3rd conference in compliance preparations for identification of medicinal products regulatory series

IDMP Compliance Challenge and Regulatory Information Management

Benchmark preparations for IDMP compliance and work towards effective data management while breaking silos between divisions

Marriott West India Quay, London, UK

17th – 19th June 2015

> Benchmark preparations for **July 2016** compliance challenge to avoid the risk of **5% gross revenue penalty** June 2015: On a 12 months runway **or runaway..!**

marcusevans

Interactive Conference Workshops day on 17th June

Workshop A: **RIMS**
Workshop B: **Preparing for IDMP Compliance Challenge**

Attending this Premier **marcus evans** Conference will Enable You to

- Receive **latest information from EMA: Roadmap and milestones**
- Evaluate the **impact of ISO IDMP** and organise subsequent prioritization of key preparatory activities
- Hear best practices **on gap analysis and steps to be taken after the gap analysis**
- **Learn from MDM projects and IDMP compliance data from source**
- **Hear a journey towards a cost-effective and scalable IDMP solution**
- Get **practical experiences** on working with other key stakeholders like manufacturing, clinical etc.
- Implement and run an efficient **Regulatory Information Management System**

Learn from Key Practical Case Studies

- **ISO Technical Committee 215 Working Group 6 member** discussing experiences with gap analysis and further steps
- **Boehringer Ingelheim Pharma GmbH & Co. KG** sharing experiences on post gap analysis steps
- **Dr. Andrew Marr** providing detailed overview and latest updates of EMA ISO IDMP Taskforce developements
- **Johnson and Johnson** ensuring having IDMP compliant regulatory data

In the Chair Day One

Dr. Andrew Marr
Internationally recognised IDMP Compliance Expert
Member, ISO Technical Committee 215, Working Group 6
Marr Consultancy Ltd, UK

In the Chair Day Two

Dr. Gerhard Noelken
Senior Director
Technology and Innovations
Pfizer

Expert Speaker Panel

Dr. Andrew Marr
Internationally recognised IDMP Compliance Expert
Member, ISO Technical Committee 215, Working Group 6
Marr Consultancy Ltd, UK

Dr. Dieter Schlaps
Member
ISO Technical Committee 215 Working Group 6

Adnan Jamil
Regulatory Operations Associate
Astellas Pharma Europe

Fares Madi
CEO
TEELIA

Larry Callahan, Ph.D.
Substance Registration System
FDA, USA
Presentation over Webex

Deborah Cooper
Vice President, Global Regulatory Affairs
Genpact Pharmalink

Rob Southon
Product Director
i4i

Kornelia Williams
RDIS Project Manager
Allergan

Dr. Gerhard Noelken
Senior Director
Technology and Innovations
Pfizer

Innis Viviers
Associate Director, RIM, Data Standards and Quality
Janssen, Pharmaceutical Companies of Johnson and Johnson

Frits Stulp
Advisor, Program Manager for IDMP Implementation
Iperion

Dr. Jörg Stüben
Senior Expert for Processes and Documentation in QRPE
Boehringer Ingelheim Pharma GmbH & Co. KG

Silver Sponsor

Teelia®

Partner Sponsors

i4i

PharmalinkConsulting
WORLDWIDE REGULATORY AFFAIRS

Documentation Sponsor

kinapse

Media Partners

Pharmaceutical – Tech.com™

MNT Medical News Today

Pharma Marketing News

PharmaVOICE

marcusevans® conferences

Interactive Conference Workshops

17th June 2015

WORKSHOP A: REGULATORY INFORMATION MANAGEMENT SYSTEMS

09.30 Registration and Coffee

10.00 Workshop Leader's Introduction and Opening Remarks

10.05 **Implementing and Running Effective Regulatory Information Management Systems**
- Objectives of a RIMS
- RIMS requirements Regulatory Affairs and other departments
- Business processes and RIMS
- Benefits and costs of a RIMS
- RIMS architecture and interface to other systems
- RIMS tools on the market

Attendees will be able to enjoy afternoon tea and networking opportunities midway through the workshop at 11.45.

