DIA EUROPE TRAINING COURSES



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Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

2013 DIA Europe Training Programme

Chemistry, Manufacturing and Controls (CMC) / Quality

 Global CTD Dossier - Regulatory aspects and focus on quality documentation including concepts of Quality by Design

1-3 December 2013 | Dubai, United Arab Emirates | ID 13562

 Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators

11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

Advanced GCP Study Monitoring

5-6 June 2013 | Basel, Switzerland | ID 13549

Clinical Aspects of Quality Risk Management and Quality by Design 19-20 September 2013 | Basel, Switzerland | ID 13560

Clinical Project Management - Part I

18-20 September 2013 | Basel, Switzerland | ID 13572

Clinical Project Management - Part II

25-27 November 2013 | Zurich, Switzerland

■ Clinical Statistics for Non-Statisticians

24-25 October 2013 | London, United Kingdom | ID 13551

Essentials of Clinical Study Management

17-19 April 2013 | Vienna, Austria | ID 13527 20-22 November 2013 | Paris, France | ID 13554

■ Practical GCP Compliance Auditing of Trials and Systems

23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects 19-22 November 2013 | Lisbon, Portugal | ID 13571

Regulatory Affairs

 Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe

18-20 September 2013 | Basel, Switzerland | ID 13546

European Regulatory Affairs: In-depth review of current registration procedures in the European Union

6-7 June 2013 | Basel, Switzerland | ID 13550 21-22 November 2013 | Paris, France | ID 13553

- Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices
 10-12 June 2013 | Amsterdam, the Netherlands | ID 13547
- Health Authority Interactions Preparation, consultation and implementation 15-16 October 2013 | Vienna, Austria | ID 13575
- Health Technology Assessment (HTA)

26-27 November 2013 | Zurich, Switzerland | ID 13561

■ Paediatric Investigation Plans (PIP)

15-16 April 2013 | Amsterdam, the Netherlands | ID 13503

■ The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)

2-4 October 2013 | Basel, Switzerland | ID 13532

 US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US

6-8 November 2013 | Paris, France | ID 13552

Safety and Pharmacovigilance

■ Benefit/Risk Management

13-14 May 2013 | Zurich, Switzerland | ID 13523 26-27 September 2013 | Prague, Czech Republic | ID 13524

- Diagnosis and Management of Drug-Induced Liver Injury (DILI) 19-20 September 2013 | Paris, France | ID 13563
- How to Prepare for Pharmacovigilance Audits and Inspections
 11-12 June 2013 | Nice, France | ID 13555
 7-8 November 2013 | Paris, France | ID 13556
- Pre-Marketing Clinical Safety

18-19 April 2013 | Vienna, Austria | ID 13526

Signal Management in Pharmacovigilance
 10-11 June 2013 | Nice, France | ID 13557
 6-7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

■ EudraVigilance Information Day

19 June 2013 | London, United Kingdom | ID 13529 22 October 2013 | London, United Kingdom | ID 13530

- Excellence in Pharmacovigilance: Clinical trials and post-marketing 18-22 November 2013 | London, United Kingdom | ID 13522
- IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day 10 December 2013 | London. United Kingdom | ID 13531
- EudraVigilance courses:

EudraVigilance – Electronic reporting of ICSRs in the EEA eXtended EudraVigilance Medicinal Product Dictionary Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

DIA Europe Tailored Training

DIA Europe Tailored Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience.

DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.

The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

Contact DIA Europe to discuss your organisation's requirements.

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training

Chemistry, Manufacturing and Controls (CMC) / Quality Training

Global CTD Dossier - Regulatory aspects and focus on quality documentation including concepts of Quality by Design

A high quality registration dossier facilitates the registration procedure essential for generics! This course provides a comprehensive description of the Common Technical Dossier structure – completely updated to reflect the latest changes in pharmaceutical regulatory affairs. The course focuses on the specific regional EU requirements for Module 1 including discussion of the relevant legislation. The requirements for the quality documentation (Module 2.3 & 3) will be presented in detail, taking into account the recent ICH-Q guidelines. The course is for new drug development, but is also very much attractive for generics. In addition, this training course addresses Quality by Design aspects and issues.

