SESSIONS

BERLIN SUMMIT: DAY 1 - WED, 6 APR

Conference Registration and Welcome Refreshments

08:00 - 09:00

Chairperson's Opening Remarks

09:00 - 09:15
IDMP

Participants

Jörg Stüben - Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH

An Update from the SPOR Taskforce

09:15 - 09:45
IDMP

- Review the latest implementation guide updates and their impacts on the industry
- Assess how the implementation guides are being interpreted
- What's next? Timelines

Participants

Patrick Middag - Associate Director – IT Business Partner Regulatory Europe/Canada/IDMP, Bristol Myers Squibb

Isabel Chicharo - Head of Regulatory Data Management, Core Services Department, European Medicines Agency

Deep Dive into the DADI Project: Digital Transformation of Electronic Application Forms

09:45 - 10:10
IDMP

- Brief overview of DADI
- How partners and stakeholders are involved in the project development
- Roadmap and timelines

Participants

Jen Klesh - Associate Director, Medicinal Product Data Management, Bristol Myers Squibb

Networking Break

10:10 - 10:45

In Discussion with Members of SPOR, DADI and UNICOM

10:45 - 11:30
IDMP

- Understand how SPOR, DADI, UNICOM, CTIS Portal and the IRIS Portal tie into each other
- WHO-UMC (Uppsala Monitoring Centre) pilot – how to implement IDMP globally
- Where does more work need to be done to align goals?

Participants

Panelist: Patrick Middag - Associate Director – IT Business Partner Regulatory Europe/Canada/IDMP, Bristol Myers Squibb

Panelist: Veronica Lipucci Di Paola - Master Data Manager & PMS Co-Business Lead, Regulatory Data Management Service, European Medicines Agency

Panelist: Kristiina Puusaari - DADI Programme Coordinator/Project Manager, EMA

Panelist: Christian Hay - Senior Consultant Healthcare, GS1

Panel Discussion: State of the Industry and IDMP

11:30 - 12:15
IDMP

- How companies are assessing their IDMP maturity levels
- Examine best practices for changing core regulatory business processes
- Key insights into developing an overall IDMP vision
- Share experiences with integrating different systems for IDMP
- Live-polling and benchmarking

Participants

Moderator: Kelly Hnat - Principal, K2 Consulting

Panelist: Jörg Stüben - Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH

Panelist: Laurent Lefebvre - RA CMC Director, RIM System Delivery Lead, Novartis

Panelist: Alastair Nixon - Director, Submission Standards, GSK

Networking Luncheon

12:15 - 13:15

How to Navigate the Unpredictable Route to IDMP Compliance: A Tale of 2 Survivors

13:15 - 14:00
IDMP

- Recent changes in IDMP in EU
- Examples of real industry challenges & solutions
- NNIT's framework to success

Participants

Niels Leander - Global Head of Regulatory Affairs, NNIT

Stefan Peev - Principal Advisory Consultant, Regulatory Affairs, NNIT

Life Sciences: Are We Ever Going to Change? The Pandemic Was a Wakeup Call – or Was It?

14:00 - 14:45
IDMP

Remco and Frits are involved in a high number of activities and projects that give them a broad view. In conversation format, they'll share their insights, views and hopes on the following:

- What was the original vision of data in Life Sciences?
- How did we apply it in the pandemic, and did we do what we'd hoped?
- What does the future look like? Would we do different in the next pandemic? And how long do we have?
- What movements do we see now from industry, regulators and interested stakeholders?
- Can we achieve a better future state through new initiatives like an agile approach?
- And how do other developments in the world (like dynamic dossiers) relate to this?

Participants

Remco Munnik - Chair of the Telematics Working Group, Medicines for Europe

Frits Stulp - Managing Director, Iperion – a Deloitte business

Afternoon Networking Café and Table Topics

14:45 - 15:15

Group discussion and ideas exchange in the exhibitor hall:

1. Looking Ahead – What's Next for Regulatory in 2023 and Beyond?
2. Use of AI in Regulatory Strategy
3. Shared experiences in registrations for global markets
4. Open Topic

Regulatory Updates from Health Canada

15:15 - 15:45
IDMP

- Current and future plans for IDMP implementation
- Overview of Health Canada's XML PM project
- Gain insights into new initiatives and how they would impact pharmaceutical manufacturers

Participants

Shannon Laforce - Executive Director, Transformation and Business Informatics, Health Canada

Global Focus: IDMP Preparation and Implementation Across the World

15:45 - 16:45
IDMP

- Snapshot of the IDMP landscape globally
- Where is IDMP applications advancing rapidly?
- Which regions are slow to adopt the IDMP standards?
- How are multinational pharma companies responding despite the lack of global harmonisation?
- What does an IDMP implementation look like?

Participants

Vada A Perkins - Executive Director, Regulatory Policy & Intelligence/Head, Regulatory Intelligence, Bayer Pharmaceuticals

Craig Anderson - Director, Information Management, Pfizer

Paul Attridge - Sr Director, Vault RIM, Veeva Systems

Keynote: Ensuring Access While Supporting Innovation: What is the European Commission's Pharmaceutical Strategy for the Future?

16:45 - 17:30
IDMP

- An overview of the EU pharmaceutical strategy – legislative and non-legislative actions
- What is the timeline for new legislation?
- What are the regulatory affairs components within the 10 points of action put forward by the Commission?

