



Continuing Professional Development / Masters of Advanced Safety Sciences Degree

Full Course Brochure
2010 – 2012

European Modular Education and Training Programme
in Safety Sciences for Medicines

Contents

Target audience.....	3
Principle Learning Outcomes.....	3
MSc of Advanced Safety Sciences and CPD	3
How to Apply.....	4
Entry requirements.....	4
MSc of Advanced Safety Sciences.....	4
Applicants who do not wish to register for an award but as a CPD course	4
Application	4
What happens next?	4
SafeSciMET Course Fees and Discounts.....	4
Core Courses.....	5
Fact File.....	5
Course information	
Course 1.1 Drug Discovery and Development	6
Course 2.1 Pharmaceuticals and Safety.....	7
Course 2.2 Regulatory Requirements and Guidelines	7
Course 2.3 Pharmacokinetics and Pharmacodynamics	8
Course 3.1 Laboratory Animals, Alternatives and Ethics.....	8
Course 4.1 Biochemical and Molecular Toxicology: Biotransformation, Bioactivation and Adverse Drug Reactions.....	9
Course 4.2 Cellular Toxicology / Predictive Toxicology.....	10
Course 4.3 Organ/Systems Toxicology	11
Course 4.4 Reproductive Toxicology.....	11
Course 4.5 Mutagenesis and Carcinogenesis.....	12
Course 4.6 Translational Safety Pharmacology	12
Course 5.1 Non-Clinical Safety Assessment Strategies, Ethics and Protocols.....	13
Course 5.2 Biomolecular Analysis: From Method Development to Clinic.....	13
Course 5.3 Predictive Cell Culture Systems.....	14
Course 5.4 Toxicogenomics and Systems Toxicology	14
Course 5.5 Animal and human pathology, histology and pathophysiology.....	15
Course 5.6 In silico ADME and Predictive Toxicology.....	15
Course 6.1 Clinical Safety: Pre-Approval.....	16
Course 6.2 Clinical Safety: Post-Approval.....	16
Course 6.3 Stratification: Pharmacogenetics and Drug Safety	17
SafeSciMET Consortium Partners	18
Public Partners.....	18
EFPIA Partners.....	18
IMI Education and Training SafeSciMET Course Programme.....	19

SafeSciMET presents a new and unique pan-European education and training network, developing and establishing a comprehensive modular Education and Training Programme in Safety Sciences for Medicines. SafeSciMET will fulfil the needs of pharmaceutical industry, regulatory authorities and academia to bridge crucial gaps in the education and training of scientists evaluating the safety of drug candidates and new medicines.

SafeSciMET, consisting of top institutes for drug safety education and research, proposes a new type, high quality and sustainable programme for education and training in Safety Sciences for Medicines, emphasis on translational and integrated safety assessments as needed in drug development and usage.

Target audience

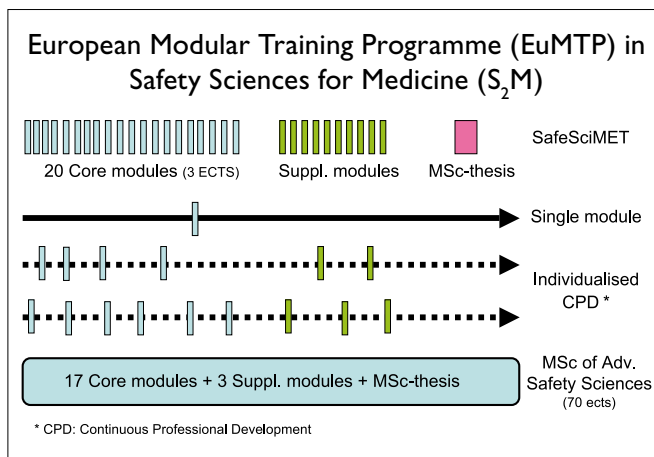
SafeSciMET courses are open to all scientists from industry, academia and regulatory agencies. The applicant will normally possess an MSc degree in a Life Science discipline or equivalent. In addition, applicants are expected to have at least one year's work experience in a related discipline. For other participants no formal entrance requirements are set, although a scientific background with at least an honours degree level is recommended.

Principle Learning Outcomes

SafeSciMET will ensure that Europe's biomedical education landscape is enhanced to provide maximum support in revolutionizing the conventional drug discovery and development paradigm.

