students also participate in evaluating the quality of the teaching by providing written feedback on appropriate evaluation forms concerning both the educational material and the delivery of the module program.

8. Attachment

- PharmaTrain Syllabus
- Assignment Evalaution Scheme
- Multiple choice questions /MCQs/: guidance notes for candidates

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PharmaTrain Head of WP5 Geographical Extension Project

PHARMATRAIN SYLLABUS 2010

PharmaTrain Syllabus V0.13 February 2010

SYLLABUS FOR PHARMACEUTICAL MEDICINE / DRUG DEVELOPMENT SCIENCE

SECTION 1	**Discovery of Medicines**	
SECTION 2	**Development of Medicines: Planning**	
SECTION 3	**Non-Clinical Testing**	
SECTION 4	**Pharmaceutical Development**	
SECTION 5	**Exploratory Development (Molecule to Proof-of-Concept)**	
SECTION 6	**Confirmatory Development: Strategies (Proof-of-Concept to Market)**	
SECTION 7	**Clinical Trials**	
SECTION 8	**Ethics and Legal Issues**	
SECTION 9	**Data Management and Statistics**	
SECTION 10	**Regulatory Affairs**	
SECTION 11	**Drug Safety and Pharmacovigilance**	
SECTION 12	**Information, Promotion and Education**	
SECTION 13	**Economics of Healthcare**	
SECTION 14	**Therapeutics**	

SECTION 1. Discovery of Medicines		
1.1	Strategy and organisation of research including collaborative approaches e.g. with academia	
1.2	Disease models, target identification, validation and selection	
1.3	Receptor-based approaches: agonists, antagonists, enzyme inhibitors, genomics, proteomics	
1.4	The principle steps in discovering, modifying, assessing and patenting new chemical and biological compounds	
1.5	Other therapeutic approaches e.g. advanced therapies, phytotherapies, herbal products	
1.6	Lead optimisation and candidate compound selection for further development	
1.7	*In vitro* and *in vivo* testing of new compounds	
1.8	Principles of translational medicine	
1.9	Relationship between animal and human pharmacology and physiology e.g. biomarkers, modeling and simulation	
SECTION 2. Development of Medicines: Planning		
2.1	The elements and functions necessary in the integrated development of a new medicine at a corporate and international level	
2.2	Quality management	
2.3	Project management techniques: drug development plan project teams, tools and decision-making from target product profile (TPP) and target product claims (TPC) to registration dossier submission	
2.4	Programme planning in special cases e.g. paediatrics, orphan drugs, elderly	
2.5	Programmes in developing countries	
2.6	R&D portfolio planning including in- and out-licensing of new medicines	
2.7	Resource planning: budgeting and cost control	
SECTION 3. Non-Clinical Testing		
3.1	Pathophysiology-based pharmacology	
3.2	Differences in non-clinical safety and toxicity packages between small molecules	

	and biologicals	
3.3	The fundamental differences and similarities between the pharmacology and toxicology of compounds and their metabolites in animals and man, and their qualitative and quantitative assessment	
3.4	The purpose of descriptive and quantitative *in vitro* and *in vivo* testing	
3.5	The choice of and the predictive value of these tests for acute, chronic, reproductive, genetic and immune toxicology, and carcinogenicity	
3.6	Common mechanisms of damage to organs and their detection or elucidation	
3.7	The scheduling of toxicology tests linked to development plans, to regulatory needs, to human and animal pharmacology, and to intended clinical use and route(s) of administration	
3.8	The size, cost and administration of the toxicology programme; its data management, quality assurance and report writing	
3.9	The regular review of toxicology, its inclusion into clinical trial protocols, and investigator brochures, and the appropriate planning and correlation with the clinical evaluation of potential and observed toxicity in patients	
3.10	Safety pharmacology, hypersensitivity	
3.11	Toxicokinetics; *in vitro* and *in vivo* study of metabolism; ADME	
SECTION 4. Pharmaceutical Development		
4.1	Pharmaceutical development of drug substance and drug product: formulations, manufacture and supply of materials, labelling and presentation, stability and storage, purity, compatibility, disposal including biotechnology products	
4.2	The economic primary production of new compounds and secondary production of research and market formulations	
4.3	The choice of formulations depending upon the characteristics of the compound and the intended uses of the product	
4.4	The principles of testing formulations for bioequivalence, stability, impurity and incompatibility leading to a final specification, including the development of biosimilar formulations	
4.5	The concept of blinding: preparing matching placebo and competitor products	
4.6	Planning clinical trials supply requirements; packaging and labelling of clinical trial supplies (including stability and storage requirements); distributing supplies and disposing of remaining stocks	
SECTION 5. Exploratory Development (Molecule to Proof-of-Concept)		
5.1	Intended therapeutic indications, biomarkers, efficacy end-points and criteria for	