Participants

Florian Schmidt - Deputy Head of Unit, DG SANTE, European Commission

BERLIN WELCOME RECEPTION

17:30 - 18:30

SCHEDULE

BERLIN SUMMIT: DAY 1 - WED, 6 APR -

Delivered as a Hybrid Event 6th - 13th April 2022
Berlin Summit: 6-8 April | Digital Experience: 11-13 April
Presented in Central European Time (CEST)

TIME	IDMP
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11:00	**11:30** - Panel Discussion: State of the Industry and IDMP
12:00	**12:15** - Networking Luncheon
13:00	**13:15** - How to Navigate the Unpredictable Route to IDMP Compliance: A Tale of 2 Survivors
14:00	**14:00** - Life Sciences: Are We Ever Going to Change? The Pandemic Was a Wakeup Call – or Was It? **14:45** - Afternoon Networking Café and Table Topics
15:00	**15:15** - Regulatory Updates from Health Canada **15:45** - Global Focus: IDMP Preparation and Implementation Across the World
16:00	**16:45** - Keynote: Ensuring Access While Supporting Innovation: What is the European Commission's Pharmaceutical Strategy for the Future?
17:00	**17:30** - BERLIN WELCOME RECEPTION

SESSIONS

BERLIN SUMMIT: DAY 2 - THUR, 7 APR

Delivered as a Hybrid Event 6th - 13th April 2022
Berlin Summit: 6-8 April | Digital Experience: 11-13 April
Presented in Central European Time (CEST)

Morning Refreshments and Conference Registration

08:30 - 09:00

Chairperson's Opening Remarks

09:00 - 09:15
Regulatory Information Management

Participants

Patrick Middag - Associate Director – IT Business Partner Regulatory Europe/Canada/IDMP, Bristol Myers Squibb

Chairperson's Opening Remarks

09:00 - 09:15
Global eSubmissions

Participants

Andreas Franken - Head of Clinical Research and eSubmission, Data Protection Officer, Bundesverband der Arzneimittel-Hersteller e.V. BAH

Practical Approaches to Leveraging New and Existing RIM Systems

09:15 - 10:00
Regulatory Information Management

- Understanding of previous system features for the design and improvement of new/existing RIM System
- How to define the requirements of an already implemented RIM based on the balance effort/ benefit
- Analysis and alignment of Vendor roadmap vs company needs
- Expanding scope of existing RIM System more than for Pharmaceutical Products (e.g. Medical Devices, Active Substance, Clinical Trials)

Participants

Ana Montoya Alarcon - Regulatory IT Manager, Novartis

Progress on the Implementation of IDMP Substance Management Solution Based on IDMP Substance Model

09:15 - 10:00
Global eSubmissions

- Establishing a solid set of IDMP-compliant substance master data
  - Increasing the quality of substances master data in Europe: data cleansing,
  - The rationale for implementing GSRS (Global Substance Registration System) software for building and maintaining substance data in Europe
  - EU-SRS implementation project: status & next steps
- Understanding the impact on industry for mapping and potential future submission requirements
  - Data alignment with regulatory authorities, within the data cleansing exercise (initialization on a common substance referential)
  - Industry process considerations for substance management (Maintenance, lifecycle)
  - Technical considerations (How to implement and play the process)
- Forward considerations: Sharing substance data with FDA, WHO Upsalla Monitoring Center, PhPID implications

Participants

Annet Rozema - Project Manager EU-SRS, Medicines Evaluation Board

Jean-Gonzague Fontaine - Product and Substance Master Data Lead, Vx, GSK

Leveraging IDMP and Available Data Connections for Business Benefit

10:00 - 10:45
Regulatory Information Management

- Gaining senior management buy-in to make budget available for IDMP investment
- Case examples
- Lessons for industry

Participants

Quentin Grignet - Head of Master Data Mgt. Strategy & Analytics, GSK

How to Accelerate Your Global Regulatory Submissions Using Data Sciences

10:00 - 10:45
Global eSubmissions

- What are the current challenges in the Global regulatory submission process?
- How can companies use advanced analytics and data sciences on regulatory information to inform strategic decision making?
- How can companies transform and accelerate the global regulatory submission process through this data-driven approach?

Participants

Siva Thiagarajan - Associate Principal, ZS Associates

Networking Break

10:45 - 11:15

Leveraging RIM for DADI and IDMP - Theory and Practice

11:15 - 12:00
Regulatory Information Management

Preparing RIM systems and their evolution in a moving regulatory context is an inevitable concern, both from the Data and the Process point of views. Keeping control over the RIM data model, while ensuring compliance with moving reporting requirements from health authorities, requires appropriate system design and capabilities, as well as a steady governance. Agile methodologies teach us that trying to reach out early for concrete outputs is most effective in the long-term.

· Best practices for RIM Data modeling in the IDMP context

· How can RIM start supporting the DADI process

· Agile FHIR message generation and viewer

Participants

Pierre Stanislawski - Product Manager, Ennov

Jörg Stüben - Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH

Maxime Delpire - Regulatory Information Management Expert, Ennov

SESSIONS

BERLIN SUMMIT: DAY 2 - THUR, 7 APR

Leveraging RIM for DADI and IDMP - Theory and Practice

11:15 - 12:00
Global eSubmissions

Participants

Pierre Stanislawski - Product Manager, Ennov

Jörg Stüben - Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH

Maxime Delpire - Regulatory Information Management Expert, Ennov

RIMS Roundtables: Problem-Solving Based on Company Size

12:00 - 12:45
Regulatory Information Management

Break out into small groups based on company size to discuss the specific challenges faced by regulatory professionals and the potential approaches to overcoming them.