SafeSciMET will provide novel competences in translational safety sciences, an aspect which was found largely lacking in today's educational programmes.

It will lead to a new generation of safety scientists who are able to perform holistic and critical evaluations of the safety of drug candidates and new medicines. Linking animal and human data more effectively, both in vitro and in vivo, will contribute to a better understanding of



drug safety and how to bridge and make best use of animal and human data collected in drug development and safety assessment.

MSc of Advanced Safety Sciences and CPD

A set of **20 core and a number of supplementary courses** will be made available. Course teachers will come from academia and industry throughout Europe, including Eastern Country States. The modular set up has major advantages:

- part-time study, spread over 2 – 5 years, is possible
- participants can follow single courses, follow sub-sets of the programme aiming at CPD-diplomas, or join the full MaS₂M programme
- dedicated quality assurance for courses, and
- the programme can be adapted to cope with new scientific insights in safety sciences and legislation or the emergence of new top-institutes for safety sciences. Apart from the core courses, a set of supplementary courses will be selected in due course. The periodicity at which the programme will be delivered (in one or two years) will be based on market research conducted as part of the preparation year of the programme.

All courses have a common format (set at 3 European Credit Transfer and Accumulation System ECTS) and will consist of one week of training by multiple teachers at an academic centre or industry location, concluded by an exam and followed by a week of self study and/ or E-learning through case studies. Each course will include translationally oriented case studies provided by the stakeholders. In this context, 'translational' typically refers to the translation of basic research into therapies for real patients.

The emphasis is on the linkage between the laboratory and the patient's bedside (i.e. 'From Molecule to Patient'). Translational drug (or medicines) safety sciences concerns all 'safety related aspects'.

The core courses will mainly be newly developed with emphasis on the integrative, translational and ethical aspects. The supplementary courses will be selected from courses offered by partners in the Network, by other IMI E&T consortia or by other third parties. Supplementary courses have to fulfil the required SafeSciMET standard.

How to Apply

Entry requirements

Participants on this programme are normally science, medical or veterinary graduates either currently working in a safety science environment or seeking to use a knowledge on safety science in some area of their career. Competence in both written and spoken English to an IELTS level or equivalent of 7.0 is an absolute requirement.

Delegates can also attend courses as "stand alone" for Continuing Professional Development (CPD).

MSc of Advanced Safety Sciences

Applicants who wish to register for the Advanced Master will normally possess a minimum of a higher academic qualification at least to Master of Science degree or equivalent in a relevant subject.

Applicants who do not wish to register for an award but as a CPD course

No formal entrance requirements are set, although a scientific back-ground with at least an honors degree level is recommended.

Application

You can apply for an MSc of Advance Safety Sciences, for Continuing Professional Development (CPD), or for Single Courses.

You upload a CV/biosketch and diplomas or certificates, if available, to show that you are eligible to take part in the SafeSciMET programme.

What happens next?

When you have applied as indicated on the previous page, your qualifications will be scrutinized by the Student Office at Uppsala University, under the supervision by an Admission Board constituted by SafeSciMET.

Within one week after application deadline you will be informed if you are accepted as a student.

You will also get a password to enter BlackBoard (Bb), administered by the Vrije Universiteit Amsterdam. Here all further communication between you and your teacher(s) take place.

Congrex® (Sweden) will instruct you how to pay the course fee.

SafeSciMET Course Fees and Discounts

Employment	€ per course
Industrial	2500
Governmental	1500
Academic	750
New Member State	400

- a) **Multiple participants from the same organization:**
2nd participant: 20% reduction; 3rd and following participants: 30% reduction.
- b) **Multiple courses for the same participant:**
3 – 5 courses: 20% off each; 6 – 9 courses 30% off each, 10 or more courses 40% off each.
- c) **Entire SafeSciMET Advanced MSc-curriculum:**
For the entire MSc-curriculum covering 20 courses, 50% reduction is offered, if signed up before completion of the first 3 courses.
- d) **Participants from EFPIA SafeSciMET partners:**
Participants from EFPIA SafeSciMET partners are not eligible for discounts, until their respective in kind contribution quota are reached.
SafeSciMET is supported financially by EU and members of European Federation of Pharmaceutical Industries and Associations (EFPIA) under the umbrella of Innovative Medicines Initiative (IMI).
Course fees for the SafeSciMET courses of participants employed by those EFPIA companies should be paid as instructed on this page.
The EFPIA companies will be continuously informed on their financial contribution by the fees paid.
- e) **Cancellations policy:**
Cancellation of a pre-registered student is possible, upon written notice until 4 weeks in advance. Before that date the Course fee will be refunded except for an administrative fee of EUR 75.- After that date, no refunds can be made for cancellations. Substitutions may be made at any time provided that the entrance level requirements are fulfilled.

