DIA

DIA Clinical & Regulatory Operational Excellence Forum

13-14 September 2017

Mercure Hotel MOA, Berlin, Germany

Welcome to the New Clinical & Regulatory Operational Excellence Forum

PROGRAMME COMMITTEE

Marta Arias-Salgado
Executive Director, Global Clinical Trial Operation, Head of Central and Eastern
Europe and Middle East Africa, Merck Sharp & Dohme, The Netherlands

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OVERVIEW

This new forum will focus on excellence in operational implementation of key actual deliverables in the areas of Sponsors & CRO's and Vendors, Clinical Operations, Records and Document Management and Regulatory Affairs. The workshop style will allow in-depth discussions with the expert instructors.

WHY IS THIS FORUM ESSENTIAL

The increasing complexities in today's drug development require a close link between Clinical Operations and Regulatory Operations to embrace working solutions and partnerships. This highly interactive forum will enable you to **perform complex tasks** to the **highest operational standards** to **shorten turnaround times** and **reduce queries and re-creation** in your development programmes.

We are bringing together experts across the fields of Clinical Operations, Records and Document Management, Pharmacovigilance and Regulatory Affairs. Moderated workshops will look at different ways to implement working solutions.

The meeting will be based on selected abstracts that **showcase working solutions** and will allow attendees to **learn from implemented best practices**.

WHO SHOULD ATTEND?

- Health Care- and R&D Professionals in the areas of Electronic Document Management, IT and Process Innovation
- Clinical Operations and Regulatory Affairs that want to excel in their day-to-day work
- R&D Quality Leads, as well as Trial Managers and Drug Programme Leads & Clinical and Regulatory Project Managers that need to get an overview of the latest gold standards in R&D Operational Excellence to set the standards for high-performing cross functional drug development teams
- New Technical Solution Vendors (data capture or data handling, software companies for data management) that want to showcase implementations utilising their solutions or want to understand and adopt to changing customer needs

| DAY ONE | WEDNESDAY, 13 SEPTEMBER 2017

08:00 REGISTRATION AND WELCOME COFFEE

09:00 KEYNOTE ADDRESS - ROOM MOA7

ACHIEVING OPERATIONAL EXCELLENCE – PROVEN STEPS TO DRIVE EFFICIENCY AND INSPECTION READINESS. STORIES OF ENCOUNTERING CHALLENGES AND PARTNERING TO OVERCOME THEM.

Birgit Ruhfus, Vice President, Clinical Project Management Therapeutic Area 2, Bayer AG, Germany

Dairine Dempsey, Vice President, Strategic Regulatory Affairs, ICON plc, Ireland

10:00 COFFEE BREAK IN THE EXHIBITION HALL

10:30 PARALLEL TRACKS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 1: HOW TO MAKE YOUR eTMF WORK FOR YOU RATHER THAN AGAINST YOU

Workshop Co-Presenters:

Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting Ltd, UK

Emma W. Mears, Senior Clinical Document Manager, Vectura, UK

Apply the principles to make your eTMF process support Clinical Operations.
Recognise the system and process barriers that lead to non-compliance and inefficiency.
Improve your company's TMF process.

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 2: IMPLEMENTATION OF ISO-IDMP FROM REGULATORY VIEW LOOKING FROM AN NCA PERSPECTIVE

Workshop Co-Presenters:

Klaus Menges, Project Manager, BfArM, Germany

The Art 57 database will provide consistently drug product data and is understood as the implementation of the IDMP standards. This will offer new opportunities to consume those data as a kind of master data in different areas. To achieve the assumed benefits, multiple factors need to be considered: quality and completeness of all controlled vocabularies, interoperable systems and platforms, data quality verification by medicinal product authorising authorities.

12:00 LUNCH BREAK IN THE EXHIBITION HALL

13:30 PARALLEL TRACKS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 3: HOW RISK-BASED MONITORING CAN BREAK DOWN CLINICAL R&D SILOS

Workshop Co-Presenters:

Véronique Grosjean, Operations Team Leader, Cluepoints SA, Belgium

Soazig Chevalier, Risk-Based Monitoring Project Leader, Sanofi, France

The traditional silos in Clinical R&D organizations and the difficulties arising from them.

- How to enable an effective RBM strategy
- How to drive greater cross-functional collaboration and understanding through RBM.

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 4: ALLOTROPE FRAMEWORK ARCHITECTURE & REGULATORY COMPLIANCE

Workshop Co-Presenters:

Eric Little, PhD, Chief Data Officer, Osthus, USA

Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy B.V., Netherlands

- **ALLOTROPE FRAMEWORK ARCHITECTURE:** standardize analytical data across industry to auto-generate Module 3 documents
- **REGULATORY ANALYTICS**: entity extraction, semantic interoperability and analytics across data, documents and dossiers

15:00 COFFEE BREAK IN THE EXHIBITION HALL

15:30 PARALLEL TRACKS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 5: WHAT TO INCLUDE IN THE STUDY ARCHIVES WHEN COLLECTING ELECTRONIC COA

Valdo Arnera, M.D. Scientific Advisor and General Manager, ERT, Switzerland

Jan Breemans, Head Data & Documents Operations, Grünenthal GmbH, Germany

The archive of all clinical trial data and content is governed by global authorities but open to interpretation. Further, the archive of electronic COA studies generally includes both eSource records as well as records transmitted to sponsors. This presentation will review two use cases of an eCOA Archive: support for inspection of the site and support for audit of the Sponsor. The review impacts Clinical Operations, Records and Document Management, Pharmacovigilance and Regulatory Affairs functions.

