Conferences, Workshops & Training Courses 2015/2016

Europe, Middle East & Africa

DIA DEVELOP INNOVATE ADVANCE

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I 2015

13-14 Oct | London, UK | #15104
(Pre-Conference on 12 Oct)
9th Annual QPPV Forum

This is the only forum designed for QPPVs by QPPVs, now in its 9th year and ever growing. Over time, one of the key successes of the Forum has been the ability to secure continuing support and involvement of key regulators. Sessions have been open and interactive with attendees appreciating opportunities to raise challenging issues in an informal environment. This 9th QPPV Forum aims to continue to attract such key speakers and encourage open debate.

26-27 Oct | London, UK I #15111
Clinical Trials Workshop

The new EU Clinical Trials Regulation is expected to become applicable in 2016. The new legislation will have implications on clinical trial sponsors preparing and submitting clinical trial applications. Member States will have to adapt their procedures and the new Regulation will impact how the conduct of a clinical trial is managed after approval has been granted. New provisions for public access to an EU Clinical Trials Database will enforce disclosure of clinical trials data and information.

29-30 Oct | Paris, France I #15110
DIA Interactive Training Workshop on IDMP: "Start Early, Finish Strong"

Irrespective of the finalisation of the implementation guidelines, IDMP requires awareness, ownership and need for change of business processes as well as software tools. The workshop will cover the practical aspects of IDMP implementation and the impact on the business processes and software tools. It is designed to be an educational environment where content focuses on actively engaging the topics presented.

Call for Abstracts on Vendor IDMP Showcases and Exhibition Opportunities Available

4-5 Nov | London, UK | #15115
Biosimilars Conference – European View on Biosimilars with a Global Outlook

This 2-day conference is the third of its kind. It will provide an update on the current status for biosimilars in EU and internationally with focus on both regulatory and scientific challenges as well as market access and experiences. Patients and physicians approach to use of biosimilars will be part of the conference scope including a discussion on biosimilars adoption into current treatment guidelines in EU.

10-11 Nov | London, UK | #15106
9th European Medical Information and Communications Conference and Exhibition

This is a unique conference organised by medical information professionals for medical information professionals. The speakers share hands-on experience of dealing with current challenges as well as successes. It provides opportunities to showcase success stories or stories to learn by, in the popular Putting Theory into Practice session and to explore the impact of new technologies on information delivery and customer interactions. A dedicated poster session will also provide an opportunity to broaden the topics at the conference to other areas.

17-18 Nov | Riyadh, Saudi Arabia I #15102
11th Middle East Regulatory Conference (MERC)

This is the 11th DIA Middle East Regulatory Conference (MERC) in partnership with the Middle East Regulatory Network (MERN). This Conference marks an important milestone – it will celebrate the 20 year anniversary of MERC and an opportunity to reflect on the significant progress made over that period. And, for the first time in that 20 year period, MERC is being co-hosted by a regulatory authority - Saudi Food and Drug Authority (SFDA).

It will continue to discuss opportunities to achieve further improvements for faster access to new, improved medicines and therapies for the population in the Middle East region. It provides a forum for all participants to contribute to active discussion and identify actions to expedite access of valued innovative medicines to Middle Eastern patients.

I 2016

22-23 Feb | Frankfurt/Main, Germany I #16109
Joint FIP/DIA Workshop on "Dissolution Testing": Testing of Solid Oral Dosage Forms During Development and Commercialization

Dissolution testing is an important tool from early development to life-cycle management of a drug product. The implementation of Quality by Design (QbD) principles requires understanding of process parameters, product attributes and their impact on in-vitro dissolution and bioavailability.

In early development, biorelevant dissolution/release testing, i.e. the evaluation of luminal behaviour of drug products in gastrointestinal lumen with in vitro methodologies, is useful for predictions of formulation and food effects on plasma levels. It is also utilised to decrease the number of in vivo studies required during the drug development process and to mitigate the risk related to in vivo bioequivalence studies.

Recent updates and case studies on these subjects will be discussed by scientists working in academia, industry and regulatory agencies from Europe, USA and Japan.