Please visit www.SafeSciMET.eu for details of the full course programme and confirmation of course dates.

Core Courses

Programme Overview

The course modules in the SafeSciMET programme are clustered within 6 separate domains . Each do-main represents one or more specialized topics. They are:

DOMAIN 1 Drug Discovery and Development

DOMAIN 2 Pharmaceutical Aspects of Drug Safety

DOMAIN 3 Laboratory Animals and Alternatives

DOMAIN 4 Adverse Drug Reactions / Predictive Toxicology/3R's

DOMAIN 5 Non-Clinical Safety Assessment, incl. 3R's

DOMAIN 6 Clinical Safety Assessment, incl. Methods

Fact File

Typical entry requirements

The applicants will normally possess an MSc degree in a Life Science discipline or equivalent. In addition, applicants are expected to have at least one year's work experience in a related discipline. For other participants no formal entrance requirements are set, although a scientific background with at least an honours degree level is recommended.

Programme length & Assessment

Each course will consist of one week of training by multiple teachers from academia and industry at an academic centre, concluded by an exam and followed by a complimentary week of self study and/or e-learning options where acquired knowledge is applied to real life case studies. The complimentary week can be done immediately after the weeks course or at a later date specified in the course brochure.

Planned Intake

30 students per course module

DOMAIN 1

Drug Discovery and Development

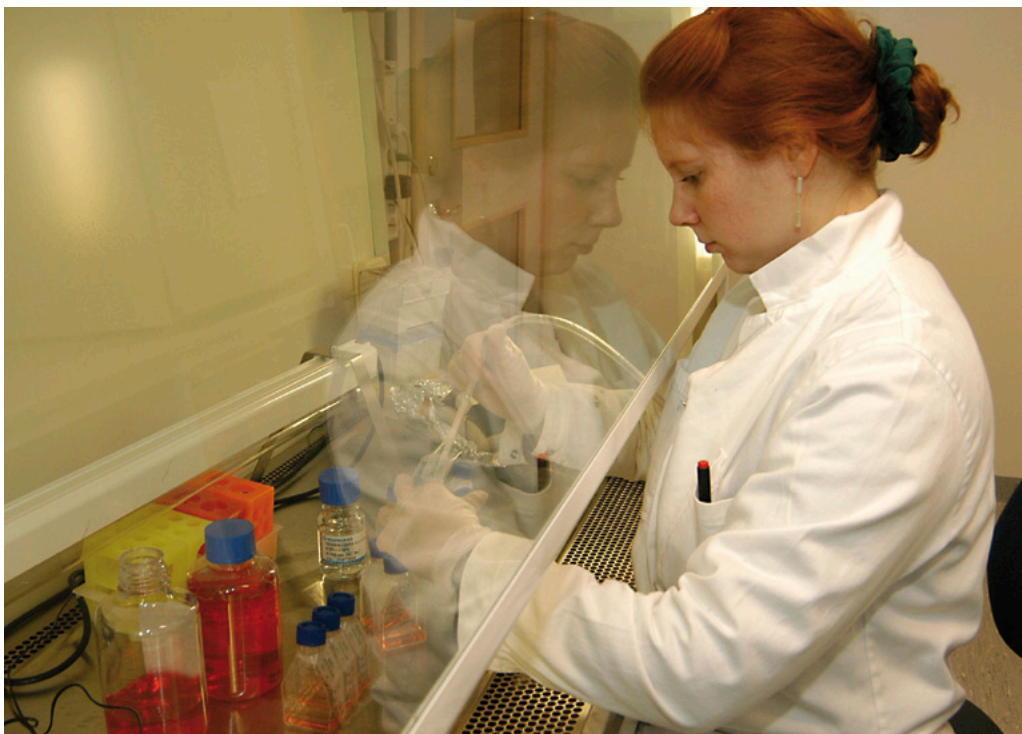
Course 1.1 Drug Discovery and Development 1 – 12 November 2010

Course Objectives

This course will provide participants with a comprehensive overview of the steps in drug development from discovery to marketing approval with special emphasis on drug safety, providing an ideal background for the more detailed and specific courses that will make up the rest of the programme.