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 6: SUBMISSION PLANNING AND CONTROL THROUGH A PRODUCT LIFECYCLE TODAY AND TOMORROW

Workshop Co-Presenters:

Tomaž Kobe, Head of Delivery Management, Amplexor, Slovenia

Mark Cottingham, Senior Business Lead, F. Hoffmann-La Roche, Switzerland

Romuald Braun, VP Strategy Life Sciences, Amplexor, Switzerland

- Trigger audience's minds into rethinking the automatization of submission execution process
- Understand how the submission process can be optimized further while increasing oversight and regulatory compliance

17:00 NETWORKING RECEPTION IN THE EXHIBITION HALL

18:00 END OF DAY ONE

| DAY TWO | THURSDAY, 14 SEPTEMBER 2017

08:30 PARALLEL TRACKS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 7: CLINICAL DATA TRANSPARENCY (EMA POLICY 0070)

Workshop Co-Presenters:
Rosalynd J Cole, Regulatory Affairs Manager, Accenture Accelerated R&D Services, UK
Marjolijn van Lier, Regulatory Affairs Scientist, eCTDconsultancy B.V., The Netherlands
Abby Cottage, GRAAS Operations Manager, Amgen Ltd, UK

- Applied definitions for CCI and PPD information
- Applied redaction technique and workflow
- Applying eCTD lifecycle now and in the future

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 8: REGULATORS AND NOTIFIED BODIES SHARE RESPONSIBILITY FOR CDx AND PRECISION MEDICINES

Moderator: **Julia Stingl,** Vice President, BfArM, Germany
Frank Breitenbücher, Project Manager, Companion Diagnostics (CDx), TÜV Rheinland, Germany

The benefit-risk balance of a medicinal product (MP) will be strongly influenced by the performance of its corresponding CDx. Acknowledging this, the new in vitro diagnostic medical devices Regulation (2017/746) institutes a mandatory consultation of the regulatory authorities that approved the MP during the certification of a CDx by the Notified Bodies (NB).

10:00 COFFEE BREAK IN THE EXHIBITION HALL

10:30 PARALLEL TRACKS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 9: DATA MINING AND ITS APPLICATION ON CLINICAL AND REGULATORY DOCUMENTATION

Workshop Presenters:
Jim Nichols, Vice President, Cunesoft Inc., USA
Daniel Koppers, CTO, Cunesoft, Germany

How data mining can be considered in the regulatory and clinical arena, with a prospective view on the application of the concepts in ETMF.

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 10: THE TOOLBOX APPROACH TO REGULATORY INTELLIGENCE

Workshop Co-Presenters:
Almut Holz, Managing Consultant Regulatory Operations & Data Management, Xendo Deutschland GmbH, Germany
Matthias Wilken, Head of Drug Regulatory Affairs Europe / Scientific Aspects in Social Law, German Pharmaceutical Industry Association (BPI), Germany

Over the past decades, the pharmaceutical industry has transformed from a production-heavy to a knowledge-heavy industry. With global compliance standards increasing or changing on a daily basis the knowledge problem in the industry is twofold:

- managing the growing body of information from external sources
- managing the internal specific product knowledge

The current solution consists of:

- RI (Regulatory Intelligence) consultancy services
- software solutions
- global databases that organise regulatory requirements that organise regulatory requirements

12:00 LUNCH BREAK IN THE EXHIBITION HALL

13:30 PARALLEL SESSIONS

Track 1 | Clinical Operations & eTMF - ROOM MOA7

Workshop 11: HOW YOUR QUALITY MANAGEMENT SYSTEM GETS YOUR INSPECTION READY

Workshop Co-Presenters:
Moderator: **Laura Galuchie**, Transcelerate Coordinator for Merck Sharp & Dohme, USA
Kathrin Droese, Biostatistics - Data Sciences, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Hanne Storgaard, Assoc. Dir, Clinical Research, MSD Danmark ApS, Denmark
Maria Magdalena Borda, Roche and TransCelerate Work Stream Lead for QMS, Switzerland

A total QMS that connect all the dots in clinical operation is key to ensure compliance and quality at all levels. We can't look at this in silos and every project needs some specific adjustments

- Your QMS will help you or fail you to be inspection ready in good shape
- Nowadays with all the new accelerated review process by major Regulatory agencies like Breakthrough designation by FDA, PRIME by EMA, all is accelerated and inspection are happening while studies are still active and ongoing so inspection ready is more important than ever

Track 2 | Regulatory Operations - ROOM MOA3

Workshop 12: HeRO FORUM - HEADS OF REGULATORY OPERATIONS

Workshop Co-Presenters:
Aileen Fisher, Head of Regulatory Affairs and Pharmacovigilance, Kinapse Ltd., UK
Gavin Outteridge, Vice President, Kinapse Ltd., UK

The HeRO Forum is a cross-industry collaboration of Top BioPharma Heads of Regulatory Operations, established and facilitated by Kinapse. Its purpose is to benefit the life sciences sector globally through non-competitive collaboration in the area of Regulatory Operations.