Conversation starters:

- Change management
- Data literacy within the organisation
- Lack of user buy-in
- Inconsistent system use
- Concerns from the top over ROI
- Personnel limitations

Participants

Mid-Size Pharma: Jason Berning - Associate Business Development Director - Regulatory Technology Solutions, IQVIA

Large Pharma: Matthias Glatz - IT-Manager Regulatory Affairs, Novartis Pharma AG

Regulatory Data: Empowering Teams to Drive Efficiencies across the Drug Development Lifecycle

12:00 - 12:45
Global eSubmissions

- This session will look at the historical underpinnings of how RIM systems came to be, what this means for us today, and the possibilities for tomorrow.
- Regulatory data acts as a catalyst for groups across the life sciences industry. By leveraging regulatory data, we can empower global teams to not only manage information but to drive the drug development process from initial R&D to drug sunset. This model will decrease time to market, costs, and time—ultimately getting drugs in the hands of patients who need them faster.
- Utilizing regulatory data, international standards, and open architecture provides regulatory affairs a true end-to-end view on development which will allow them to make better-informed decisions to deliver higher quality products faster.

Participants

Robin Schilling - Global IDMP Product Manager, ArisGlobal

Jim Hilferty - Associate Vice President Product Management Regulatory, ArisGlobal

Networking Luncheon & ArisGlobal Tech Tour: LifeSphere Regulatory is Revolutionizing Regulatory Information Management

12:45 - 13:45

- Seamless transitions between Regulatory Affairs and Regulatory Operations
- Precision automation to accelerate workflows
- Dashboards that provide 360° visibility into the regulatory lifecycle

The Future of Documents: Structured Content, Integrated Data

13:45 - 14:30
Regulatory Information Management

The Future of Documents is shaped by a fundamental change in how information is shared. This future sees a shift from traditional 'e-paper', formatted and optimized for reading by humans, towards semantically tagged information in an open digital format.

- Define Structured Content. What is it and why is it so fundamentally different from formatted documents?
- What are the essential parts of a content architecture, and why is it important?
- Use cases: Labeling, Clinical,Regulatory, Reporting
- Operational aspects: how can writers be engaged and turned into enthusiasts.
- What can we learn from industries where structured content authoring is common practice?

Participants

Jan Benedictus - CEO, Fonto

Examine the Intersection Between eCTD and IDMP

13:45 - 14:30
Global eSubmissions

- Understand how the submission of more product data, in the form of structured data, could impact the eCTD dossier process
- Where can eCTD and IDMP meet?
- What are the long-term goals?

Participants

Andreas Franken - Head of Clinical Research and eSubmission, Data Protection Officer, Bundesverband der Arzneimittel-Hersteller e.V. BAH

End-to-End RIM: The Global Labelling Use Case

14:30 - 15:15
Regulatory Information Management

- Understanding the Challenges of Managing the Global Labelling Process
- The cross-functional Nature of Labelling
- Managing Structured Content

Participants

Mark Willoughby - Head of Life Sciences, Generis

SESSIONS

BERLIN SUMMIT: DAY 2 - THUR, 7 APR

A considered review of the practicalities of implementing eCTD 4.0

14:30 - 15:15
Global eSubmissions

- A review of the impacts on current processes and documentation
- Strategies for raising Organisational User Awareness
- Review of new terminologies, concepts and changes to Lifecyle
- Impacts for authors, reviewers, submission planners & publishers
- Strategies for the Management of keywords and controlled vocabularies
- Factors for implementation
- A discussion of vendor challenges

Participants

Karen Harry - Director, Regulatory Information Management, Calyx

Networking Break

15:15 - 15:45

Building Comprehensive Future-Proof Pharmaceutical Labelling Management

15:45 - 16:30
Regulatory Information Management

- Assessing the challenges of Pharma Labelling Management and the impact of global regulatory requirements
    - eg: Japan eLabeling regulation, Electronic Product Information-ePI, Electronic Patient Leaflet-ePIL, Health Canada Product Monograph, additional Risk Minimization Measures-aRMM, Drug Supply Chain Security Act-DSCSA)
- Identify technology solutions or approaches (SCM, AI, NLP, XML, Block Chain etc)
- Outlining architecture and road map/timeline for adopting “appropriate” technology solutions
- How does this approach position adopters in the future?

Participants

Cham Williams - Associate Director, Business Systems, IQVIA

EFPIA Recommendations for eCTD

15:45 - 16:30
Global eSubmissions

- Overview of eCTD implementation progress globally
- Recommended timelines & approach for new countries considering adopting eCTD
- How industry can engage and influence locally, and support the approach taken by health agencies
- Highlight the benefits that eCTD brings and share examples from existing regions

Participants

Anna Sokolowicz - Senior Manager, Submission Production & MSR Coordination, GSK

Exposing the Value of Regulatory Information Management Beyond Data and Documents

16:30 - 17:15
Regulatory Information Management

- Examine the need for a digital transformation within life sciences
- How will IDMP implementation benefit companies and what else is required?
- Benefits of implementing integrated RIM (platform) solutions vs. standalone systems

Participants

Laurent Lefebvre - RA CMC Director, RIM System Delivery Lead, Novartis

The Evolution of UK Medicines in the National and Global Context: An ABPI Perspective

16:30 - 17:15
Global eSubmissions

- Overview of new UK regulatory frameworks, and their impact in the national, European and Global contexts
- Pros and cons for industry – how are these new frameworks supporting or challenging pharma manufacturers