KEY TOPICS

- CTD, eCTD
- Regional requirements of EU Module 1
- Regulatory environment:
 - o New applications
 - o Past approval changes
- Risk based approach
- Module 3
 - o Pharmaceutical Development and Quality Risk Management
 - o Quality of Active Substance including Purity Issues (ASMF, CEP)
 - o Impurity Testing
 - o Stability Testing
 - o Setting of Specifications
 - o Design Space
 - o Control Strategy

Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators

In this short course the key elements of Quality by Design (QbD), i.e. Quality Risk Management (QRM), process characterisation, Design of Experiments (DoE), development of a design space and control strategy, as well as the tools of knowledge management will be introduced. In a case study all participants will prioritise the potential critical formulation and process parameters with QRM, propose a DoE to define the critical parameters and eliminate uncritical parameters. The knowledge gained will be used to establish a design space and essential elements of the control strategy. Knowledge management will be introduced to keep the information and knowledge gained both transparent and available for the full lifecycle of the product. The case study will also demonstrate that a systematic approach to pharmaceutical development will be faster and will lead to robust processes. Potential internal savings will be discussed and regulatory flexibility will be discussed with a key European regulator. The course will also give an overview of relevant EU regulations and discuss opportunities for an optimal QbD submission.

KEY TOPICS

- Quality by design for biotech products and small molecules
- Prior Knowledge, Knowledge Management and QTPP Development
- Initial Risk Assessment (FMEA), Introduction to Process Characterisation and Design of Experiments
- Experimental Work, Multi-variate Data Analysis (MVA) and Knowledge Space Establishment

- Design Space Definition
- Control Strategy
- Technologies Assisting QbD Approach
- Regulatory Flexibility and QbD submission strategies
- Post-Approval Change Management Protocol

Clinical Research Training

Advanced GCP Study Monitoring

Clinical research monitors perform a critical role in the conduct of a clinical trial. As the primary liaison between the sponsor and the site, the monitor must verify that the clinical trial is conducted according to Good Clinical Practice (GCP), the safety and rights of subjects are protected, the Investigational Medicinal Product (IMP) is handled correctly and the data is of the highest quality. This course will expand and strengthen the monitoring skills of Clinical Research Associates (CRAs), enabling them to perform their role more proficiently and effectively. Using case studies, monitors will learn how to handle monitoring problems and proactively manage risks before they become audit findings later. This course includes an invaluable "shared experience session" which will enable colleagues to discuss monitoring challenges they face as well as a risk-based monitoring plan workshop.

KEY TOPICS

- · Research misconduct
- · Risk management for the monitor
- Elements of Corrective and Preventive Action Plans (CAPA)
- Advanced monitoring techniques and tools
- Benchmarking for site performance evaluation
- Source document/data evaluation
- Electronic source data verification
- Risk-based monitoring plans

■ Clinical Aspects of Quality Risk Management and Quality by Design

This course will deliver an in-depth overview of risk-based quality management and how to assess risk and improve quality in your organisation. As an introduction, general risk management concepts and methodologies will be presented as the basis for Quality by Design (QbD), Quality Risk Management (QRM) and Risk-based Monitoring, as applied to clinical development and pharmacovigilance. There follows a review of applicable and meaningful metrics for clinical development and pharmacovigilance processes, how these can be best applied and what change management challenges need to be considered.

- General risk management aspects
- QRM & QbD: Latest update on regulations
- QRM methodologies such as Failure Mode and Effects Analysis (FMEA)
- Key Risk Indicators (KRI) and other tools
- Case studies and practical exercises
- Implementation of QRM and change management aspects
- Proactive QbD methodologies
- QbD examples and exercises for protocol design and study set up
- Risk-based monitoring principles and implementation approaches

Clinical Project Management - Part I

As clinical trials become more complex and there is increasing demand for efficiency and cost effectiveness, the knowledge and skills required to manage all aspects of a clinical project are critical. This course provides a comprehensive foundation in clinical project management. Using the Project Management Body of Knowledge (PMBOK*) as a guide, participants will be taught how to apply project management strategies, tools and techniques to their clinical trial projects.

KEY TOPICS

In two independent modules of three days each, the following topics will be covered:

- Project definition and organisational context
- · Project management tools and techniques
- Scope management, resource estimating and budget management of a clinical trial
- Project quality management
- · Project risk management
- · Communication and stakeholder management
- Procurement management
- Team management and leadership skills

This course includes many practical examples and case studies which will enable participants to successfully implement and manage their own clinical trial projects effectively. The course is based on Alexander Gissler's (PMP, Project Management Consultancy and Training) concept on clinical project management.