	'go, 'no-go' decisions	
5.2	Assessment of non-clinical data and risk as prerequisite before administration to man	
5.3	Exploratory phase 0 trials	
5.4	The early clinical development plan: the objectives, design, conduct and analysis of early exploratory development studies: modelling and simulation, tolerability, metabolism, pharmacokinetics, pharmacodynamics and safety in man, problems of participant's safety in the concept of blinding.	
5.5	Pharmacokinetics, ADME and pharmacokinetic / pharmacodynamic models	
5.6	Concepts of half-life, volume of distribution, clearance	
5.7	Bioavailability and bioequivalence	
5.8	Drug-drug and drug-disease interactions (extrinsic factors)	
5.9	Studies in different populations (intrinsic factors)	
5.10	Population pharmacokinetics	
5.11	Pharmacogenetics / pharmacogenomics	
5.12	Applicability of pharmacokinetics to dosage regimen and study design	
5.13	First administration to patients: principles of proof of concept and dose-finding studies	
5.14	Impact of results on planned therapeutic indications, on predicted dosage schedule, on additionally required animal toxicology and on drug delivery concepts / forms	
SECTION 6. Confirmatory Development: Strategies (Proof-of-Concept to Market)		
6.1	Final definition of therapeutic indications, categories of patients, delivery system(s), dosage forms and dosage regimens	
6.2	Planning and global coordination / harmonisation of pre-licensing and post-licensing clinical trial programmes; use of non-clinical and existing clinical trial data	
6.3	Estimated treatment population, clinical trial supplies and costs up to registration	
6.4	Decision points, schedules and resources required for a confirmatory clinical development plan (CDP)	
6.5	Life-cycle management planning: extension of therapeutic claims, new formulations, new dosage schedules by peri-marketing trials, post-marketing (surveillance) studies and quality of life measures	
6.6	Regulatory review of existing and emerging research results	
6.7	Strategy for product life-cycle management	

SECTION 7. Clinical Trials		
7.1	Choice of trial design, of placebo and other comparators, of patient populations, of sample size, of locations, of randomisation, of end-points and of statistical analysis	
7.2	New trial designs e.g. adaptive design	
7.3	Non-interventional / observational study design	
7.4	Principles of Good Clinical Practice and procedures applied in all stages of the clinical trial process to ensure subject protection, scientific validity and safety	
7.5	Investigator's brochure: content, review and maintenance	
7.6	Protocol preparation according to ICH E6 and review	
7.7	Feasibility and investigator recruitment	
7.8	Pre-study visits and investigator meetings / investigator training	
7.9	Project management including resources / vendors and budget	
7.10	Contractual arrangements with investigators and contract research organisations including publication rights	
7.11	Clinical trial registries	
7.12	Investigative site management	
7.13	Study medication handling and drug accountability	
7.14	Adverse event assessment and reporting; emergency coverage	
7.15	Monitoring and source document verification	
7.16	Trial Master File	
7.17	Quality management system; SOPs; quality assurance and quality control; independent audits; inspections,	
7.18	Aggregate clinical trial report reviews, including annual reports and common technical document summaries	
SECTION 8. Ethics and Legal Issues		
8.1	Ethical issues in biomedical research and pharmaceutical medicine.	
8.2	Ethics: principles, history incl. Declaration of Helsinki, Directive 2001/20/EC, ethical review, informed consent, safety and human dignity of research subjects.	
8.3	Protection of research subjects, minimising risk incl. site qualification assessment	
8.4	Ethical aspects in research questions and study designs for First-in-Human to post marketing and epidemiological studies, including placebo and comparator choice	
8.5	Conflict of interest and equipoise	

