eDM 2018 - Clinical and Regulatory Operational Excellence Forum

29-30 November 2018
Hotel Fairmont Rey Juan Carlos I, Barcelona, Spain

PROGRAMME COMMITTEE

Kristen Bretzius
Document Center Manager, PSI Pharma Support America, United States

Eldin Rammell
Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

Karen Roy
Chief Strategy Officer, Phlexglobal, United Kingdom

Hans van Bruggen
Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

WIFI
Network: **DIA Conference**
Password: **Barcelona18**

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.

This conference has been accredited with 10.50 credits.

Overview

eDM 2018 - Clinical and Regulatory Operations Forum will focus on how can we adapt to this digital era by embracing working solutions and partnerships. This highly interactive forum will enable you to perform complex tasks to the highest operational standards, shortening turnaround times and reducing queries and re-creation in your development programmes. Additionally, this Conference provides multiple opportunities for networking, knowledge sharing, and education for all attendees.

We are bringing together thought leaders across the fields of:

- Clinical Operations
- Regulatory Affairs
- Records and Document Management
- Health Authorities
- Supportive software vendors
- CROs

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

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Who Will Attend

- 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
- Health Care and R&D Professionals in the areas of Electronic Document Management, IT and Process Innovation
- New Technical Solution Vendors

DAY ONE | THURSDAY, 29 NOVEMBER

09:00 REGISTRATION AND WELCOME COFFEE

10:00 INTRODUCTION

10:10 KEYNOTE SPEECH

John Cogan, Head of Innovation, Kinapse, United Kingdom
Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

10:50 SESSION 1

SESSION 1: ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING
Session Chair:
Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

What is AI? Extract Knowledge from Unstructured Documentation to Improve Quality and Accuracy
Barry Sacks, Chief Technology Officer, Phlexglobal, United Kingdom

Automated Risk Detection Using Machine Learning Techniques in Clinical Trials
Laura Trotta, R&D Manager, Product Manager, CluePoints, Belgium

Experiences with Automated Solutions at Industry and Agency
Jason Berning, Project Manager R&D, Lorenz, Germany

12:20 LUNCH

13:30 SESSION 2 - PARALLEL SESSION

SESSION 2A

PROCESS AUTOMATION - CLINICAL
Session Chair:
Karen Roy, Chief Strategy Officer, Phlexglobal, United Kingdom

Robotic Process Automation
Jason Berning, Project Manager R&D, Lorenz, Germany

Facilitated Group Discussion

Moderators:
Eldin Rammel, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom
Jason Berning, Project Manager R&D, Lorenz, Germany
Karen Roy, Chief Strategy Officer, Phlexglobal, United Kingdom

- Barriers to Process Automation
- Opportunities for Process Automation
- Success Factors: How to Make it Work

Group Feedback and Concluding Remarks

SESSION 2B

PROCESS AUTOMATION - REGULATORY
Session Chair:
Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

All the Way Around the RIM: From Registration Data to Documents to Dossiers and Back
Joel Finkle, Associate Offering Management Director, Regulatory Innovation, ACUTA, an IQVIA Company, United States

Transforming Regulatory Affairs through Technology - End to End Tech Platform Approach
Peter Lassoff, Vice President and Head, Global Regulatory Affairs, IQVIA, United Kingdom

Automating Regulatory Maintenance - Better Compliance and Costs
Jim Nichols, Chief Operations Officer, Cunesoft, United States
Des McMahon, VP Global Regulatory Affairs, Genpact, United Kingdom

15:00 COFFEE BREAK

15:30 SESSION 3

RISK AND COMPLIANCE
Session Chair:
Lisa Mulcahy, Owner, Principal Consultant, Mulcahy Consulting, United States

Sisyphus' Rock? A Risk Based Approach to Records Management
Sheila Mahoney Jewels, CEO, LifeSciHub, United States

Validating an EDMS or eTMF System Using a Standardized Protocol
Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

Let's Destroy Paper Documents FOREVER! A Review of the Framework for the Destruction of Paper v2.0 and Project Activities
Lisa Mulcahy, Owner, Principal Consultant, Mulcahy Consulting, United States

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

| Disclosure Policy

Unless otherwise disclosed, DIA 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. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

| Hotel Information

Fairmont Rey Juan Carlos I
Av. Diagonal 661 - 671
08028 Barcelona
Spain

Closest airport: Aeropuerto de Barcelona
Distance to the hotel: 25km
How to get to the hotel? Please click here.

DAY TWO | FRIDAY, 30 NOVEMBER

08:00 WELCOME COFFEE

08:30 SESSION 4

DATA AND DOCUMENT INTEGRITY
Session Chair:
Karen Roy, Chief Strategy Officer, Phlexglobal, United Kingdom

Data Integrity and Audit Trail Review
René Kasan, CEO, 37 Centigrades, Switzerland

Data Integrity - A Regulatory Update
Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

Facilitated Group Discussions:

- A Digital World - How Has the Data Integrity Challenge Changed?
- The 'Real Word' vs 'the Inspection' - What Are the Challenges?
- What Are the Future Trends?

