

ISPE/DIA Workshop on Computer Systems Compliance

“Maintain Data Integrity to Reduce Risk for the Patient”

Event #14112

6-7 November 2014

Hotel Pullman Basel Europe, Basel, Switzerland



Programme Committee:

Representing DIA

Rolf Banholzer

Global Head GxP IT Systems & Processes,
Development QA, Novartis Pharma AG,
Switzerland

Breffni Martin

Legal Representative, Optum, Ireland

Representing ISPE

Chris Clark

Head of Computerised Systems QA, Bard
Pharmaceuticals Ltd, United Kingdom

Anders Brummerstedt

Senior Project Manager, PEC A/S, Denmark

Exhibition Opportunities Available

Limited spaces available – register early!

Contact Roxann Schumacher, tel. +41 61 225 51 38
or email roxann.schumacher@diaeurope.org for

Overview

Data integrity surrounding computerised system supported business processes throughout the product life cycle has been at the forefront of recent news, in connection to Ranbaxy in the USA. The awareness of these issues has changed the approach used by both EU and US regulators in conducting inspections in recent years. As data integrity increasingly becomes a focus of the regulatory authorities, the industry has to recognise and ensure controls for data integrity are implemented and appropriately managed throughout the entire life cycle of the data. Problems with data integrity manifest themselves differently in each phase of the life cycle. Therefore improvements must be managed differently during each phase, based on business risk.

This 2-day conference will provide a forum for information, discussion on conceptual and practical questions and experience exchange through lectures, panel discussions, and interactive workshop sessions. It will focus on the work being conducted by two leading organisations within the life sciences sector who approach the subject from differing directions but with the same clear objective of ensuring data integrity to reduce the risk to the patient. It will focus on the well-established approaches used, identifying the similarities of key principles and practice, and the challenges facing the industry with the availability of new technologies such as cloud computing.

Key Topics

- The regulatory perspectives on data integrity and the use of new technologies
- The principles of GAMP® 5 and its relationship to Clinical systems
- Understanding Business Process Risk Management
- Maintaining data integrity
- The challenges to the industry and regulators of emerging computing strategies like the use of mobile and cloud-based platforms

Objectives

Participants will:

- Gain an awareness of the principles of the GAMP® 5 risk-based approach to compliant GxP computerised systems and how they support the maintenance of data integrity.
- Understand the principle regulatory concerns and how they may be addressed.
- Discuss and identify the key challenges and opportunities of the new technology.
- Recognise how companies and industry organisations are developing principles and practical advice to meet these challenges to data integrity throughout the entire product life cycle.
- Have the opportunity to exchange views between regulators, industry and other stakeholders.

Who Will Attend

This conference is aimed at intermediate and experienced professionals from:

- The pharmaceutical industry and Contract Research Organisations including:
 - Staff from clinical science and clinical operations
 - Monitors, auditors of clinical trials
 - Regulatory affairs personnel
 - Information Technology and CSV practitioners
 - Research and clinical quality assurance staff
- Regulatory agencies
- IT service provider organisations
- Academic institutions
- GXP compliance professionals

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.



Connecting a World of
Pharmaceutical Knowledge



THURSDAY | 6 NOVEMBER 2014

8:00 REGISTRATION AND WELCOME COFFEE

9:00 **Setting the Scene:**

- Why are we here?
- Why is data integrity so important?
- What is a risk-based approach to validation?

9:15 **Session 1**

DATA INTEGRITY AND A RISK-BASED APPROACH

Session Chair:

Breffni Martin, Legal Representative, Optum, Ireland

This opening session will provide an insight into the regulatory challenges facing the life sciences industry from the emergence and introduction of new technologies such as cloud computing and mobile applications/devices and the impact upon data integrity. It will also look at how we may adopt a risk-based approach to ensuring continued GxP compliance of computerised systems in this new environment.