Frits Stulp
Advisor, Program Manager for IDMP Implementation
Iperion

13.00 Closing Remarks for the Workshop A

13.05 Lunch

WORKSHOP B: PREPARING FOR IDMP COMPLIANCE CHALLENGE

14.30 Registration

14.10 Workshop Leader's Introduction and Opening Remarks

14.15 **Preparing for IDMP Compliance Challenge**
- Analyse and evaluate the impact of ISO IDMP
- What are the priorities and concrete steps to be taken considering the remaining time to reach IDMP compliance
- Harnessing key challenges and technical considerations
- Incorporating IDMP into the short-term and long term strategy
- Addressing organizational change management as part of your IDMP initiatives

Attendees will be able to enjoy afternoon tea and networking opportunities midway through the workshop at 15.30

Frits Stulp
Advisor, Program Manager for IDMP Implementation
Iperion

17.10 Closing Remarks from the Workshop Leader

Testimonials

"Very fruitful conference, excellent presenters. Thank you."
IDMP Project Lead
Novartis Pharma AG

"Great job!"
Research Director
Gartner

"Very targeted and productive event. Topic is timely and current."
VP, Life Sciences R&D Practice,
HighPoint Solutions

marcus evans conferences
Producers of high quality business to business conferences designed to address the strategic information needs of senior executives. Speakers are practitioners from international blue-chip organisations and financial institutions, as well as business schools, academic bodies and government ministries. More than 1,000 conferences take place each year, attracting over 100,000 delegates and 16,000 speakers.

marcus evans summits
Producers and promoters of over 150 of the world's leading business and economic summits every year for senior decision makers at exclusive locations around the world. These events provide attendees with a unique opportunity to access the latest developments in their chosen industry and to network in a structured environment with leading industry practitioners.

marcus evans professional training
Sector Focused and General Management Training through high quality courses, videos and CD-ROMs enables organisations of any size and geographical location to benefit from working with **marcus evans** for all their training needs. The clients' demands for high quality hands-on training drives the focus for content, and thorough research ensures a compatibility with current business concerns.

marcus evans language training
marcus evans linguarama offers effective training in language, communication and culture for business and professional people. With more than 30 years' experience and over 20 centres in Europe, we are one of Europe's largest business language and communication training organisations. Each year **marcus evans** linguarama trains people from over 60 countries worldwide and provides over 1,000 companies and organisations with total training solutions where our courses are focused entirely on the needs of the individual participant or group and have practical relevance to business and professional life.

marcus evans corporate hospitality
Specialists in corporate hospitality linked to the premier international sporting events around the world. Trading as The Hospitality Group (thg), Sports Marketing Group (smg) and International Championship Management, the event diary is nothing less than an international sporting directory.

marcus evans congresses
marcus evans congresses bring together the leading vendors and decision makers from a wide range of services and industries. Each event provides an opportunity for key suppliers to exhibit and demonstrate their products to the region's key professionals. In addition to the exhibition format the event's educational conference is attended only by delegates who are pre-qualified, in most cases to a minimum spend of US$5 million and many with budgets in excess of $50 million.

Day One

18th June 2015

08.30 Registration and Coffee

09.10 Opening Address from the Chair

REGULATORY UPDATE

09.20 Keynote

Latest IDMP Regulatory Update and Understanding the ISO IDMP Standards

- Latest information from EMA and ISO: Roadmap and milestones
- Timelines for issuing regional implementation guidelines
- Data relationships between XEVMPD and IDMP
- Understanding the main ISO implementation guides
  - Medicinal Product
  - Substances and Specified substances
- Anticipating EU regional requirements
- The importance of establishing a single version of truth

Dr. Andrew Marr
Internationally recognised IDMP Compliance Expert
Member, ISO Technical Committee 215, Working Group 6
Marr Consultancy Ltd, UK

10.30 Refreshme

11.10 Case Study

What Comes First Regulatory Information Management Systems or ISO Identification of Medicinal Products?

- What does the ISO IDMP Data model provide that supports your RIMS roadmap?
- What steps will you need to go through to build ISO IDMP ready data?
- What is the impact on your current process, goverance and systems once you know where the data is?

Deborah Cooper
Vice President, Global Regulatory Affairs
Genpact Pharmalink

11.35 Case Study

Documents = Data

- Your documents are the culmination of all the data about your products
- Overcoming the challenge of accessing the data in your documents
- The evolution of machine processable information exchange
- Maintaining your product documents as the golden source of your data

Rob Southon
Product Director
i4i

12.00 Lunch

13.15 Keynote

FDA Perspective on IDMP

- EMA/FDA roadmap
- Technical specifications
- Assessing the latest developments and requirements

Presentation over Webex
Larry Callahan, Ph.D., Substance Registration System
FDA, USA

PANEL DISCUSSION

14.00 **The Challenge of Achieving IDMP Compliance**

- What does the roadmap to IDMP compliance look like?
- What are the technical challenges you anticipate, or are facing
- What are the organisational challenges you anticipate, or are facing

To be joined to speakers and invited guests

Panelists:

Dr. Andrew Marr
Internationally recognised IDMP Compliance Expert
Member, ISO Technical Committee 215, Working Group 6
Marr Consultancy Ltd, UK

Kornelia Williams
RDIS Project Manager
Allergan

Innis Viviers
Associate Director, RIM, Data Standards and Quality
Janssen, Pharmaceutical Companies of Johnson and Johnson

Dr. Jörg Stüben
Senior Expert for Processes and Documentation in QRPE
Boehringer Ingelheim Pharma GmbH & Co. KG

14.50 Refreshme

IDMP PREPARATION AND GAP ANALYSIS

15.30 Case Study

Gap Analysis

- Data analysis and IT strategy project, which aims to achieve the following:
  - Understanding the IDMP data as managed both within the company and by partners
  - Determining both a short term and strategic IT solution that will enable us to be compliant
  - Evaluating the as-is and define the to-be business processes that describe the creation and maintenance of the data
- Risks anticipated and those that were not expected
- Issues, how we overcame them and next steps

Dr. Dieter Schlaps
Member
ISO Technical Committee 215 Working Group 6

PANEL DISCUSSION

16.30 **Benchmarking IDMP Implementation in Supply Chain, Patents, Clinicals and Other Key Areas**

- Specified substance: Definition, points for action
- Clinical environment: Safety, reporting
- How vaccines fit into the whole picture
- Relation with manufacturing site: How can we connect with the different world of material, connecting with IDMP data model
- Supply chain and Patents
- Clinicals and coding

To be joined to speakers and invited guests

17.20 Closing Comments from the Chair and End of Day One

Day Two

19th June 2015

08.30 Registration and Coffee

09.00 Opening Address from the Chair

COMPLIANCE ROADMAP IN PRACTICE

09.10 Case Study

2016 Compliance Roadmap

- IDMP Gap Analysis case study – how much of the IDMP data do we have and what does it look like
- IDMP/XEVMPD Business Case – Share which parts of the business is involved and who is sponsoring
- IDMP and RIM integration – ensuring we have IDMP compliant regulatory data
- Not just a data problem – What else is needed to make IDMP sustainable?
- Our roadmap to 2016 compliance

Innis Viviers
Associate Director, RIM, Data Standards and Quality
Janssen, Pharmaceutical Companies of Johnson and Johnson

10.10 Case Study

Gap Analysis Completed: Further Steps

- The gap analysis is an essential preparation part of any IDMP activity. Once done, you should know your individual companies data situation
- Data piloting – use real data to verify gap analysis findings and data linking possibilities
- Galvanise your seniors – demonstrate real IDMP scope using tangible data
- Clearing the way: Possible streams for an IDMP project

Dr. Jörg Stüben
Senior Expert for Processes and Documentation in QRPE
Boehringer Ingelheim Pharma GmbH & Co. KG

11.10 Refreshme

11.50 Case Study

Data Accuracy across Systems and Organisations: Systems Enhancement to Fulfil Requirements

Fares Madi
CEO
TEELIA

12.40 Lunch

MANAGING STAKEHOLDERS

13.50 Case Study

Structured Authoring of Product Information as Stepping Stone Towards IDMP Compliance (Astellas Case study)

- Case study of the structured authoring project on product information at Astellas
- Identifying the clinical particulars in the product information (SmPC)
- Global user requirements identification and vendor selection, leading to an implementation project
- Role of this tool in the overall Astellas IDMP architecture
- Benefit versus risk of this approach

Frits Stulp
Advisor, Program Manager for IDMP Implementation
Iperion

Adnan Jamil
Regulatory Operations Associate
Astellas Pharma Europe

14.50 Refreshme

15.20 Case Study

How IDMP Could Enable the Seamless Flow of Analytical Data Through your Organisation

- Allotrope Foundation and Framework
- Data Lifecycle in IDMP
- Allotrope Data standard evaluation
- Analytical data in IDMP
- Regulatory Benefits of Allotrope Framework

Dr. Gerhard Noelken
Senior Director Technology and Innovations
Pfizer

16.10 Closing Comments from the Chair and End of Conference

Who Should Attend

SVPs / Heads / Directors / Managers / Process Owners/ Team Leaders /Leads/ Programme / Project Managers of:

- Regulatory Affairs Operations
- Regulatory Affairs
- Submissions / Document Management
- Regulatory IS/IT / Systems
- Regulatory Information/Documentation
- Pharmacovigilance
- Master Data Management
- Data Governance/Data Quality
- Manufacturing / Safety /Supply Chain

Sponsor Profiles

Silver Sponsor

Teelia is a consulting company providing innovative and tailored solutions for the phamaceutical industry.
We support our clients specific needs and improve their efficiency Information management technologies and solutions for IT strategy and transformation projects, Data warehousing and Business intelligence capabilities, Computerized Systems Validation and Business Processes Management. Our experts anticipate IDMP impacts, technological changes, business evolutions to define the "what" of each solutions. They combine pragmatism and creativity to decline the strategy and build the "how". Our consultants will help your enterprise to navigate the entire IDMP implementation process and your success will be our main achievement.