Group Feedback and Concluding Remarks

10:00 COFFEE BREAK

10:30 SESSION 5

INFORMATION GOVERNANCE
Session Chair:
Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

GDPR to Stimulate Data Sharing
Francis P. Crawley, Executive Director, Good Clinical Practice Alliance - Europe (GCPA) and Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Belgium

World Class RIM Survey
Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

Impact of Brexit on Regulatory Submissions for CP and MRP/DCP
Gordon Elger, Regulatory Affairs Affiliate Lead , Astellas, United Kingdom

12:00 LUNCH

13:15 SESSION 6 - PARALLEL SESSION

SESSION 6A

DOCUMENT FLOW AND INTEROPERABILITY
Session Chair:
Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

Transformation Through Innovative Information Management - A Regulatory Perspective
Doug McKinnell, Director Risk Advisory, Deloitte, Switzerland
Niamh McNamara, Roche Products Ltd, United Kingdom

Interoperability – A Path to Automated Quality Checking in eTMFs?
Jaclyn Morrill, Director of Clinical Operations, LMK Clinical Research Consulting, United States

TMF Reference Model eTMF-EMS - Towards a First Industry Standard for Interchange
Paul Fenton, CEO, Montrium, Canada

SESSION 6B

RELIABLE DATA AND APPLIED TECHNOLOGY
Session Chair:
Frits Stulp, Managing Director Iperion Life Sciences Consultancy, The Netherlands

The use of SPOR/IDMP and the Impact on Regulatory Affairs and RIM Solutions in the EU
Remco Munnik, Regulatory Information Director, Asphalion, Spain

eCTDs for NPs, Baselines Submissions and Validation Issues for NP and MRP/DCP
Armand Vermaire, Regulatory Operations Manager, Qdossier, The Netherlands

Global Submission Management: RIM Perspectives on Planning, Reporting and Automation
David Ross, Global Regulatory Operations Strategy and Change Management, AstraZeneca, United States

Panel Discussion

14:45 COFFEE BREAK

15:00 SESSION 7

STANDARDISATION
Session Chair:
John Cogan, Head of Innovation, Kinapse, United Kingdom

IDMP - Overall Setting and Current Status
Dimitri Stamatiadis, Maia Consulting, Switzerland

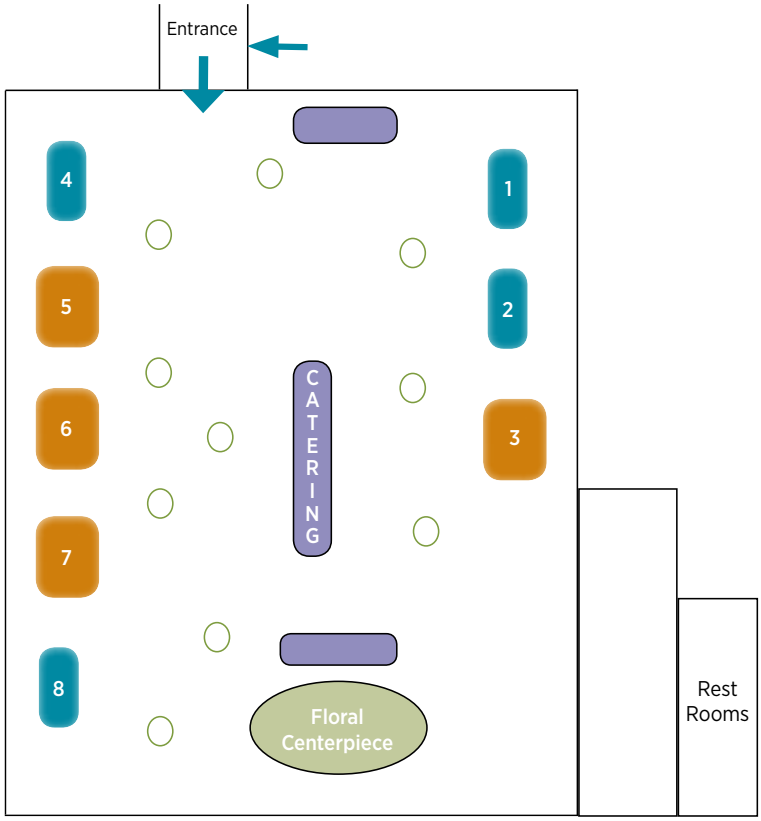
EU-SRS
Frits Stulp, Managing Director, Iperion Life Sciences Consultancy, The Netherlands

CDISC CTR2
Paul Houston, Formerly CDISC, France

Panel Discussion
Comment on "Standardisation Topics from a Clinical Document Management Perspective"
Paul Fenton, CEO, Montrium, Canada

16:30 END OF CONFERENCE

EXHIBITION FLOORPLAN



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