Clinical Project Management - Part II

As clinical trials become more complex and there is increasing demand for efficiency and cost effectiveness, the knowledge and skills required to manage all aspects of a clinical project are critical. This course provides a comprehensive foundation in clinical project management. Using the Project Management Body of Knowledge (PMBOK*) as a guide, participants will be taught how to apply project management strategies, tools and techniques to their clinical trial projects. In two independent modules of three days each, the following topics will be covered:

Part I:

- Project definition and organisational context
- Project management tools and techniques
- Scope management, resource estimating and budget management of a clinical trial

Part II:

- Project quality management
- Project risk management
- Communication and stakeholder management
- Procurement management
- Team management and leadership skills
- Clinical Project Management I and II are taught as two independent modules.

Participants will gain the most benefit from the course if they enrol in both modules. This course includes many practical examples and case studies which will enable participants to successfully implement and manage their own clinical trial projects effectively.

The course is based on Alexander Gissler's (PMP, Project Management Consultancy and Training) concept for clinical project management.

KEY TOPICS

- · Quality management
- · Procurement management
- · Leadership skills
- · Project team management
- Communication and stakeholder management
- Risk management
- Lessons learned

Clinical Statistics for Non-Statisticians

This course is designed to be an introduction of basic statistical concepts fundamental to clinical research, for professionals who have regular exposure to statistics either through studies or professional experience. The materials cover many key statistical topics, such as the interpretation of odds ratios and hazard ratios, meta-analysis and non-inferiority studies. While the course includes a few formulae for individuals who are interested in computational details, the course emphasises the application of statistical concepts to clinical investigation.

KEY TOPICS

• Basic statistical principles pertinent to clinical research

■ Essentials of Clinical Study Management

The success of a clinical study is very much dependant on its efficient preparation and effective conduct. Study managers should be knowledgeable about required quality and regulatory standards, roles and responsibilities of team members, and be able to select and oversee internal and external resources. Study managers also should be able to anticipate potential problems, offer creative solutions and develop strategies to mitigate risk. This training course provides a comprehensive overview of the essential elements of study management and the clinical study environment in the context of the overall drug development process. After successful completion of the training course, participants will be able to plan, execute and manage a clinical study from protocol to final report.

- Drug development process
- Feasibility assessment
- Study planning tools
- Regulatory framework
- Quality management system
- Essentials of site management
- Resource management
- Investigational product handling
- Risk management
- · Safety reporting
- Study evaluation and reporting

■ Practical GCP Compliance Auditing of Trials and Systems

This GCP auditing course is designed to provide practical training resulting in a harmonised, common audit methodology in Europe. The ICH GCP guideline implemented in the EU, Japan and the USA is being widely incorporated into guidelines worldwide. Systems audits, previously seen as "advanced auditing", have become a basic task of many audit groups and are an essential element of inspections in Europe.

The course material is regularly updated with the objective of experience sharing in order to pave the way for mutual recognition and acceptance, reduced costs and stimulating efficiency, allowing faster medicinal product development that benefit patients and health care.

KEY TOPICS

- Regulatory framework EU and ICH
- Quality management, defining quality, risk-based approach to audit and inspection
- Trial audit in practice
- System audits
- Communication of audit findings
- Inspections by European and other authorities

Non-Clinical Safety Sciences Training

■ Non-Clinical Safety Sciences and their Regulatory Aspects

Featuring tailor-made case studies including in-depth discussion of specific contemporary scientific/regulatory preclinical issues, case-studies and/or instructor-led group work on specific cases.

This course provides a full introduction to preclinical safety testing relating to regulations and guidelines in Europe (national, CHMP, ICH level). The course faculty is comprised of or made up of or comprises/includes European-based leading experts in preclinical safety testing and safety sciences. Topics will be presented through interactive lectures and hands-on workshops, with an emphasis on practical application of the regulations and guidelines pertinent to preclinical and clinical medicines development and registration. The content for this course focuses on development of small molecule medicines and biologically-derived medicines.

KEY TOPICS

- Role of preclinical safety studies in medicines development and registration in Furope
- Outline of preclinical medicines discovery and development: regulatory and industry perspectives
- Translational aspects of preclinical safety sciences, including safety biomarkers
- Scope and type of preclinical safety studies and timing to clinical development and registration
- Contemporary scientific and regulatory topics of interest: environmental risk assessment, single and repeat dose toxicity, establishing first human dose, juvenile animals studies, safety pharmacology, toxicity to the immune system, genotoxicity carcinogenicity testing, pharmaco-toxicokinetics, metabolism, reproduction toxicology protocols and interpretation for pregnancy labelling of pharmaceuticals, when mechanistic studies are needed, impurities and others
- Specific aspects of e.g., vaccines, anti-cancer medicines, biotechnologyderived medicines
- The Common Technical Document and assessment report structures in
- Europe may be included on a case-by-case basis

Regulatory Affairs Training

Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe

This 3-day training course focuses on the highly important contribution of biopharmaceuticals to new drug development. As the functions of biopharmaceuticals are fully explored and utilised, they will become increasingly relevant to the drug development community.