Participants

Steve Hoare - Quality, Regulatory Science & Safety Policy Director, The Association of the British Pharmaceutical Industry (ABPI)

Case Study: RIM Strategy Towards Digital Transformation

17:15 - 18:00
Regulatory Information Management

- Implications for implementing new RIM practices or developing existing ones
- Roche example

Participants

Mr Quentin Darrasse - Global Quality Manager for Regulatory Operations, F. Hoffmann - La Roche AG

SCHEDULE

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10:00	**10:00** - How to Accelerate Your Global Regulatory Submissions Using Data Sciences **10:45** - Networking Break	**10:00** - Leveraging IDMP and Available Data Connections for Business Benefit **10:45** - Networking Break
11:00	**11:15** - Leveraging RIM for DADI and IDMP - Theory and Practice	**11:15** - Leveraging RIM for DADI and IDMP - Theory and Practice
12:00	**12:00** - Regulatory Data: Empowering Teams to Drive Efficiencies across the Drug Development Lifecycle **12:45** - Networking Luncheon & ArisGlobal Tech Tour: LifeSphere Regulatory is Revolutionizing Regulatory Information Management	**12:00** - RIMS Roundtables: Problem-Solving Based on Company Size **12:45** - Networking Luncheon & ArisGlobal Tech Tour: LifeSphere Regulatory is Revolutionizing Regulatory Information Management
13:00	**13:45** - Examine the Intersection Between eCTD and IDMP	**13:45** - The Future of Documents: Structured Content, Integrated Data
14:00	**14:30** - A considered review of the practicalities of implementing eCTD 4.0	**14:30** - End-to-End RIM: The Global Labelling Use Case
15:00	**15:15** - Networking Break **15:45** - EFPIA Recommendations for eCTD	**15:15** - Networking Break **15:45** - Building Comprehensive Future-Proof Pharmaceutical Labelling Management
16:00	**16:30** - The Evolution of UK Medicines in the National and Global Context: An ABPI Perspective	**16:30** - Exposing the Value of Regulatory Information Management Beyond Data and Documents
17:00		**17:15** - Case Study: RIM Strategy Towards Digital Transformation

SESSIONS

BERLIN SUMMIT: DAY 3 - FRI, 8 APR

Morning Refreshments

08:30 - 09:00

Chairperson's Opening Remarks

09:00 - 09:15
Regulatory Information Management

Participants

Steve Hoare - Quality, Regulatory Science & Safety Policy Director, The Association of the British Pharmaceutical Industry (ABPI)

Chairperson's Opening Remarks

09:00 - 09:15
Global eSubmissions

Participants

Rodrigo Palacios - Global Regulatory Policy Lead, F. Hofmann-La Roche

Transforming the Management of Regulatory Intelligence to Drive Efficiency and Better Regulatory Outcomes

09:15 - 10:00
Regulatory Information Management

Having accurate and up-to-date global regulatory intelligence covering both requirements, intelligence and precedent has always been key for Regulatory Affairs to meet business objectives and align with the company strategy. During this session, discuss the following:

- Today's challenges of managing regulatory intelligence on a global scale
- How to intelligently manage regulatory intelligence in the future
- Specific use cases of how to leverage regulatory intelligence to drive efficiency within RA
- What does the journey towards the future look like and what are the critical success factors?

Participants

Jens-Olaf Vanggaard - Senior Director, Global Safety, Regulatory and Quality Solutions, IQVIA

Supporting Emerging Countries During the Transition from Paper to Electronic Submissions

09:15 - 10:00
Global eSubmissions

- Building a step-by-step internal strategy for preparing countries for eCTD
- Providing the tools for local colleagues to educate and communicate with their health authorities
- Ensuring that the country's esubmissions ecosystem (i.e. people and processes) is ready for launch

Participants

Sophia Huang - Senior Director/Regional Group Head Regulatory Submission Management Beijing, Bayer

Building a Regulatory Platform to Harmonize Regulatory Processes, Data and Technology as a Foundation for the Digital Future

10:00 - 10:45
Regulatory Information Management

- Gaining buy-in from the top and middle
- Setting up an empowered project team
- Challenges and pitfalls
- Successes and failures before go-live
- Hidden success factors
- Lessons learnt after go-live

Participants

Maike Diepen-Engisch - Associate Director Global Regulatory Affairs Informatics, Merck

HMA/EMA Big Data Group Initiatives

10:00 - 10:45
Global eSubmissions

- HMA/EMA big data steering group- data standardization strategy and ongoing initiatives
- Learn about upcoming changes in regulatory submissions and data standards from the regulators' perspectives
- What are the future goals of the national competent authorities?

Participants

Jesper Kjaer - Director of Data Analytics Centre, Co-chair HMA / EMA Big Data Steering Group, Danish Medicines Agency

Networking Break

10:45 - 11:15

5 Essential IDMP Readiness Checkpoints for your Future-Proof RIM platform

11:15 - 12:00
Regulatory Information Management

This session will focus on 5 key aspects that pharma companies should consider when assessing whether their RIM platform is ready for all the challenges of the ever-changing IDMP implementation requirements.