Key areas covered by this course

- Roadmap to drug discovery and development
- Target evaluation and validation
- Lead optimization and synthesis
- Pharmacology and animal biology
- Pharmacokinetics, safety pharmacology and toxicology
- Development of biologics
- Pharmaceutics
- Translational medicine
- Clinical development and safety
- Regulatory process
- Health economics, IP and marketing



DOMAIN 2

Pharmaceutical Aspects of Drug Safety

Course 2.1 Pharmaceuticals and Safety 28 February – 4 March 2011

Course Objectives

The course will introduce the various aspects of the administration, the formulation, and the manufacturing of medicines.

Key areas covered by this course

- Administration routes and drug formulation
- General pharmaceuticals
- Excipients and dosage forms
- Unit operations and manufacturing
- Regulatory aspects



Course 2.2 Regulatory Requirements and Guidelines 26 – 30 September 2011

Course Objectives

This course will provide participants with a comprehensive overview of the drug development process and of the required nonclinical studies for the characterization of the potential benefits and risks associated to their human use, from clinical trials into the marketing. The International and European guidelines for different studies, their use and their adaptations will be discussed and presented. The course intends to provide the participants with the knowledge for planning nonclinical development programs for different types of new drugs intended to treat a variety of pathologies.

The basis for the interpretation, integration and translation of the outcome of the different studies into man will be provided.

Key areas covered by this course

- Overview of drug development program and studies; concepts of Good Laboratory Practice, vaccines, orphan, paediatric, oncological drug developments;
- The regulatory requirements for clinical trials, for use in pregnant and fertile populations and for marketing authorization; the ICH process.
- In vitro and in vivo nonclinical studies; the 3Rs principles
- Species selection, criteria for species relevance and translational principles
- First in human studies and criteria for first dose estimation
- Translational aspects of pharmacokinetics and toxicokinetics
- Special nonclinical studies, immunotoxicity
- Particular aspects of biopharmaceuticals including biosimilarity

Course 2.3 Pharmacokinetics and Pharmacodynamics 4 – 8 April 2011

Course Objectives

The course consists of 5 days in Uppsala with lectures and casework followed by a week at home dedicated to individual assignments. It is built around case studies provided by the EFPIA partners and aims to integrate discussions on methods and their applications. It will thus provide both theoretical knowledge and practical understanding of PK/TK, PD/TD and their applications.

Key areas covered by this course

- Principles of ADME (PK/TK), with focus on conventional low molecular weight drugs and some discussion on biologicals
- In vitro-in vivo correlations and interspecies scaling of PK
- Preclinical applications of ADME(T)
- Principles and applications of PK/PD and TK/TD modelling
- Causes of inter-individual variance in PK/TK
- PK/TK and PD/R+TD in preclinical and clinical drug development

DOMAIN 3 Laboratory Animals and Alternatives

Course 3.1 Laboratory Animals, Alternatives and Ethics

Please contact: info@safescimet.eu

Course Objectives

The course aims to introduce the various aspects of the use of animals for drug development and testing.

Key areas covered by this course

- Ethical, welfare, and legislative aspects of using animals for research (20 %)
- Application of the 3Rs (20%)
- Animal models (30 %)
- Experimental setup and evaluation (30 %)



DOMAIN 4

Adverse Drug Reactions/ Predictive Toxicology/3R's

Course 4.1 Biochemical and Molecular Toxicology: Biotransformation, Bioactivation and Adverse Drug Reactions 27 June – 1 July 2011

Course Objectives

The course will provide participants with an overview of different types of ADME studies but with an emphasis on bioactivation and reactive, active and disproportionate metabolites. The course will focus on the biological effects of metabolites (cellular targets and defense systems) and potential safety concerns resulting from perturbation of these processes (e.g. through drug interactions).

Key areas covered by this course

- ADME studies and how they are integrated into drug development
- Role of drug metabolism in pharmacokinetics, toxicology and clinical adverse drug reactions.
- Current regulatory guidance on metabolites and drug interactions
- Biotransformation of drugs in general but with an emphasis on active, reactive and disproportionate metabolites.
- Enzymology of drug metabolizing enzymes and role of genetic factors.
- Drug interactions and adverse events resulting from induction or inhibition of human enzymes/transporters.