The course introduction provides an overview of both classical and biotechnology derived medicinal products and on the pathways used for scientific advice, clinical trials and marketing authorisations in Europe. The course will also cover in detail the particular requirements for the CMC section, comparability packages, and the important safety procedures required for infectious agents.

The particular aspects of the non-clinical and clinical development of biopharmaceuticals will be presented. A case study discussing how to develop a protein, without the relevant animal model, will also be examined. Case studies on monoclonal antibodies will illustrate the approach taken to identify benefit/risk ratio. An overview will be given on the most essential issues relating to ATMPs. A detailed presentation of the specific considerations for the development of biosimilar medicinal products, part of the EU provisions related to biopharmaceuticals, will be given during the course.

KEY TOPICS

- Definition and characteristics of biopharmaceuticals
- Topics of particular relevance to biopharmaceuticals such as comparability, immunogenicity, adventitious safety, bioassay
- ATMPs
- Biosimilar medicinal products
- Modules 3, 4 and 5 of the EU CTD of biopharmaceuticals
- Regulatory pathways for scientific advice, clinical trials and marketing authorisations of biopharmaceuticals

■ Building the eCTD - Practical solutions to compile electronic submissions

This course will offer insight into the compilation of the eCTD, share experience and best practice gained during eCTD submissions in the EU, and during the eCTD review process. The focus will be on practical experience gained in preparing and submitting electronically.

- Overview of eCTD readiness at the agencies
- Impact of the eCTD on regulatory processes and procedures
- Practical experience of submitting an eCTD in the EU
- eCTD compilation and lifecycle
- Document granularity and readiness
- Regulatory strategy facing technical issues
- Specifications and standards versus regions and procedures
- \bullet Non-eCTD electronic Submissions (NeeS) and its role in eSubmission

Comprehensive Training on European Regulatory Affairs: Keeping Your Finger on the Pulse of Marketing Authorisations

The course provides both description and discussion of the complete spectrum of essential regulatory procedures: Marketing authorisation registration procedures, variation procedures, renewal procedures and more. Expert instructors use practical examples and experiences to illustrate procedures. The course focuses on Europe but also reviews regulations in other regions including the USA and Japan.

KEY TOPICS

- · Drug regulations
- Role of regulatory affairs in drug development/approval/marketing
- Efficient interactions between regulatory agencies and the pharmaceutical industry
- Regulatory strategy
- Key differences of international regulatory environments

European Regulatory Affairs: In-depth review of current registration procedures in the European Union

The course will cover the evolution of the registration systems available for approval of products since January 1995 in the European Union, together with major changes in New Medicines Legislation. Title IV of Regulation EC726/2004 on the European Medicines Agency-Responsibilities and Administrative Structure, came into effect on May 20, 2004. The remainder of the Regulation and all of Directive 2004/27/EC became effective in November 20, 2005. The very important changes in New Medicine Legislation concerning regulatory procedures, access to Centralised and Mutual Recognition Procedures, reduction in Regulatory Data protection will be described in detail. Detailed review will be offered on the changed Centralised and Mutual Recognition Procedures and New Decentralised Procedure with discussion of practical examples of product types suitable for each procedure. Other issues that impact on successful regulatory strategy in Europe, Harmonisation of Summary of Product Characteristics, Article 30 and Article 31 referrals and Supplementary Protection Certificate for Patents will be described. Also reviewed and discussed is the legal status of medicinal products and the procedure for switching from prescription only sale to OTC sale, legislation controlling medical devices and the Clinical Trial Directive. This course will provide strategic advice on how to file applications for marketing authorisations in the European Union for staff involved in regulatory affairs. Regulatory strategy which impacts on commercial, business and licensing arrangements will be of importance to those responsible for business development.

KEY TOPICS

- European Union
- Centralised Procedure
- Decentralised Procedure
- Mutual Recognition Procedure
- National Procedure
- Key issues to consider for business opportunities
- Regulatory strategy
- Legal status of products and switching from Rx to OTC
- Medical devices legislation
- Clinical Trial Directive

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices

The course will give clear, practical guidelines on how to develop a medical device and how to identify the correct development path.