Learn about recent deliverables such as:

- Publishing a position paper on the value of Regulatory Operations
- Developing a standard playbook and dataset for Reg Ops support to M&A
- Benchmarking Reg Ops group operating models to identify good practice and innovative trends

15:00 COFFEE BREAK IN THE EXHIBITION HALL

15:30 SUMMARY: BRINGING CLINICAL AND REGULATORY TOGETHER - ROOM MOA7

Marta Arias-Salgado, Executive Director, Global Clinical Trial Operation, Head of Central and Eastern Europe and Middle East Africa, Merck Sharp & Dohme, The Netherlands

Karen Roy, Senior Vice President, Client Solutions, Phlexglobal, UK

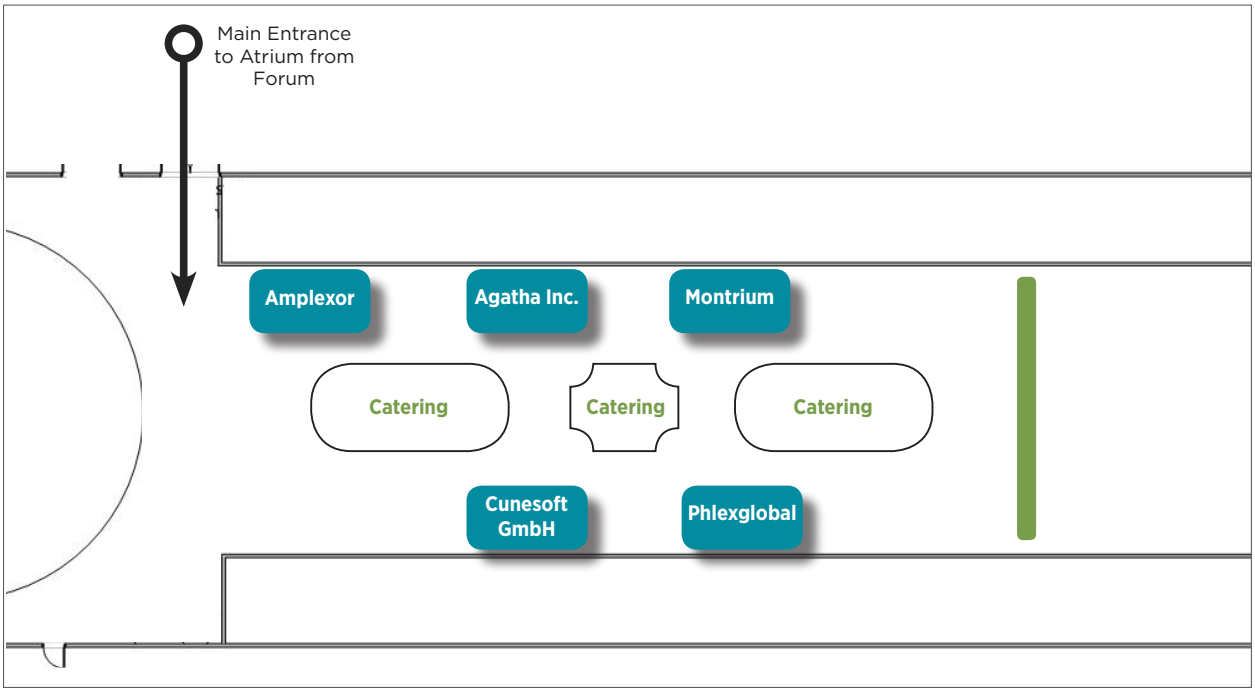
Peter Schueler, Senior Vice President, Drug Development Services, ICON, Germany

Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy B.V., The Netherlands

16:30 CONFERENCE CONCLUSIONS & FEEDBACK

17:00 END OF CONFERENCE

EXHIBITION AREA FLOOR PLAN



Access Presentations

As a benefit of your registration, presentations are made available on the DIA website.

- Presentations are made available to full conference attendees
- To access presentations, go to www.diaglobal.org and click on "Sign in" at the very top. Once you have successfully logged in, go to My Presentations
- No paper copies of the presentations will be provided

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

Evaluation

Your comments and views on the content and organisation of the event are highly valued. The evaluation form will be available online: http://bit.ly/2eYkBDo

Certificate of Attendance

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance to the conference.

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 11.5 credits.

To get a **free USB stick** at the end of the meeting, simply come to see a DIA staff member. We will give this USB **to all attendees who have completed the evaluation!**