- Cellular targets of reactive metabolites and resulting toxicological consequences.
- Constitutive and inducible defense systems against reactive metabolites.
- Hypotheses concerning molecular mechanisms underlying idiosyncratic drug reactions.



SafeSciMet – Network for Translational Safety Sciences for Medicines Training

See page 18 for a full list of Academic and Industry partners.

Course 4.2 Cellular Toxicology / Predictive Toxicology 20 – 24 June 2011

Course Objectives

This course will provide participants with a comprehensive overview of how cells deal with chemical stress at the molecular and cellular level and make them familiar with the fundamentals necessary to understand cellular mechanism of adverse drug reactions. This knowledge will help to evaluate unknown compounds and will create an understanding for identifying weak points as well as for the recognition where, when and how specialist of a given field will have to become involved in order to achieve a multidisciplinary solution to the issue at hand.

Key areas covered by this course

- Consequences of cell injury and biochemical mechanisms
- Cellular defense mechanisms against cell stress.
- Molecular mechanisms of cellular senescence, autophagy or cell death.
- Intra- and intercellular signaling and mechanisms of cell injury.
- Translation of cell injury to in vivo models and the clinic.
- Molecular mechanisms of idiosyncratic drug toxicities.
- Molecular mechanisms of ADRs and drug development.
- Stem cell technology and applications in understanding mechanisms of toxicity.
- Functional genomics technologies in understanding cellular mechanisms of adverse drug reactions.



Course 4.3 Organ/Systems Toxicology **10 – 14 October 2011**

Course Objectives

This course will provide participants with a comprehensive overview of organ specific toxicity and therefore make them familiar with the fundamentals necessary to understand toxicological mechanisms. This knowledge helps to evaluate unknown compounds and creates an understanding for identifying weak points as well as for the recognition where, when and how specialist of a given field will have to become involved in order to achieve a multidisciplinary solution to the issue at hand.

Key areas covered by this course

- Physiology and function of main organs systems
- Acute, subchronic and chronic effects
- Apical, pre-clinical and clinical endpoints
- Mechanistic understanding of toxicity (molecular, biochemical, pathological level)
- Distinction between primary organ with subsequent systemic effects from prima facie systemic effects
- Extrapolation from animals to humans
- Experimental design
- Principal requirements for the detection, robust analysis and evaluation of end points
- Statistical evaluation of endpoints and measure for extrapolation



Course 4.4 Reproductive Toxicology **31 October – 4 November 2011**

Course Objectives

This course will provide participants with a comprehensive overview of the various aspects of reproductive toxicology from fertility impairment, possible disturbance of prenatal and postnatal development and others. Thus the total course will provide participants with a comprehensive overview of the various aspects of reproductive toxicology from fertility impairment, possible disturbance of prenatal and postnatal development and others.

Key areas covered by this course

- Morphology and physiology of the male and female reproductive tract
- Prenatal and postnatal development of the mammalian organism
- Standard testing for fertility impairment and developmental toxicity
- Developmental neurotoxicity
- Developmental immunotoxicity
- Reproductive toxicity of selected drugs and workplace chemicals
- Relevance of maternal toxicity
- Pharmacokinetic issues in reproductive toxicology
- Endocrine disrupting chemicals
- Toxicogenomics in developmental toxicology
- Guidelines (ICH, OECD etc.)

Course 4.5 Mutagenesis and Carcinogenesis **28 November – 2 December 2011**

Course Objectives

This course will provide participants with a comprehensive overview of principles in mutagenesis and carcinogenesis. This knowledge will help successful attendees to identify and to characterise mutagenic and/or carcinogenic action of chemical compounds. They also will achieve skills allowing them to interpret safety data for risk assessment and to perform risk-benefit evaluations.