Part One: Philosophy and Legislation

Part One will deliver the knowledge base for the subsequent parts. It will give an overview of the EU device legislative system and the principles and philosophy behind it. It will explain the definition of a medical device and the demarcation between medical devices and pharmaceuticals. It will also explain risk classification of medical devices and the relationship between risk classification and conformity assessment procedures. This first part will highlight the role of the notified bodies and the legal basis for the requirements for clinical evaluation and clinical investigation. Also, the regulatory route for different types of combination products will be explained. A comparison of the EU and US regulatory systems will conclude this part.

Part Two: Operational Aspects I - Clinical and Vigilance

For medical devices that need to be tested clinically, the process of planning, conducting and reporting a clinical investigation with medical devices will be explained. The practical differences between the clinical development of pharmaceuticals and medical devices will be explored and the challenge of developing a drug device combination product will be touched upon. Responsibilities in post-marketing surveillance of medical devices (and drug device combination products) according to the Medical Device Vigilance System will be explained and illustrated with examples.

Part Three: Operational Aspects II - Quality Management, Risk Management, and Design Dossier

Part Three will start with the ins and outs of working with notified bodies. It will continue with the application of quality management and risk management to the development of medical devices, including the discussion of applicable ISO-standards. Differences between risk management of medical devices and pharmaceutical products will be pointed out. Furthermore, the process of 'constructing' a design dossier will be highlighted, both for medical devices and for combination products.

Part Four: In Vitro Diagnostics and Companion Diagnostics

- Medical device regulation: philosophy, content and structure
- Risk-classification of medical devices
- Drug-device combination products
- CE mark
- ISO 14155
- 93/42/EC, as amended by 2007/47/EC
- Clinical evaluation and clinical investigation
- Medical devices vigilance system
- In Vitro Diagnostics (IVD)
- Difference between IVD and personalised medicine

Health Authority Interactions - Preparation, consultation and implementation

Health Authority (HA) meetings with the major HAs (ICH region) are an essential part of drug development. Each pharmaceutical company will sooner or later be faced with such meetings. This important course covers HA meetings in the EU and in the US.

KEY TOPICS

- Different kinds of HA meetings in the EU and in the US
- How to prepare for HA meetings
- The questions to ask
- How to get the most out of HA meetings
- · How to negotiate

■ Health Technology Assessment (HTA)

A Health Technology Assessment (HTA) is a comprehensive document which consists of evidence to support the adoption and utilisation of medical technologies. An HTA includes clinical, economic, social and ethical information regarding technologies. These include pharmaceuticals, diagnostics and other treatment approaches. HTA is used to guide decision makers in their evaluation of new technologies. Decision makers include professionals from diverse backgrounds such as healthcare payers (government agencies; medical insurance schemes) and healthcare providers (hospital management teams; healthcare professionals). As a result there is an increasing need for an introductory course which will provide new users with a sound overview of HTA and its application.

KEY TOPICS

- Key principles and practice
- Identification of HTA reports
- Systematic reviews and meta-analysis
- Clinical evaluation
- Economic evaluation
- Critical appraisal
- Quality assessment
- Context-specific application
- HTA from different perspectives (decision makers, industry, etc.)

■ Paediatric Investigation Plans (PIP)

Overview of the Paediatric Investigation Plan (PIP) procedure, including indepth discussion of specific scientific/regulatory issues in relation to PIPs, case-studies and instructor-led group work on specific cases.

This course will provide a full introduction to PIPs and the EU Paediatric Regulation. The course faculty are European-based leading experts from EMA and industry. Topics will be presented through interactive lectures and handson workshop training.

KEY TOPICS

- EU paediatric regulation
- PIP lifecycle
- How to get your PIP approved
- PIPs after approval

Practical Approaches to Compiling Electronic Submissions - Building the eCTD

During this interactive workshop participants will learn about the Electronic Common Technical Document (eCTD), its components and history, preparing submission ready documents, as well as best practices for changing your business processes in preparation for moving towards electronic submissions. Participants will then apply this information and compile a two-sequence submission for a single country EU national procedure using LORENZ DocuBridge®, as well as repurpose the EU compilation for Switzerland.