Participants

Renato Rjavec - Director of Product Management, Amplexor Life Sciences

Update on eSubmissions in the Balkans

11:15 - 12:00
Global eSubmissions

- eSubmissions of medicines are becoming mandatory for all types of Applications
- Regional regulatory aspects are moving towards global electronic submissions/eCTD
- Get an in-depth look at regulation compliance from the emerging markets and keep up to date on country-specific environments

Participants

Marjan Dzeparoski, PhD - RA & PhV Manager, BIONIKA PHARMACEUTICALS

Networking Luncheon

12:00 - 13:00

The Potential of RIMS Through the Integration of Artificial Intelligence (AI) Capabilities

13:00 - 13:45
Regulatory Information Management

- Advance regulatory intelligence- connecting RIMS to regulatory intelligence
- Fast-track regulatory submissions using predictive techniques
- Answer regulatory authority queries in real-time using NLP

Participants

Sairam Iyer - Service Delivery Manager – Health Registration Mgmt & IDMP, Novartis

A New Platform for Global Collaboration: Accumulus Synergy

13:00 - 13:45
Global eSubmissions

- Overview of the Accumulus Synergy cloud platform for sponsor-regulator data exchange and collaboration
- Progress on pilots for collaborative review and CMC data exchange
- Roadmap overview and next steps

Participants

Rodrigo Palacios - Global Regulatory Policy Lead, F. Hofmann-La Roche

The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?

13:45 - 14:30
Regulatory Information Management

Experts ponder these questions and give their predictions for:

- How will the regulatory environment change in the EU, UK, US and China?
- What are the key areas of expertise for the Regulatory Professional of the future?
- What is the next big digital trend in regulatory, and pharmaceuticals overall?

Participants

Panelist: Steve Hoare - Quality, Regulatory Science & Safety Policy Director, The Association of the British Pharmaceutical Industry (ABPI)

Panelist: Mark Willoughby - Head of Life Sciences, Generis

Panelist: Stefano Accorsi - Head of Regulatory Affairs "Rest of the World", Chiesi Farmaceutici S.p.A.

The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?

13:45 - 14:30
Global eSubmissions

Experts ponder these questions and give their predictions for:

- How will the regulatory environment change in the EU, UK, US and China?
- What are the key areas of expertise for the Regulatory Professional of the future?
- What is the next big digital trend in regulatory, and pharmaceuticals overall?

Participants

Panelist: Steve Hoare - Quality, Regulatory Science & Safety Policy Director, The Association of the British Pharmaceutical Industry (ABPI)

Panelist: Mark Willoughby - Head of Life Sciences, Generis

Panelist: Stefano Accorsi - Head of Regulatory Affairs "Rest of the World", Chiesi Farmaceutici S.p.A.

SCHEDULE

BERLIN SUMMIT: DAY 3 - FRI, 8 APR -

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10:00	**10:00** - HMA/EMA Big Data Group Initiatives **10:45** - Networking Break	**10:00** - Building a Regulatory Platform to Harmonize Regulatory Processes, Data and Technology as a Foundation for the Digital Future **10:45** - Networking Break
11:00	**11:15** - Update on eSubmissions in the Balkans	**11:15** - 5 Essential IDMP Readiness Checkpoints for your Future-Proof RIM platform
12:00	**12:00** - Networking Luncheon	**12:00** - Networking Luncheon
13:00	**13:00** - A New Platform for Global Collaboration: Accumulus Synergy **13:45** - The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?	**13:00** - The Potential of RIMS Through the Integration of Artificial Intelligence (AI) Capabilities **13:45** - The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?

SESSIONS

DIGITAL EXPERIENCE: DAY 4 - MON, 11 APR

Chairperson's Day 1 Opening Remarks - Asia Pacific

09:55 - 10:00
Global Markets – Asia-Pacific, Latin America

Participants

Alan Chalmers - Director, Pharma International

On-Demand Content

09:55 - 11:30
IDMP, Regulatory Information Management and Global eSubmissions

Experience all of the Regulatory Information Management session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Delving into China's Regulatory Framework

10:00 - 10:45
Global Markets – Asia-Pacific, Latin America

- Recent legislation and updates
  - Adoption of ICHQ4 Chinese Pharmacopeia
- Comparison to EU and FDA Pharmacopeia
- Upcoming regulations to expect

Participants

Ching Li - Regulatory Affairs Manager, Biotest

Expedited Drug Development Regulatory Pathways in China

10:45 - 11:30
Global Markets – Asia-Pacific, Latin America

- Selecting the right regulatory pathway
- Key cultural challenges
- How to work with the NMPA
- Opportunity of convergence with other nations

Participants

Stefano Accorsi - Head of Regulatory Affairs "Rest of the World", Chiesi Farmaceutici S.p.A.

Efficient ISO IDMP Implementation in Different Profiles of Pharma Companies: Practical Experience and FAQs

11:30 - 12:00
Global Markets – Asia-Pacific, Latin America

This session will focus on Asphalion experience supporting the ISO IDMP transition for the small, the medium and the large portfolio companies and the complexity of different RIM scenarios.