Key areas covered by this course

- Overview on the biology of carcinogenesis
- Basic principles in mutagenesis and carcinogenesis
- Prototypical examples of the action of chemical mutagens/ carcinogens at the cellular, biochemical, and molecular level
- Design of proper experimental setups to specifically identify mutagenic/carcinogenic compounds
- Interpretation of dose-response curves
- Extrapolation from experimental data to humans
- Training to review and to assess safety data generated for prototypical mutagenic/carcinogenic compounds
- Estimation of the probability of occurrence of mutagenic and/or carcinogenic effects (risk assessment)
- Contribution to risk-benefit evaluation

Course 4.6 Translational Safety Pharmacology **9 – 13 January 2012**

Course Objectives

This module aims to introduce the principles of translational safety pharmacology and how it is used to build Confidence in Safety including pharmacology, physiology as it relates to how we adapt to chemical exposure, identification and management of risk to humans, chemical design, variation in drug metabolism, allergic reactions to drugs, immunological toxicology, PK-PD modelling and biomarkers of drug safety.

Key areas covered by this course

- Chemical and molecular basis of on- and off- target adverse drug reactions
- The ADME of drug safety: species and individual variation
- In vitro / ex vivo and in vivo models of ADRs
- Biomarkers of drug safety and general concepts
- Use of integrated animal models in safety pharmacology
- Organ-specific safety pharmacology – different organ systems
- Safety pharmacology of biotechnology agents
- Emerging trends in safety pharmacology
- Implications for rational chemical design and re-design
- Case studies

DOMAIN 5

Non-Clinical Safety Assessment, incl. 3R's

Course 5.1 Non-Clinical Safety Assessment: Strategies, Ethics and Protocols **23 – 27 January 2012**

Course Objectives

This course will provide the participants with a comprehensive overview of the steps in a non-clinical safety programme and inter relationships with other components of drug discovery and development covered by the remainder of the SafeSciMET programme.

Key areas covered by this course

- Regulatory requirements behind non-clinical safety testing
- Investigative toxicology and pathology
- Experimental design and application of the 3 R's
- Translation from non-clinical to first in human studies
- Special approaches and special products
- The role of non-clinical safety assessment in drug development

Course 5.2 Biomolecular Analysis: From Method Development to Clinic **30 January – 3 February 2012**

Course Objectives

The objectives of the course are that knowing the physicochemical properties of the analytes, either low- or high-molecular weight, the required sample pre-treatment, separation, detection and identification procedures can be predicted by using decision trees. Using the same physico-chemical properties both instrumental analytical and assay formats can be optimized and matrix-effects can be recognized and solved.

Key areas covered by this course

- Physico-chemical parameters at the basis of method development
- Bioanalytical strategies for small molecules: sampling, sample pre-treatment, separation, detection, validation and data handling.
- General consideration in bioanalytical strategies for biopharmaceuticals
- PK, PD, and biomarker assay formats
- Development of immunogenic assay strategies: background, assay strategies, predictive immunogenicity
- Integrated bioanalytical assay strategies
- Novel developments: therapeutic oligonucleotides, reactive drug metabolites, profiling of body fluids and metabolomics



Course 5.3 Predictive Cell Culture Systems 13 – 17 February 2012

Course Objectives

This course will provide the participants with a comprehensive overview of predictive cell culture systems and special emphasis on application of the in vitro models to drug discovery and development. Thus the total course will provide the participants with a comprehensive overview of predictive cell culture systems with special emphasis on application of in vitro models to drug discovery and development.

Key areas covered by this course

- Limits and strengths of permanent versus primary cells
- Robust parameters to monitor cell functions
- Early cellular responses to stressors
- Test batteries for cytotoxicity and cellular dysfunction
- Competence to cope with oxidative/cellular stress
- Pathways of toxicity involving impairment of glutathione
- Use of 'omics technologies to identify critical pathways of toxicity
- Cell cultures systems to detect substrates/inductors of cytochrome P450/drug metabolizing enzymes
- Search for drug targets versus drug safety using in vitro tests
- Requirements on cell culture systems for screening/high throughput techniques
- Alternative methods and regulatory requirements



Course 5.4 Toxicogenomics and Systems Toxicology 19 – 23 March 2012

Course Objectives

This course will provide participants with established and novel methods in toxicogenomics and systems toxicology research and their application in drug safety and in individual toxicant responses. It aims to introduce the principles of the various genomic and bioinformatics tools used in toxicogenomics, as well as the design of such studies, the statistical evaluation and biological interpretation of the data, cross-platform consistency and extrapolations from in vitro to in vivo, and from animal to man.