KEY TOPICS

- eCTD components and history
- eCTD vs non-eCTD electronic Submissions (NeeS)
- Creating submission ready documents
- Regional differences in eCTD requirements
- eCTD compilation
- eCTD publishing
- eCTD validation
- eCTD lifecycle management
- Regulatory strategy and best practices
- Co-ordinating global eCTD submissions

The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)

Generics are becoming increasingly central in both industrialised countries and in developing countries. The overall requirements for generics will be detailed including problems in relation to generic substitution and falsified medicines.

The course will consider the important aspects for Active Pharmaceutical Ingredient (APIs), such as requirements to the production and supplier qualification and certification. The implementation of ICH Q11 will be discussed. Bioequivalence testing is an integral part of the development both of new medicinal products and of generics. Revised EU guidance has been developed and the impact of the new guidance will be thoroughly discussed.

Globalisation is an important element in the production of drug substances and drug products to be licensed and marketed in Europe. This course will focus on three essential topics which are particularly influenced by production in a global environment.

The course will be taught with a combination of presentations by the faculty and work in small groups assisted by faculty members. A significant amount of time will be devoted to working on case studies. Results from the working groups will be presented to the full audience.

- API production/API supplier qualification and certification
- Bioequivalence testing
- Generic medicines

US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US

As drug development becomes a global process, have you had questions about US Regulatory requirements? Do you wonder why your US colleagues ask for certain documents or information? This course is specifically designed for persons with a background in pre-clinical research (e.g., pharmacology, toxicology, and drug metabolism), clinical research, quality assurance or academia, with novice to intermediate experience in Regulatory Affairs, who need knowledge of the US regulatory processes. This course will also enhance understanding and be beneficial to persons who work in clinical research, data management, biostatistics, basic research, project management and marketing, etc. DIA Europe also welcomes attendance by regulatory agency staff members. Participants need to have some knowledge of the ICH and in particular the Common Technical Document (CTD). Participants will gain a better understanding of the US regulation of investigational new drugs (INDs) and biologics, of the basics of submission of applications seeking marketing approval for a product and post-marketing regulatory requirements in the US.

KEY TOPICS

- Regulation of drugs and biologics: The basics
- · Overview of the FDA
- Regulatory requirements for drug development and approval
- The IND A general introduction
- The IND In detail
- IND Amendments and maintenance
- Procedures for reporting Adverse Events (AEs) that occur during clinical investigations
- Submitting the NDA in CTD format What's unique to FDA
- Post-approval regulatory requirements for NDAs
- Interactions with FDA
- US regulatory requirements for advertising and labelling
- Regulatory compliance and FDA Inspections: What to expect after submitting the NDA
- Navigating the FDA on the internet

Safety and Pharmacovigilance

■ Benefit/Risk Management

The balance of benefits and risks of a product is the basis for all key decisions in the pharma industry. Thus the balance must not be left to chance – it can be and should be effectively managed. This intensive course explores current opportunities made possible by the new legislation, advances in information technology and a new scientific methodology to enhance and modernise the approaches in the product lifecycle management.

The course starts with the current regulatory thinking about the benefit/risk methodology, including the relevant project of the European Medicines Agency (EMA) / Committee for Medicinal Products for Human Use (CHMP). It gives a basis for the second part of the course, exploring the new European benefit/risk management planning - a notion stemming from the experience gathered over five years with the EU Risk Management Plans (EU-RMPs).

Participants will learn how to take advantage of the efficacy follow-up options given by both the European Paediatric Regulation and the Advanced Therapies Regulation. A practical training in drafting key aspects of the regulatory submissions is included. Although a lot of things may be planned and controlled, there are always unforeseen scenarios. The last part of the course will help participants to deal with the most dangerous ones – when the benefit/risk of the product is suddenly affected by emerging information.

Participants will be trained on how to deal with such a situation, using the most effective techniques in risk communication and media crisis management.

KEY TOPICS

- Take advantage of the new legal possibilities for benefit optimisation and risk minimisation of your products in the EU.
- Enjoy comprehensive and practical training in designing benefit/risk management systems using current, as well as new, regulatory tools, including EU Risk Management Plans (EU- RMP), Risk Evaluation and Mitigation Strategies (REMS), Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR), Follow-Up Measures (FUMs), and potentially EU Benefit Risk Management Plan (EU-BRMP)
- Learn which study designs are best for safety and efficacy follow-up, and how to measure their effectiveness
- Get trained for situations when benefit-risk of your product is at stake and you need to manage a media, legal and regulatory crisis

■ Diagnosis and Management of Drug-Induced Liver Injury (DILI)