Partner Sponsors

i4i is a world leader in the development of structured content applications. i4i has brought its innovative technology and regulatory expertise to the Life Sciences industry with solutions that enhance compliance by delivering intelligent content reuse, repurposing and tracking across your organization as products and regulations evolve. Our solutions cover the CCDS, Global Labeling, CMC and clinical documents as well as offering unique applications specific to SPL submissions and IDMP data.

Genpact Pharmalink transforms the way Life Sciences companies manage regulatory affairs activities globally. We combine Pharmalink's specialized domain expertise in consulting, project support and outsourced regulatory affairs services with Genpact's global delivery, BPO, technology and analytics offerings for the global life sciences market.

Partner Sponsor

Kinapse provides expert advisory, capability building and operational services to the life sciences industries. We collaborate with our clients to innovate for exceptional results Our expert teams partner with our clients to advice on strategy and operations, implement capability-building programs and deliver outsourced operational solutions.
We bring industry insights and technical expertise throughout our engagements. We develop actionable recommendations and innovative solutions which are implemented successfully. Our clients are the world's leading life sciences organizations, their customers, suppliers and regulators. Our client references are the strongest testament to the exceptional results we deliver in partnership with them.
We are one global business with expert teams providing excellent services With over 400 professionals worldwide, we select our teams to deliver the best possible solutions. Our deeply held values and operational processes drive our teams to ensure excellent client service on all our engagements.

Our Services
Kinapse provides expert advisory, capability building and operational services to the world's leading life sciences organizations, their customers, suppliers and regulators.

1. Building Quality and Compliance – The Foundations of a Quality Culture
2. Supporting you with Regulatory Affairs, Worldwide
3. Development Operations built for the future
4. Kinapse Medical Information Service – Informed By You
5. Shaping Life Sciences Policy in the Real World
6. Clinical Operations – making transformations work
7. Getting it right first time
8. Medical Affairs – Your Affairs are Our Affairs

Media Partners

Pharmaceutical-tech
In the realm of Pharma industry, where innovation is rapid, Pharmaceutical-tech stands adept at conceptualizing unique ideas relevant to the B2B space. Pharmaceutical-tech is essentially a B2B online business and media platform that has under it wraps the largest global database of Pharma buyers and suppliers. Pharmaceutical-tech.com covers in-depth trends that shape industry dynamics and metamorphose global economics.
With services like search engine optimization, social media marketing, product video showcase, e-mail marketing, e-newsletter sponsorship's, banner advertising, event marketing and micro-website within our platform, Pharmaceutical-tech.com has created a recognition that spans over a global audience, thereby revolutionizing how businesses transact.

Medical News Today is the largest independent medical and health news site on the web – with over 10,000,000 monthly unique users it is ranked number one for medical news on all major search engines. Medical News Today is used by pharmaceutical, biotech and health organizations, advertising agencies, PR companies and vertical ad networks to deliver targeted campaigns to HCPs, patients and caregivers. To find out how Medical News Today can help you to reach the right audience contact **peter@medicalnewstoday.com** or visit: **www.medicalnewstoday.com**

Pharma Marketing News is an independent monthly electronic newsletter focused on issues of importance to pharmaceutical marketing executives. It is a service of the Pharma Marketing Network – The First Forum for Pharmaceutical Marketing Experts – which brings together pharmaceutical marketing professionals from manufacturers, communications companies, and marketing service providers for wide ranging discussions and education on a multitude of current topics. Pharma Marketing Network & Pharma Marketing News provide executive-level content coupled with permission-based e-marketing opportunities.

PharmaVOICE magazine, reaching more than 41,000 BPA-qualified life-sciences executives, is the forum that allows business leaders to engage in a candid dialogue on the challenges and trends impacting the industry. PharmaVOICE provides readers with insightful and thought-provoking commentary in a multiple-perspective format through forums, topics, and articles covering a range of issues from molecule through market. PharmaVOICE subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, White Papers, E-Surveys and e-Alerts. Additionally, PharmaVOICEMarketplace.com provides a comprehensive directory of products, services, and solutions for the life-sciences industry.
To Raise Your VOICE, contact: **feedback@pharmavoice.com**.