Key areas covered by this course

- Design of DNA-microarray experiments.
- Quality Control, data pre-processing, normalisation and statistics.
- High-throughput data visualisation and presentation.
- Other -omics technologies for safety evaluation: (phospho)-proteomics and metabolomics.
- Building biological networks and systems toxicology.
- (High throughput) functional genomics screening to identify biological networks.
- Genetic susceptibility and inter-individual variation.
- Predictive toxicology and omics-based biomarkers of adverse effects.
- From in vitro to in vivo and extrapolations from animal data to the human situation.
- Regulatory aspects, toxicogenomics data and drug registration.
- Perspectives for future developments in toxicogenomics and systems toxicology and their possible applications in drug research.
- Emphasis on the development, validation and use of relevant biomarkers in toxicology and early phase clinical development.

Course 5.5 Animal and human pathology, histology and pathophysiology **16 – 20 April 2012**

Course Objectives

This course will provide participants with a comprehensive overview of pathology as used in preclinical toxicity assessment. It will cover fundamental mechanisms of pathology and the use of this data in preclinical safety assessment.

Key areas covered by this course

- Pathological processes and causes of cell injury. General pathology including acute and chronic inflammation
- Pathology of organ systems including the immune and cardiovascular system
- Disorders of tissue growth including neoplasia
- Introduction to toxicological pathology
- Integration of anatomic and clinical pathology
- Distinguishing spontaneous from test article related lesions in toxicity studies
- Determining adverse versus non-adverse findings
- Interpretation and reporting of pathology, including data from carcinogenicity studies
- Extrapolation of animal data to human risk assessment
- Specialised techniques used in histology and electron microscopy including image analysis

Course 5.6 In silico ADME and Predictive Toxicology **7 – 11 May 2012**

Course Objectives

This course will provide the participants with comprehensive overview of in silico methods in the drug discovery and development process, where in silico methods can be used, and what their strengths and weaknesses are. Further more participants will get hands on experience with several predictive in silico methods as well as get an introduction to the principle behind the methods. During the individual assignment you will get the opportunity to focus further on methods relevant for your interest and employment.

Key areas covered by this course

- The drug discovery and development process – with special focus on ADME/Tox
- Absorption and distribution from a PK point of view
- Critical analysis of experimental data
- Prediction of absorption and distribution
- Phase I and II metabolism – The cytochrome P450 enzymes
- Prediction of metabolism – Classification
- Prediction of metabolism – Site of metabolism
- Genomic effects on metabolism and toxicity
- Different QSAR systems available



DOMAIN 6

Clinical Safety Assessment, incl. Methods

Course 6.1 Clinical Safety: Pre-Approval **28 – 31 May 2012**

Course Objectives

This course will provide participants with an overview of the current knowledge in translational safety and safety management throughout clinical development.

Key areas covered by this course

- Integrated and translational drug safety
- Signal detection and biomarkers
- Clinical safety with organ focus on: immune system, liver, kidney, lung, cardiovascular, vascular system, neurotoxicity
- Clinical trials methodology and safety issues
- Integrated safety management planning
- Risk benefit assessment, stratification and management
- Risk evaluation, mitigation strategies

Course 6.2 Clinical Safety: Post-Approval **11 – 15 June 2012**

Course Objectives

This course will provide participants with an overview of the current knowledge on the clinical assessment and follow-up of drug safety post-approval, and human toxicology.

Key areas covered by this course

- Modalities of detection, analysis and validation of drug induced adverse events (pharmacovigilance)
- Pharmacoepidemiology as a tool for the identification and study of drug induced adverse events
- Diagnosis and management acute drug poisonings
- Risk minimization activities in the post-marketing phase
- Medication errors
- Assessment of drug abuse and misuse
- Occupational safety in workers exposed to active drug ingredients
- Post-approval safety commitment
- Legal, societal and economic aspects of adverse drug reactions



Course 6.3 Stratification: Pharmacogenetics and Drug Safety

27 – 31 August 2012

Course Objectives

This course will provide participants with an overview of the current knowledge in pharmacogenetics with functional importance for adverse drug reactions. This involves the basics of genomics as well as methods for optimal use of pharmacogenetic information.