This brand new DIA training course is entirely dedicated to Drug-Induced Liver Injury (DILI) and led by a Hepatologist with extensive experience in clinical assessment of DILI, who published 'RUCAM' the widely used causality assessment method of DILI. The course will cover the progress that has been made in the clinical detection and prevention of DILI in clinical trials and in postmarketing phase. New regulatory guidelines and their application need to be understood for an optimal assessment of DILI cases. Better use of typical tools is emphasised in order to improve patient safety and drug monitoring during new drug development, especially in large populations. This course will provide tools, explanations, examples and exercises for a better understanding of DILI and how best to apply that knowledge in day to day work.

The medical approach presented in this training course is also based on the conclusions of international consensus meetings on adverse drug reactions and guidelines published by regulatory authorities

KEY TOPICS

- Medical evaluation of ADRs
- The liver: Functional anatomy and physiology concepts
- Epidemiology, definitions and classification of DILI
- Clinical aspects of DILI and "Hy's Law"
- Causality assessment of DILI
- DILI: Individual and aggregated data
- How to monitor and prevent DILI in the post-marketing phase?

■ EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing

This course is designed to provide a firm grounding in key aspects of Global Clinical Pre- and Post- Marketing Safety. This five-day training course, presented by the European Medicines Agency, now also includes highlights and updates on the implementation of the new pharmacovigilance legislation and the latest news on the international harmonisation and standardisation activities in pharmacovigilance.

- Definitions and methods in pharmacovigilance
- Regulatory aspects in pharmacovigilance and practical examples
- Diagnosis and management of adverse drug reactions
- Signal detection
- Risk management

■ How to Prepare for Pharmacovigilance Audits and Inspections

Every pharmacovigilance function will, at one time or another, undergo governmental or health authority inspections as well as audits by license partners, internal auditors and others. The course will teach you how to prepare for an audit / inspection from the time of the receipt of the announcement (or of the arrival of the inspectors at your doorstep) to the conclusion of the audit or inspection.

KEY TOPICS

- The basics
- European and FDA Inspections
- Pharmacovigilance requirements and findings
- Responding to the findings and preparing the CAPA
- Onsite audit / inspection
- Preparation for audits and inspections

Medical Approach in Diagnosis and Management of Adverse Drug Posetion

The 19th edition of this annual training course, considered by many experts as one of the pillars of medical training in pharmacovigilance, focuses on how to use medical knowledge in the diagnosis and management of selected Adverse Drug Reactions (ADRs).

A medical approach is needed for the identification, labelling and understanding of ADR mechanisms. It can also help assess the probability that a medicinal product may have played a role in the occurrence of an adverse event. This is particularly useful for the first 2 or 3 cases of serious reactions occurring during clinical trials when important decisions must be taken regarding a new drug under development.

The medical approach presented during this training course is mainly based on the conclusions of international or national consensus meetings on adverse drug reactions.

KEY TOPICS

- Medical approach in clinical safety and pharmacovigilance
- Drugs-associated affective symptoms
- Drug-induced serious skin reactions
- Drug-induced qt prolongation
- Drug-induced blood disorders
- Drug-induced acute renal failure
- latrogenic and drug-induced respiratory reactions
- Drug-induced liver injury
- Results of the international consensus meeting on liver injuries and signal
- Drug-induced liver injury: causality assessment and case studies

■ Practical Guide for Pharmacovigilance: Clinical trials and post-marketing

This is a basic overview course, intended for individuals who have limited experience in pharmacovigilance/drug safety monitoring. The focus will be on pharmacovigilance with traditional medicinal products, both investigational and marketed, intended for human use in clinical trials, in post-marketing studies, and in the healthcare setting following product launch.

KEY TOPICS

- Legal basis for safety reporting including a historical perspective
- Basic definitions and tools
- Data collection and processing in post-marketing phase
- Medical evaluation

- Safety reporting requirements in the pre-marketing phase
- A workshop and practical exercises
- Safety reporting requirements in the post-marketing phase
- An introduction to risk communication
- Inspections in pharmacovigilance
- Introduction to risk management, epidemiological methods for signal detection and risk assessment

■ Pre-Marketing Clinical Safety

DIA Europe presents an intensive course for professionals involved in the management of safety information of clinical trials in the EU. Participants will be guided through all the regulations and guidelines pertinent to premarketing safety in the EU. The course offers an overview of all the current major methodological approaches and hands-on solutions for day-to-day challenges. Attendees will learn how to produce Development Safety Update Reports (DSURs), and how to bridge a Development Risk Management Plan, EU-Risk Management Plan (EU-RMP) and Risk Evaluation and Mitigation Strategies (REMS) to be ready for a marketing authorisation application.