8.6	Ethical aspects in subject contact and recruitment	
8.7	Ethical issues in reimbursement, compensation and inducement	
8.8	Risks, benefits and burden of study participation	
8.9	The informed consent process	
8.10	Privacy, confidentiality and data protection	
8.11	Indemnity, insurance for participants/investigators/institutions, and complaint procedures	
8.12	Ethical aspects in study follow-on	
8.13	Ethical aspects in clinical trials in vulnerable populations	
8.14	Ethical aspects in advanced therapy medicinal products	
8.15	Ethical aspects in clinical trials in third world and emerging countries	
8.16	Fraud and misconduct in biomedical research and clinical development	
SECTION 9. Data Management and Statistics		
9.1	Options for data collection (manual and electronic) and standardisation	
9.2	Case report form (CRF) design and review	
9.3	Creation, maintenance and security of databases, software validation and archiving	
9.4	From source document to CRF completion, CRF review and corrections, data entry, query generation and resolution, coding of adverse events, database lock	
9.5	Within-trial decisions, data management, extraction and manipulation	
9.6	The purpose and fundamentals of statistics	
9.7	Role and responsibilities of the statistician	
9.8	The statistical analysis plan	
9.9	Trial design: pre-trial decisions and specifications; risk factors; confounding variables	
9.10	Hypothesis testing: the null hypothesis, Type I and II errors, significance, power	
9.11	Sample size calculation	
9.12	Minimising bias	
9.13	Types of data and standardisation of measurement	
9.14	Patient-reported outcomes e.g. diaries, quality of life measures	
9.15	Statistical analysis of efficacy end-points and of safety	
9.16	Interim analysis	
9.17	Paired and non-paired tests, parametric and non-parametric tests, confidence limits	

9.18	Handling of rating and visual analogue scales, patient diaries and laboratory values	
9.19	Handling of missing data	
9.20	Sensitivity and specificity of tests	
9.21	True and apparent incidence and prevalence	
9.22	Interpretation of analyses; assessment of violations, withdrawals, errors, bias	
9.23	Statistical principles and issues in statistical report writing: data manipulation, transformation, merging, preparation of the statistical report	
9.24	Clinical interpretation of trial results	
9.25	Dealing with confounding factors and bias	
9.26	Critical review of publications.	
SECTION 10. Regulatory Affairs		
10.1	Background to and general principles of medicines regulation	
10.2	Philosophy of regulatory oversight; practical input of international bodies e.g. WHO, WMA, CIOMS etc and national agencies	
10.3	The evolution of control mechanisms; differences between agencies	
10.4	Activities and contribution of International Conference on Harmonisation (ICH).	
10.5	Good Manufacturing Practices; Good Laboratory Practices; Good Clinical Practices	
10.6	Integration of regulatory affairs into pre- and post-marketing; planning and review of product strategy.	
10.7	The approval, appeals and referrals processes in Europe, aspects of confidentiality / transparency and updating; maintaining Marketing Authorisations	
10.8	Orphan drugs, paediatric data, advanced therapies, biosimilars, generics	
10.9	Medicines regulation in EU in comparison with the USA, Japan and emerging markets	
10.10	Clinical Trials regulations; EU Directives and Guidances and their diversity in national implementation, CTA including IMPD substantial amendments. Clinical trial regulations in other regions e.g. the US IND process	
10.11	Common Technical Document (CTD and eCTD), Overviews	
10.12	The preparation and submission of marketing applications in major countries (MAA, NDA, JNDA, CNDA); regulatory management systems in Europe, US, Japan and local special regulatory requirements and the various authorisation procedures	
10.13	Product Information regulation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets; Prescribing Information	
10.14	Advertising and promotion regulation: promotional material	
10.15	Prescription-only versus over-the-counter medicines	

10.16	Provisions for and use of unlicensed medicines.	
10.17	Product defects and recall	
10.18	Medical device regulations	
10.19	Pharmacopoeias	
10.20	Risk management: Risk Management Plans (RMPs) in the EU; Risk Evaluation and Mitigation Strategies (REMS) in the USA	
10.21	Safety Specification	
10.22	Direct Healthcare Professional Communication	
10.23	Product withdrawal procedures	
10.24	Drug abuse and dependence	
10.25	Off-label use and misuse	
SECTION 11. Drug Safety and Pharmacovigilance		
11.1	The role of the pharmaceutical professional in drug safety and pharmacovigilance	
11.2	Assessment and classification of adverse events (AEs), adverse drug reactions (ADRs), Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs)	
11.3	The concept of benefit / risk assessment, determination of causal relationship between the medicinal product and the adverse event.	
11.4	Collection of adverse events in clinical trials	
11.5	Role of sponsors and investigators in reporting, and regulatory requirements	
11.6	Predisposing factors in health and disease	
11.7	Spontaneous reporting post-marketing	
11.8	Dosage, accumulation, medication errors and interactions	
11.9	Periodic Safety Update Reports	
11.10	Pharmacoepidemiology	
11.11	Main sources of epidemiological pharmacovigilance information	
11.12	Signal detection, interpretation and management	
11.13	Post-authorisation safety studies	
11.14	Post-authorisation risk management including Issue and crisis management	
11.15	Assessment of evidence for causality and association	
SECTION 12. Information, Promotion and Education		