Participants

Lourdes Alejandra Martín - Regulatory Information Specialist, ASPHALION

Networking Lunch & Tech Tour

12:00 - 13:00

Chairperson's Day 1 Opening Remarks – Latin America

13:00 - 13:05
Global Markets – Asia-Pacific, Latin America

Participants

Cammilla Horta Gomes - Regulatory Policy Lead for Latin America, Roche

On-Demand Content

13:00 - 14:45
IDMP, Regulatory Information Management and Global eSubmissions

Experience all of the Regulatory Information Management session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Pandemic Readiness - Lessons Learned from COVID-19 in Ensuring Regulatory Agility

13:05 - 14:05
Global Markets – Asia-Pacific, Latin America

- Evaluating the response to the COVID-19 pandemic
- How have different regions adapted?
- Enabling access to vaccines
- Lessons learned

Participants

Moderator:: Louise Gill - VP, Regulatory Policy, GSK

Panelist:: Lawrence Liberti - Adjunct Research Professor, Temple University, School of Pharmacy

Panelist:: Mario Alanis, PhD - Senior Advisor, CIRS - Centre for Innovation in Regulatory Science

Panelist:: Mic McGoldrick - Associate Director, Global CMC Policy, MSD

Panelist:: Kristina Bayramyan - Director EM Regulatory Policy, Global Regulatory Affairs, GSK

ICH Adoption in Brazil & Wider Latin America: Challenges & Opportunities

14:05 - 14:45
Global Markets – Asia-Pacific, Latin America

Participants

Gustavo Mendes Lima Santos - General Manager of Medicines and Biological Products, ANVISA

Pedro Franco - Director for Global Regulatory & Scientific Policy, Merck, EFPIA

Networking Break

14:45 - 15:20

Expedited Regulatory Pathways for Latin America

15:20 - 16:00
Global Markets – Asia-Pacific, Latin America

- Priority review
- Rare diseases
- Innovative drug products
- The impact of COVID-19 on regulatory systems

Participants

Ana Padua - Associate Director, Global Regulatory Affairs CMC Regulatory, Merck

Susan Koepke - Head of Regulatory Affairs for Latin America, EMD Serono, Inc

SESSIONS

DIGITAL EXPERIENCE: DAY 4 - MON, 11 APR

On-Demand Content

15:20 - 17:30
IDMP, Regulatory Information Management and Global eSubmissions

Experience all of the Regulatory Information Management session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

The Application of Real-World Data (RWD) & Real World Evidence (RWE) in Latin America Regulatory Decision-Making

16:00 - 16:40
Global Markets – Asia-Pacific, Latin America

- Local Data and PV requirements in regulatory submission
- Use of RW and Outcomes Evidence – Intersection between Regulatory and HTA submissions in the region

Participants

Claudia Soares - RWE & Value Access Senior Director - Emerging Markets, GSK

E-Labelling Implementation in Brazil and Across Latin America

16:40 - 17:20
Global Markets – Asia-Pacific, Latin America

- Examining the Latin American landscape
- Challenges of drug product information
- Case study: E-labelling in Brazil
- Drug traceability

Participants

Erika Rufino - Senior Manager, Regulatory Affairs, Janssen

Urimara Argotti - Regional Regulatory Policy Manager for LATAM – PDR, Roche

Mariana Ramirez - Regulatory Affairs Specialist, Roche

SCHEDULE

DIGITAL EXPERIENCE: DAY 4 - MON, 11 APR -

Delivered as a Hybrid Event 6th - 13th April 2022
Berlin Summit: 6-8 April | Digital Experience: 11-13 April
Presented in Central European Time (CEST)

TIME	GLOBAL MARKETS – ASIA-PACIFIC, LATIN AMERICA	IDMP, REGULATORY INFORMATION MANAGEMENT AND GLOBAL ESUBMISSIONS
09:00	**09:55** - Chairperson's Day 1 Opening Remarks - Asia Pacific	**09:55** - On-Demand Content
10:00	**10:00** - Delving into China's Regulatory Framework **10:45** - Expedited Drug Development Regulatory Pathways in China	
11:00	**11:30** - Efficient ISO IDMP Implementation in Different Profiles of Pharma Companies: Practical Experience and FAQs	
12:00	**12:00** - Networking Lunch & Tech Tour	**12:00** - Networking Lunch & Tech Tour
13:00	**13:00** - Chairperson's Day 1 Opening Remarks – Latin America **13:05** - Pandemic Readiness - Lessons Learned from COVID-19 in Ensuring Regulatory Agility	**13:00** - On-Demand Content
14:00	**14:05** - ICH Adoption in Brazil & Wider Latin America: Challenges & Opportunities **14:45** - Networking Break	**14:45** - Networking Break
15:00	**15:20** - Expedited Regulatory Pathways for Latin America	**15:20** - On-Demand Content
16:00	**16:00** - The Application of Real-World Data (RWD) & Real World Evidence (RWE) in Latin America Regulatory Decision-Making **16:40** - E-Labelling Implementation in Brazil and Across Latin America	

SESSIONS

DIGITAL EXPERIENCE: DAY 5 - TUES, 12 APR

Chairperson's Day 2 Opening Remarks - Asia Pacific

09:40 - 09:45
Global Markets – Asia-Pacific, Latin America

Participants

Alan Chalmers - Director, Pharma International

On-Demand Content

09:40 - 11:15
IDMP, Regulatory Information Management and Global eSubmissions

Experience all of the Regulatory Information Management session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Global Focus: IDMP Preparation and Implementation Across the World

09:45 - 10:45
Global Markets – Asia-Pacific, Latin America

- Snapshot of the IDMP landscape globally
- Where is IDMP applications advancing rapidly?
- Which regions are slow to adopt the IDMP standards?
- How are multinational pharma companies responding despite the lack of global harmonisation?
- What does an IDMP implementation look like?