6-8 Apr | Hamburg, Germany | #16101
28th Annual EuroMeeting

In a world in which new therapies are being developed at a phenomenal rate, is innovation always the answer?

The DIA 28th Annual EuroMeeting brings stakeholders together to collaborate on when, where and how innovation leads to advances in health care product development.

25-26 May 2016 | Leiden, the Netherlands I #16110
16th Conference on Electronic Document Management

Join to find out about the latest trends in document management, content and information management, electronic submissions and a lot more.

This conference is currently in development and more information will be available shortly.

26-28 May | Edinburgh, UK I #16106
8th European Conference on Rare Disease & Orphan Products (ECRD 2016) – Game Changers in Rare Diseases: Delivering 21st century healthcare to rare disease patients: Together We Can Change the Future!

This biennial conference is the unique platform/forum across all rare diseases, across all European countries, bringing together all stakeholders - patients' representatives, academics, researchers, health care professionals, industry, payers, regulators and policy makers.

ECRD covers research, development of new treatments, health care, social care, information, public health and support at European, national and regional levels. ECRD provides the state-of-the-art of the rare disease environment, monitoring and benchmarking initiatives.

OCTOBER I #16103
Clinical Forum

2016 is a key year with notable changes in the clinical landscape with the new Regulation and ICH guideline. The Clinical Forum is unique amongst European conferences in bringing together thought leaders from all core disciplines in clinical research - clinical operations, data management and drug safety – to discuss the implications and discover best practice with professional colleagues from all disciplines, providing additionally an excellent opportunity for networking. *This conference is currently in development and more information will be available shortly.*

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Training Courses 2015/2016

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CHEMISTRY, MANUFACTURING AND CONTROLS

7-9 Sep 2016 | Vienna, Austria | #16543

Quality by Design - Making Next Generation Process Efficiency a Reality for Chemical and Biotech Product Development and Optimisation

Quality by Design (QbD) concepts are becoming the defacto best practice spearheaded by the FDA and EMA. But how can you implement ICH Q8-Q10 with confidence for small molecules and biotech products? As part of our Chemical Manufacturing series, DIA brings together expert faculty from Regulatory agencies, ICH and DoE expertise to accompany you to building a practical knowledge base.

CLINICAL RESEARCH

14-16 Oct 2015 | London, UK | #15531

Practical GCP Compliance Auditing of Trials and Systems

This course provides practical training for industry auditors and regulatory authority inspectors, who are faced with the task of auditing clinical trials and related systems. It will also be of interest to those with managerial responsibilities.

15-16 Oct 2015 | London, UK | #15532

Clinical Statistics for Non-Statisticians

This course is an introduction of basic statistical concepts fundamental to clinical research, for professionals who have regular exposure to statistics.

2-4 Nov 2015 | Basel, Switzerland | #15557

Essentials of Clinical Study Management

After successful completion of the training course, participants will be able to plan, execute and manage a clinical study from protocol to final report.

19-21 Sep 2016 | Paris, France | #16542

Clinical Project Management – Part I

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.

16-18 Nov 2015 | London, UK | #15555

Clinical Project Management – Part II

This is the second part of the 2-part course on Clinical Project Management, concentrating on specific concepts such as project quality risk management.

REGULATORY AFFAIRS

4-5 Nov 2015 | Paris, France | #15556
19-20 Apr 2016 | Paris, France | #16541

Essentials and Overview of the Regulatory Framework in Europe

This is the must-attend training course for anyone needing to learn the essentials of European Regulatory Affairs.

16-18 Nov 2015 | London, UK | #15554

US Regulatory Affairs: A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US

This course is designed for persons with a background in pre-clinical research, clinical research, quality assurance or academia, who need knowledge of the US regulatory processes.

9-10 Nov 2015 | Dubai, United Arab Emirates | #15562
5-6 Dec 2016 | Dubai, United Arab Emirates | #16562

Building the eCTD - Practical Approaches to Compiling Electronic Submissions

Participants will learn about the Electronic Common Technical Document (eCTD), its components and history, preparing submission ready documents, and how to change your business processes in preparation for moving towards electronic submissions.

Next occurance to be announced

HTA for Non-HTA user

A foundation course designed especially for non-HTA experts interested in gaining a better insight into the role of HTA in decision making processes in the health care sector.