12.1	Principles and practice of marketing, market analysis	
12.2	Information to patients and patient organisations, prescribing and compliance	
12.3	Product Information content and preparation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets; Prescribing Information	
12.4	Product support and promotion	
12.5	Codes of conduct: promotional policy and procedures, Good Promotional Practice	
12.6	Advertising: claims, ethics, control and approval	
12.7	Publication strategy	
12.8	Sales representative training: material and aids	
12.9	Educational meetings; sponsored meetings and sponsored publications	
SECTION 13. Economics of Healthcare		
13.1	Principles of healthcare economics; principles of justice and equity in healthcare economics	
13.2	Evidence Based Medicine; outcomes research	
13.3	Quality of Life, concept and measurement instruments	
13.4	Market structure and competition, price negotiations, national and local formularies (reimbursement)	
13.5	Measurement of healthcare efficiency, governmental policy and third party reimbursement	
13.6	Economics of industry, competition, licensing, co-marketing	
13.7	Financial control, return on investment, fixed assets, budgeting, accounting, profitability	
13.8	Generics, parallel imports, OTC; switching strategies	
13.9	Health Technology Assessments (HTA) including meta-analyses and systematic reviews; health economics evaluation studies	
SECTION 14. Therapeutics		
14.1	Major therapeutic areas: epidemiology, pathophysiology, diagnosis and treatment	
14.2	Major areas of unmet medical need: epidemiology, pathophysiology, diagnosis and treatments	
14.3	Major drug classes, including small molecules, biologicals, advanced therapies: mode of action, use, safety, benefit-risk balance	

14.4	Gene therapy, somatic cell therapy, tissue, medical devices, device-drug combinations, vaccines: mode of action, use, safety, benefit-risk balance	
14.5	Drug-related Diagnostics	
14.6	Prescribing for particular populations e.g. children, elderly, pregnant and breast-feeding women, patients with renal or hepatic impairment	
14.7	Drug interactions	
14.8	Controlled drugs, drug abuse and drug dependence	
14.9.	Overdose and treatment of poisoning	
14.10	Therapeutic drug monitoring	

ASSIGNMENT EVALUATION SHEET

MODULE:		**DEADLINE:**	
STUDENT NUMBER:		**SUBMISSION DATE:**	
Title of assignment:			
Rate by providing credit points from best (5) to worst (1)			

Selection and coverage of material			
Question answered	*Completely (5)*		*Not at all (1)*
Independent study	*Strongly evident (5)*		*No evidence (1)*
Material chosen	*Appropriate (5)*		*Irrelevant (1)*
Presentation of material	*Accurate (5)*		*Inaccurate (1)*
Understanding			
Arguments	*Sound, well supported (5)*		*Absent, inaccurate,*
Original thought	*Strongly evident (5)*		*No evidence (1)*
Critical evaluation	*Strong (5)*		*Absent or inaccurate (1)*
Structure and presentation			
Logic and structure	*Strongly evident (5)*		*Absent (1)*
Clarity of expression	*Excellent (5)*		*Poor, confused, verbose*
Tables and graphics	*Clear, support text (5)*		*Poor, unclear redundant*
Outside reading	*Strongly evident (5)*		*Absent (1)*
References	*Accurate (5)*		*Inaccurate (1)*

Add the individual points and enter the sum into box below. Maximal sum of points: 60 (100%)

1st MARKER		**2nd MARKER**		**AVERAGE POINTS:**	
1st MARKER		**2nd MARKER GRADE**		**AVERAGE GRADE**	

Grades are based on the sum of credit points. Grades that differ with ≥ 2 marks between 2 markers will be