Regulations and Guidance for eData Integrity

Teri Stokes, Director GXP International, USA

GAMP® 5 – Risk-based approach to GXP compliant computerised systems

Siôn Wyn, Owner, Conformity, United Kingdom

Panel Discussion, Question & Answers

10:30 COFFEE BREAK

11:00 **Session 2**

ENABLING DATA INTEGRITY WITH E-CLINICAL SYSTEMS

Session Chair:

Rolf Banholzer, Global Head GxP IT Systems & Processes, Development QA, Novartis Pharma AG, Switzerland

Whilst 10 years ago, Computerized Systems Validation was a priority for many organisations, the today's industry and regulators key focus is on data integrity. As a prerequisite for end to end clinical data integrity, computerized systems have to be validated and to be kept in a validated state. In particular in large Pharmaceutical Organizations and with full service providers, there is a level of Systems, Process, Organizational and Geographical Complexity that require another layer of governance and oversight than the typical controls described in numerous publications. Furthermore, additional data collection tools such as ePRO systems and eSource data concepts have to be properly integrated in clinical study setups.

The objective of this session will be to consider how eClinical IT systems and platforms can enable end-to-end data integrity in today's context of further going electronic and paperless, implementing global data management operations, insourcing of resources and outsourcing of services. In addition, Systems retirement and data storage and archiving will be addressed.

Ending the clinical IT lifecycle with Decommissioning of GcP Clinical Data and System

Jesper IIm, Senior Consultant, epista IT, Denmark

Enabling Data Integrity with eClinical Systems when Collected by the Patient

Valdo Arnera, General Manager Europe, PHT Corporation, Switzerland

Electronic Integrity at the Frontiers of e-Clinical Systems

Teri Stokes, Director GXP International, USA

Panel Discussion, Question & Answers

12:30 LUNCH

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.

14:00 **Session 3 A**

BREAK-OUT SESSION: RISK-BASED APPROACH

Session Chair:

Volker Erat, Quality Manager, DI/IGM, Novartis, Switzerland

The session chair will provide a 20 min introduction to business risk-based approach to Computerized System Implementation followed by an interactive workshop discussing concrete, real world business process risk management assessments, including typical pitfalls and challenges that should be avoided or managed carefully.

14:00 **Session 3 B**

BREAK-OUT SESSION: DATA INTEGRITY

Session Chair:

Thomas Haag, Data Integrity Process Expert, Novartis, Switzerland

The session chair will provide a 20 min introduction to the multiple dimensions impacting data quality and data integrity including technology, systems, processes and organisational complexities, followed by an interactive workshop to further elaborate all dimensions based on real world examples provided by the workshop participants.

15:30 COFFEE BREAK

16:00 **Session 4**

FEEDBACK SESSION FROM BREAK-OUT SESSIONS

Session Chair:

Breffni Martin, Legal Representative, Optum, Ireland

The Session chairs of Session 3a and 3b will provide a brief summary of the discussions and conclusions to all meeting participants. There will be a further opportunity to discuss how business risk-based implementations of Computerized Systems effectively enable data integrity in complex business environments.

17:00 NETWORKING DRINKS RECEPTION

18:00 END OF DAY ONE

FRIDAY | 7 NOVEMBER 2014

09:00 **Session 5**

THE CHALLENGES OF CLOUD COMPUTING

Session Chair:

Kathleen Gniecko, IT Quality Management Services Head, F. Hoffmann La Roche, USA

These are challenging times for most pharmaceutical companies. The competitiveness of the market place, loss of patents, increasing international regulatory requirements, and downward pressure on health care costs are just a few of the factors that are driving pharmaceutical companies to adopt strategies for cutting resources and costs. At the same time IT needs to support the challenges the businesses are facing and are being asked to deliver effective solutions while cutting costs without compromising quality, compliance, agility and flexibility. This has led to greater interest in cloud computing. The promises of cloud computing are certainly considerable: extremely fast and flexible solution delivery, on-demand scalability, high-demand business continuity services with easy solutions for backup and archiving. This session aims to look at the issues surrounding the adoption of such technologies and asks "Will cloud computing provide the capabilities and adoption levels while simultaneously meeting the regulatory compliance needs that are core to the pharmaceutical sector?"

Cloud Infrastructure as a Service (IaaS)

Anders Vidstrup, Senior IT Quality Subject Matter Expert, NNIT, Denmark

Software as a Service (SaaS)

Ekaterina Sidorova, IGM Global Risk Manager for NIBR, Novartis Pharma AG, Switzerland

Alternative Accreditation Models for Cloud Providers

Magdalena Kurpierz, Life Science Consultant, Kvalito AG, Switzerland

Panel Discussion, Question & Answers

10:30 COFFEE BREAK

11:00 Session 6

REGULATED MOBILE APPLICATIONS

Session Chair:

Siôn Wyn, Owner, Conformity, United Kingdom

The accessibility of mobile platforms to the general public has become nearly universal in much of the world. In 2013 sales of smartphones exceeded the sales of standard mobile phones, and this trend shows no sign of slowing. With this much computing power in everyone's pocket it was inevitable that regulated companies would recognise an opportunity to use it for a variety of purposes. Some examples of leveraging mobile technology are of relatively low impact and will not interest regulators, some fall very clearly into the regulated arena, and finally some are not so clear. Even once the scope of regulatory relevance is settled, mobile devices present a significant challenge to control. The possibility of putting regulated applications, some of which may be classified as medical devices, into the pockets of the public is new ground for the industry. Never before has regulated software run on platforms where the process owner has little or no control over the platform. This session is intended to consider a risk-based approach to implementing and supporting mobile devices in a regulated environment.

Using a Mobile App for Review and Approval in a Validated Document Management System

Markus Kast, Solution Architect, F. Hoffmann-La Roche Ltd, Basel

Delivering GxP Compliant mHealth and Mobile Applications – A practical case study

Mark Stevens, Operations Director and Principal Consultant, Formpipe, GxP, United Kingdom

Regulated Mobile Applications

Siôn Wyn, Owner, Conformity, United Kingdom

Panel Discussion, Question & Answers

12:30 LUNCH

14:00 Session 7A

BREAK-OUT SESSION: CLOUD COMPUTING

Session Chair:

Kathleen Gniecko, IT Quality Management Services Head, F. Hoffmann-La Roche, USA

This session will provide an opportunity for participants to be involved in an interactive workshop based on cloud computing

14:00 Session 7B

BREAK-OUT SESSION: REGULATED MOBILE APPS

Session Chair:

Siôn Wyn, Owner, Conformity, United Kingdom

This session will provide an opportunity for participants to be involved in an interactive workshop based on mobile applications

15:30 COFFEE BREAK

16:00 Session 8

FEEDBACK SESSION FROM BREAK-OUT SESSIONS

Session Co-Chairs:

Kathleen Gniecko, IT Quality Management Services Head, F. Hoffmann-La Roche, USA

Siôn Wyn, Owner, Conformity, United Kingdom

This session will allow the participants of the two break-out sessions on Cloud Computing and Mobile Applications to feed back and share their experience with the full conference group.

17:00 SUMMARY OF TWO WORKSHOP DAYS, OUTCOME, FUTURE

17:30 WRAP UP AND END OF WORKSHOP

HOTEL INFORMATION

A limited number of rooms are available at a special rate at the meeting hotel:

Hotel Pullman Basel Europe
 Clarastrasse 43
 4058 BASEL
 Switzerland
 Telephone: (+41)61/6908080
 Fax: (+41)61/6908880
 Email: h5921@accor.com

The DIA rate is guaranteed until 9 October 2014, or until room block is filled. Participants should make reservations as soon as possible. Single CHF 180.00 including breakfast and VAT. To make your booking, please use the booking form available on the DIA website .

About ISPE

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle.

ISPE is committed to the advancement of the educational and technical efficiency of its members through forums for the exchange of ideas and practical experience

ISPE Headquarters are in Tampa, FL, USA, with Chapters and Affiliates in Asia-Pacific, Europe, North America, and South America.

For more information, visit www.ispe.org, email ASK@ispe.org or call ISPE +1-813-960-2105

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation headquartered in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

REGISTRATION FORM

ISPE/DIA Workshop on Computer Systems Compliance
6-7 November 2014 | Hotel Pullman Basel Europe Basel, Switzerland



ID #14112

Early-bird rates available for DIA and ISPE members: Register by 25 September 2014

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. (www.diahome.org/membership).

€ 1'300.00

FEES

	Member (DIA or ISPE)*	Non-Member*
Industry	€ 1'450.00 <input type="checkbox"/>	€ 1'600.00 <input type="checkbox"/>
Academia/Charitable/Government/Non-profit (Full-time)	€ 725.00 <input type="checkbox"/>	€ 855.00 <input type="checkbox"/>
Join DIA now to qualify for the member rate		€ 130.00 <input type="checkbox"/>

I am an ISPE member

*All fees will be subject to the Swiss VAT at 8%

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to availability - please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

Prof Dr Ms Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my VISA MC AMEX

Card N°

Exp. Date /

Cardholder's Name

Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #14112 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on <http://www.diahome.org/EUTerms>

Date

Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.