Jun 2016 | London, UK | #16552

Paediatric Investigation Plans (PIP)

This course will provide a full introduction to PIPs and the EU Paediatric Regulation.

14-15 Oct 2015 | London, UK | #15546
18-19 Oct 2016 | Dusseldorf, Germany | #16546

How to Manage a Successful Health Authority Interaction

This course covers Health Authority (HA) meetings and other interactions in the EU and the US. You will learn by performing role plays yourself and by many case studies.

25-27 Nov 2015 | Vienna, Austria | #15545
19-21 Sep 2016 | Paris, France | #16545

The Development of Biopharmaceuticals - The Big Picture, Innovation and Scientific Requirements

Participants will learn about the legislative and regulatory framework for biopharmaceuticals in Europe and the roles of the European Medicines Agency and National Competent Authorities in market access.

OCT 2015 | Dubai, United Arab Emirates | #15561

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview

This is a complete comprehensive in-depth training on European regulatory affairs, exploring all aspects of medicinal product lifecycle management.

Next occurance to be announced

Approval of Generic Medicines in the EU. Focus on CMC requirements and bioequivalence

The overall requirements for the approval of generics will be detailed including problems in relation to generic substitution and falsified medicines.

SAFETY AND PHARMACOVIGILANCE

19-20 Apr 2016 | London, UK | #16550

How to Prepare for Pharmacovigilance Audits and Inspections

The course will teach you how to prepare for an inspection from the announcement (or of the arrival of the inspectors at your doorstep) to the conclusion.

5-6 Nov 2015 | Paris, France | #15549
18-19 Apr 2016 | London, UK | #16534
23-24 Nov 2016 | Basel, Switzerland | #16549

Signal Management in Pharmacovigilance

The course will teach basic concepts of signal detection and signal management and how to apply them within the participants' functions.

3-4 Nov 2015 | Paris, France | #15547
10-11 Mar 2016 | Prague, Czech Republic | #16533
21-22 Nov 2016 | Basel, Switzerland | #16547

Benefit/Risk Management

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

1-5 Feb 2016 | London, UK | #16548
14-18 Nov 2016 | London, UK | #16558

Joint MHRA/DIA Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

By attending this course you will gain a firm grounding in key aspects of safety and pharmacovigilance from a European and global standpoint.

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Next occurance to be announced

ICH Endorsed Pharmacovigilance

Participants will gain solid knowledge and a clear understanding of international approaches to drug safety pharmacovigilance, as well as the best practices for successful local and global regulatory applications.

26-27 Jan 2016 | London, UK | #16539

Pre-Marketing Clinical Safety

Participants will be guided through all the regulations and guidelines pertinent to pre-marketing 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.

13-14 Jun 2016 | Location to be confirmed | #16540

Medical Approach in Diagnosis and Management of ADRs

How to use medical knowledge in the diagnosis and management of selected Adverse Drug Reactions (ADRs).

14-15 Jun 2016 | Location to be confirmed | #16544

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

This course will provide tools, explanations, examples and several exercises for a better understanding of DILI and how best to apply that knowledge in day to day work.

13-14 Jun 2016 | Location to be confirmed | #16535

Post-Authorisation Safety Studies (PASS)

This course delivers insight in (pharmaco-)epidemiological methodology for non-interventional studies, and the concept of multi-departmental collaboration for the development and conduct of a PASS. Its components and history, preparing submission ready documents, and how to change your business processes in preparation for moving towards electronic submissions.

EUROPEAN MEDICINES AGENCY (EMA)

EudraVigilance training courses:

Year round | London and selected European Cities
- Electronic reporting of ICSRS in the EEA
- Extended EudraVigilance Medicinal Product Dictionary
- Introduction to Pharmacovigilance and Rules for Expedited Reporting of ICSRs in Europe

EMA Information Day:

07 Dec | London, UK | #15594
Information Day on services and systems in Pharmacovigilance - Preparing for Business Change

SAVE TIME AND TRAVEL COSTS WITH IN-HOUSE TRAINING

All DIA Training Courses can be held on your premises and tailored to your needs.

Get the best value and train your whole team !

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