KEY TOPICS

- Management of adverse events
- Unblinding strategies
- SUSARs reporting
- How to inform of ethics committees
- Development safety update reports
- EudraVigilance CT module
- · Risk assessment in clinical trials
- Safety risk management

■ Signal Management in Pharmacovigilance

Signal Management is a critical processes of Pharmacovigilance required by EU Good Pharmacovigilance Practices. It is the scientific component that underpins Pharmacovigilance, and the very reason why Pharmacovigilance was created in the first place.

The entire course has been updated in line with the latest guidelines on EU Good Pharmacovigilance Practices (GVP): Module IX - Signal management, Commission Implementing Regulation (EU) No. 520/2012, and CIOMS VIII.

Time has been set aside for exercises, questions and discussions.

- Signal detection Theory, methods and regulatory basis
- Signal detection Application and workshop
- Data mining Theory, methods
- Data mining Application
- Signal management process, methods, regulatory expectations

Eudra Vigilance

Information Days at the European Medicines Agency:

- EudraVigilance Information Day
- The New Identification of Medicinal Products (IDMP) International Standards, ICH M5/M2 and the Implementation of Electronic Submission of Medicinal Product Information in the EU (Article 57(2) Requirements of the New Pharmacovigilance Legislation) Information Day
- The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day

These Information Days are being offered to provide an important forum to update stakeholders about the latest developments in the area of pharmacovigilance, EudraVigilance and the international standardisation activities related to drug safety in the pre- and post-authorisation phase. Detailed information on the content of each Information Day is available shortly before the event. Please consult the DIA homepage for more information.

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of EudraVigilance

This one day course is designed for newcomers in pharmacovigilance, in particular individuals dedicated to data entry and quality review of ICSRs. The attendees will learn about the essentials of pharmacovigilance, the format, structure and content of ICSRs as well as data quality and coding principles, which are prerequisites to comply with EU and international reporting requirements. This introductory course is strongly recommended to individuals that will be transmitting ICSRs to EudraVigilance.

KEY TOPICS

- Legal/regulatory basis
- Compliance with reporting requirements for ICSRs
- What is a pharmacovigilance case: scope, criteria for validity
- Classification of cases: Solicited/ unsolicited, serious/not serious, etc
- Overview of the ICH E2B requirements
- Main differences of data elements and adverse reaction reporting during clinical trials and in the postauthorisation phase
- Overview of the case flow in the EU
- Concepts and data elements of an ICSR (the main part of the training, focusing on content and quality criteria of each important element)
- Case Follow-up: when and how it needs to be transmitted.
- · Basic coding principles
- Data privacy requirements

■ EudraVigilance Training - Electronic Reporting of ICSRs in the EEA

EudraVigilance is the European data-processing network and management system, established at the European Medicines Agency to support the electronic exchange, management and scientific evaluation of Individual Case Safety Reports (ICSRs) related to all medicinal products authorised in the European Economic Area (EEA).

Participants who pass the knowledge evaluation following the course will receive a notification from the European Medicines Agency that will allow them to register with EudraVigilance and to report ICSRs to the European Medicines Agency and/or the National Competent Authorities in the EEA.

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course

The EMA has prepared this eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) course to facilitate the practical implementation of the requirements including technical aspects and all related procedures on electronic submission of information on medicines by marketing authorisation holders in the European Union (EU).

The training focuses on explaining the guidance, specifically the mandatory data elements necessary for the electronic submission of information on medicinal products applying the format of the eXtended EudraVigilance Product Report Message (XEVPRM) and the use of the XEVMPD data entry tool also known as EVWEB.

Participants who successfully pass the knowledge evaluation following the course will receive a notification from the European Medicines Agency that will allow them to register with EudraVigilance for the electronic submission of information on medicines in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004..

KEY TOPICS

- · General terms and definitions
- Registration in EV and QPPV registration
- XEVPRM XSD Schema
- XEVPRM data elements and examples
- XEVPRM and Structured Substance Information including examples of various substance classes
- Operation types
- Data ownership
- XEVMPD technical validation rules

DIA Tailored Training

DIA Tailored Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience.

DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.

The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

Contact DIA Europe to discuss your organisation's requirements.

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