Grades: 5(60-54; 100-90%); **4**(53-45; 89-75%); **3**(44-36; 74-60%;); **2**(35-30; 59-50%); **1** /fail/ (< 30;

MODULE:		**DEADLINE:**	
STUDENT NUMBER:		**SUBMISSION DATE:**	

Title of assignment:	
FIRST MARKER COMMENTS:	
FIRST MARKER SIGNATURE:	**DATE:**

MODULE:		**DEADLINE:**	
STUDENT NUMBER:		**SUBMISSION DATE:**	

Title of assignment:	
SECOND MARKER COMMENTS:	
SECOND MARKER SIGNATURE:	**DATE:**

Multiple choice questions (MCQs): guidance notes for candidates

PharmaTrain examinations use two different types of multiple choice questions (MCQ): "Multiple True-False questions" and "Single Best Answer question". Each examination paper will tell you clearly what type of MCQ it contains. These notes explain how these two types of question differ and what you are expected to do when you answer them. Some simple (trivial!) examples are shown.

Multiple true-false questions

Multiple true-false questions consist of a question or a statement followed by a number of suggested answers. The question will be worded so that any number of the suggested answers could be correct. The completions are independent of each other so that any number may be "true" or "false" even if for a particular MCQ, only one is actually true or false. You have to write on your answer sheet which of the answers you think are "true" and which are "false". For some questions, all will be correct. For others 1 or 2 or 3 or 4 will be correct, and for some questions all of the completions might be wrong.

Examples

1	Which animals have 4 legs?	Correct answer
A	Bird	F
B	Cat	T
C	Crab	F
D	Dog	T
E	Rat	T

2	Which animals have 4 legs?	Correct answer
A	Bee	F
B	Crab	F
C	Dog	T
D	Prawn	F
E	Spider	F

3	Which animals have 4 legs?	Correct answer
A	Bee	F
B	Bird	F
C	Crab	F
D	Prawn	F
E	Spider	F

4	Which animals have 4 legs?	Correct answer
A	Cat	T
B	Dog	T
C	Mouse	T
D	Pig	T
E	Rat	T

All the examples ask the same question. You can see that, depending upon what the suggested answers are, any number can be true. Thus, 3 answers are true in Q1 (and 2 false); 1 is true in Q2; all are false in Q3 and all are true in Q4. Even when only one of the answers is actually true, as in Q2, it was possible that other answers might have been true if you didn't know the answer. So these are all multiple true-false MCQ.

When we mark your answers, we will give you credit for every completion that you get correct. We will <u>not</u> deduct marks for any that you get wrong. So, if a completion is true and you say it is true, you get credit; if a completion is false and you say it is false, you get credit. If a completion is true and you say it is false, or one is false and you say it is true, you will get no credit. You will also get no credit if you do not give a

response (leave it blank). You should give a response for every answer, even if you think it is false or you need to guess.

Single best answer questions

Single best answer questions are worded so that only one completion can possibly be true, that is, it is "the best". In English, this is generally indicated by a word ending in "-est" such as best, highest, greatest, longest or by the use of the word "most" e.g., most likely, most appropriate. In this type of question, you will be shown a list of suggested answers and you must choose the one that you think is the best, i.e., better than all the others. In the single best answer MCQ, the completions are not independent of each other: only one can be "the best" by comparison with the other, which may not be absolutely wrong, just less good. Candidates must use their judgment to choose which one of the plausible completions is the best. This tests problem-solving skills in applying knowledge to make deductions from different pieces of information.

Example

A friend gives you a glass of alcoholic drink. You will be driving so you ask how strong it is. Your friend says it is 12.5% alcohol.

What type of drink is it most likely to be?

A Beer

B Cocktail

C Sherry

D Whisky

E Wine

Correct answer E

Note that some of the other answers could contain 12.5% alcohol: there are some very strong beers and, depending upon the amount of soft drink added, cocktails could be 12.5%, etc. Also, some wines are weaker and others stronger than 12.5%. However, the question asks which is most likely; this is wine.

You get credit for identifying the correct answer. If you give no response or if you give more than one answer, you will get no credit.

Overall grading at the end of the module:

The grading will be based on the % of correct answers. The maximum number of correct answers will be calculated for each session separately considering the selected MCQs

5 (100-90%); **4** (89-75%); **3** (74-60%); **2** (59-50%); **1** (failed) < 50%)