Participants

Panelist:: Vada A Perkins - Executive Director, Regulatory Policy & Intelligence/Head, Regulatory Intelligence, Bayer Pharmaceuticals

Panelist:: Craig Anderson - Director, Information Management, Pfizer

Panelist:: Paul Attridge - Sr Director, Vault RIM, Veeva Systems

The Application of Real-World Data (RWD) & Real World Evidence (RWE) in Regulatory Decision-Making in Asia-Pacific

10:45 - 11:30
Global Markets – Asia-Pacific, Latin America

- Regulatory initiatives in place
- Efforts to promote uptake
- Key challenges and opportunities

Participants

Gracy Crane - International Regulatory Policy Lead for RWD, Roche

Networking Lunch & Tech Tour

11:30 - 13:15

Keynote: Ensuring Access While Supporting Innovation: What is the European Commission's Pharmaceutical Strategy for the Future?

13:15 - 14:00
Global Markets – Asia-Pacific, Latin America

- An overview of the EU pharmaceutical strategy – legislative and non-legislative actions
- What is the timeline for new legislation?
- What are the regulatory affairs components within the 10 points of action put forward by the Commission?

Participants

Florian Schmidt - Deputy Head of Unit, DG SANTE, European Commission

On-Demand Content

13:15 - 14:55
IDMP, Regulatory Information Management and Global eSubmissions

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Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Chairperson Day 2 Opening Remarks – Latin America

14:00 - 14:05
Global Markets – Asia-Pacific, Latin America

Participants

Cammilla Horta Gomes - Regulatory Policy Lead for Latin America, Roche

PANEL: Updates on Convergence & Reliance Efforts for LATAM

14:05 - 15:05
Global Markets – Asia-Pacific, Latin America

- Progress made to date
- Strengthening regulatory systems/the Americas
- PAHO – Ongoing activities & efforts

Participants

Cammilla Horta Gomes - Regulatory Policy Lead for Latin America, Roche

Analia Porras, PhD - Unit Chief, Medicines and Health Technologies, Pan American Health Organization

Lawrence Liberti - Adjunct Research Professor, Temple University, School of Pharmacy

Mario Alanis, PhD - Senior Advisor, CIRS - Centre for Innovation in Regulatory Science

Networking Break

15:05 - 15:35

Panel Discussion: Strengthening Regulatory Systems for ATMPs in Brazil

15:35 - 16:20
Global Markets – Asia-Pacific, Latin America

- Initiatives launched by ANVISA
- Comparison: Brazil vs global regulations
- Expected developments

Participants

Panelist:: Leandro Lozano - Senior Consultant and Owner, RegStrat

Panelist:: Patricia Pigola - Regulatory Affairs Director, Novartis

Panelist:: Lilian Gonzalo - Senior Regulatory Affairs Manager, Novartis

On-Demand Content

15:35 - 17:00
IDMP, Regulatory Information Management and Global eSubmissions

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Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Mexico: Updates of Accelerated Regulatory Pathways & Reliance

16:20 - 17:00
Global Markets – Asia-Pacific, Latin America

New opportunities for sponsors & manufacturers

Participants

Maria de la Luz Lara Méndez - CEO, Udelá

Iván Calderón - Consultant & Former Executive Director of Marketing Authorisations and Establishments, COFEPRIS, Udela

SCHEDULE

DIGITAL EXPERIENCE: DAY 5 - TUES, 12 APR -

Delivered as a Hybrid Event 6th - 13th April 2022
Berlin Summit: 6-8 April | Digital Experience: 11-13 April
Presented in Central European Time (CEST)

TIME	GLOBAL MARKETS – ASIA-PACIFIC, LATIN AMERICA	IDMP, REGULATORY INFORMATION MANAGEMENT AND GLOBAL ESUBMISSIONS
09:00	**09:40** - Chairperson's Day 2 Opening Remarks - Asia Pacific **09:45** - Global Focus: IDMP Preparation and Implementation Across the World	**09:40** - On-Demand Content
10:00	**10:45** - The Application of Real-World Data (RWD) & Real World Evidence (RWE) in Regulatory Decision-Making in Asia-Pacific	
11:00	**11:30** - Networking Lunch & Tech Tour	**11:30** - Networking Lunch & Tech Tour
12:00		
13:00	**13:15** - Keynote: Ensuring Access While Supporting Innovation: What is the European Commission's Pharmaceutical Strategy for the Future?	**13:15** - On-Demand Content
14:00	**14:00** - Chairperson Day 2 Opening Remarks – Latin America **14:05** - PANEL: Updates on Convergence & Reliance Efforts for LATAM	
15:00	**15:05** - Networking Break **15:35** - Panel Discussion: Strengthening Regulatory Systems for ATMPs in Brazil	**15:05** - Networking Break **15:35** - On-Demand Content
16:00	**16:20** - Mexico: Updates of Accelerated Regulatory Pathways & Reliance	

SESSIONS

DIGITAL EXPERIENCE: DAY 6 - WED, 13 APR

Chairperson's Day 3 Opening Remarks - Turkey, Middle East & Africa

09:55 - 10:00
Global Markets - Turkey, Middle East & Africa

Participants

Ilona Putz - Consultant, PULONA Emerging Markets FZE

On-Demand Content

09:55 - 12:05
IDMP, Regulatory Information Management and Global eSubmissions

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Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

Implementation of ICH Guidelines in Turkey

10:00 - 10:45
Global Markets - Turkey, Middle East & Africa

- The status of implementation in Turkey
- The challenges of global harmonization

Participants

Figen Kabadas Oge - Head of Regulatory Affairs, Delpharm

The Impact of COVID-19 on Regulatory Systems in MENA

10:45 - 11:30
Global Markets - Turkey, Middle East & Africa

- Key changes to regulations in MENA following the COVID-19 outbreak
- Access to innovation
- What to expect for the future