Key areas covered by this course

- Human genome and web accessible databases
- Methods to identify mutations and to study their functionality
- Clinical important genetic polymorphism of drug metabolizing enzymes
- Clinical important genetic polymorphism of drug transporters
- Pharmacogenetics of importance for therapy of different types of diseases
- Association between certain HLA alleles and adverse drug reactions
- Useful pharmacogenomic biomarkers for prediction of adverse reactions
- Regulatory guidelines for pharmacogenetics in drug development
- Ethical issues in pharmacogenetics and the use of material from biobanks
- Personalized medicine in the future



SafeSciMET Consortium Partners



Public Partners

VU University Amsterdam
University of Konstanz
University of Surrey
EUFEPS
Uppsala University
University of Copenhagen
University of Leiden
Top Instituut Pharma Leiden
University Henri Poincare Nancy
Hospices Civils de Lyon
Martin-Luther-University Halle
Karolinska Institutet Stockholm
University of Vienna
University de Paris-Sud
MRC Centre for Drug Safety Science
University de Lisboa
Charite University Medicine Berlin

EFPIA Partners

Almirall
Astrazeneca Ltd
Bayer-Schering Pharma AG
Boehringer-Ingelheim Pharma
Eli-Lilly & Co Ltd
GlaxoSmithKline Research and Development Ltd
F. Hoffmann-La Roche
H Lundbeck A/S
Merck KGaA
Novartis Pharma AG
Novo Nordisk A/S
Orion Pharma
Pfizer
Sanofi-Aventis
UCB Pharma S.A.

IMI Education and Training SafeSciMET Course Programme

Courses	Course leader Academic/EFPIA	Locations	Course Date
1.1: Drug Discovery and Development	Crommelin/Piner	Copenhagen	1.11.2010 – 5.11.2010
2.1: Pharmaceutics and Safety	Alderborn/von Keutz	Uppsala	28.2.2011 – 4.3.2011
2.2: Regulatory requirements and guidelines	Silva Lima/von Keutz	Lisbon	26.9.2011 – 30.9.2011
2.3: Pharmacokinetics & dynamics	Hammarlund-Udenaes/Morgan	Uppsala	4.4.2011 – 8.4.2011
3.1: Laboratory animals, alternatives & ethics	Kornerup Hansen/Robinson	Copenhagen	Please contact: info@safescimet.eu
4.1: Biochemical & molecular toxicology: Biotransformation, bioactivation and ADRs	Commandeur/Harrel	Amsterdam	27.6.2011 – 1.7.2011
4.2: Cellular toxicology/ predictive toxicology	van de Water/von Keutz	Leiden	20.6.2011 – 24.6.2011
4.3: Organ/Systems Toxicology	Dietrich/Karlsson	Konstanz	10.10.2011 – 14.10.2011
4.4: Reproductive Toxicology	Stahlmann/Bouisset-Leonard	Berlin	31.10.2011 – 4.11.2011
4.5: Mutagenesis and carcinogenesis	Grasl-Kraupp/Martus	Vienna	28.11.2011 – 2.12.2011
4.6: Safety Pharmacology	Park/Holbrook	Liverpool	9.1.2012 – 13.1.2012
5.1: Non-clinical safety assessment: Strategies, ethics & protocols	Schmerold/Taupin	Vienna	23.1.2012 – 27.1.2012
5.2: Biomolecular analysis: From method development to clinic	Niessen/Herling	Amsterdam	30.1.2012 – 3.2.2012
5.3: Predictive cell culture systems	Foth/Mueller	Halle	13.2.2012 – 17.2.2012
5.4: Toxicogenomics and Systems Toxicology	Meerman/Hewitt	Leiden	19.3.2012 – 23.3.2012
5.5: Animal & human pathology, histology and pathophysiology	Price/Haworth	Guildford	16.4.2012 – 20.4.2012
5.6: In silico ADME & predictive toxicology	Steen Jørgensen/(Amberg)	Copenhagen	7.5.2012 – 11.5.2012
6.1: Clinical safety: Pre-Approval	Descotes/van der Auwera	Basel (Roche)	28.5.2012 – 1.6.2012
6.2: Clinical safety: Post-Approval	Descotes/Caplain	Lyon	11.6.2012 – 15.6.2012
6.3 Stratification: pharmacogenetics and drug safety	Ingelman-Sundberg/Johansson/Jones	Stockholm	27.8.2012 – 31.8.2012

For courses already delivered, new dates will be planned for 2013.





European Modular Education and Training Programme in Safety Sciences for Medicines

Website: www.safescimet.eu

E-mail: info@safescimet.eu

Blackboard: bb.vu.nl

Student Office Telephone:

+46-70-167 9130

+46-18-471 0000