Participants

Qutaiba Al Manaseer - Government Affairs Director, AstraZeneca

Plenary: Supporting Emerging Countries During the Transition from Paper to Electronic Submissions

11:30 - 12:10
Global Markets - Turkey, Middle East & Africa

- Building a step-by-step internal strategy for preparing countries for eCTD
- Providing the tools for local colleagues to educate and communicate with their health authorities
- Ensuring that the country's esubmissions ecosystem (i.e. people and processes) is ready for launch

Participants

Sophia Huang - Senior Director/Regional Group Head Regulatory Submission Management Beijing, Bayer

Networking Lunch & Tech Tour

12:10 - 13:10

Convergence & Reliance in the Middle East & Africa

13:10 - 14:10
Global Markets - Turkey, Middle East & Africa

- Regional and global efforts
  - Establishment of the African Medicines Agency
  - ICH
- Expediting pathways through reliance
- Key challenges

Participants

Moderator: Nevena Miletic - Regulatory Policy Head Eastern Europe, Middle East & Africa (EEMEA), Global Regulatory Policy, F. Hoffmann-La Roche & IFPMA Africa Regulatory Network Chair

Panelist: Nawaf Almutairi, MPharm - Regulatory Affairs Expert, Saudi Food and Drug Authority

Panelist: Amira Younes - Regulatory Policy & Intelligence, Associate Director, AbbVie, Member of IFPMA

Panelist: Abdul Mateen - Regulatory Affairs Consultant, AstraZeneca, UK

Panelist: Abebe Alamneh, B Pharm, MSc, - Medicine Registration Expert & Vice president, Ethiopian Food and Drug Authority (EFDA) & East Africa Regulatory Affairs Association (EARAPA), respectively

On-Demand Content

13:10 - 14:50
IDMP, Regulatory Information Management and Global eSubmissions

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Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

The Push for Local Manufacturing in MENA

14:10 - 14:50
Global Markets - Turkey, Middle East & Africa

- What is the current status in MENA
- Impact on regulatory landscape
- Objectives for local manufacturing
- Opportunities and challenges for domestic and foreign manufactures

Participants

Ilona Putz - Consultant, PULONA Emerging Markets FZE

Networking Break

14:50 - 15:20

The Status of Biosimilar Regulations in the MENA Region

15:20 - 16:05
Global Markets - Turkey, Middle East & Africa

- Regulatory requirements for biosimilars
- How to improve uptake
  - Lessons learned from Europe and the FDA
- Regulatory obstacles for biosimilars in MENA

Participants

Ammar Almaaytah - Dean of Pharmacy, Middle East University

SESSIONS

DIGITAL EXPERIENCE: DAY 6 - WED, 13 APR

On-Demand Content

15:20 - 17:35
IDMP, Regulatory Information Management and Global eSubmissions

Experience all of the Regulatory Information Management session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the IDMP session recordings from the Berlin Summit on-demand at your convenience.

Experience all of the Global eSubmissions session recordings from the Berlin Summit on-demand at your convenience.

E-labelling Initiatives in the Middle East & Africa

16:05 - 16:50
Global Markets - Turkey, Middle East & Africa

- E-labeling – A step towards a bigger vision
- Key global case studies
- Brief overview of the MEA landscape
- Focus on key MEA elabeling initiatives

Participants

Rana Al-Ahwal - Labelling Team Lead, Pfizer

The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?

16:50 - 17:35
Global Markets - Turkey, Middle East & Africa

Experts ponder these questions and give their predictions for:

- How will the regulatory environment change in the EU, UK, US and China?
- What are the key areas of expertise for the Regulatory Professional of the future?
- What is the next big digital trend in regulatory, and pharmaceuticals overall?

Participants

Steve Hoare - Quality, Regulatory Science & Safety Policy Director, The Association of the British Pharmaceutical Industry (ABPI)

Mark Willoughby - Head of Life Sciences, Generis

Stefano Accorsi - Head of Regulatory Affairs "Rest of the World", Chiesi Farmaceutici S.p.A.

SCHEDULE

DIGITAL EXPERIENCE: DAY 6 - WED, 13 APR -

Delivered as a Hybrid Event 6th - 13th April 2022
Berlin Summit: 6-8 April | Digital Experience: 11-13 April
Presented in Central European Time (CEST)

TIME	GLOBAL MARKETS - TURKEY, MIDDLE EAST & AFRICA	IDMP, REGULATORY INFORMATION MANAGEMENT AND GLOBAL ESUBMISSIONS
09:00	**09:55** - Chairperson's Day 3 Opening Remarks - Turkey, Middle East & Africa	**09:55** - On-Demand Content
10:00	**10:00** - Implementation of ICH Guidelines in Turkey **10:45** - The Impact of COVID-19 on Regulatory Systems in MENA	
11:00	**11:30** - Plenary: Supporting Emerging Countries During the Transition from Paper to Electronic Submissions	
12:00	**12:10** - Networking Lunch & Tech Tour	**12:10** - Networking Lunch & Tech Tour
13:00	**13:10** - Convergence & Reliance in the Middle East & Africa	**13:10** - On-Demand Content
14:00	**14:10** - The Push for Local Manufacturing in MENA **14:50** - Networking Break	**14:50** - Networking Break
15:00	**15:20** - The Status of Biosimilar Regulations in the MENA Region	**15:20** - On-Demand Content
16:00	**16:05** - E-labelling Initiatives in the Middle East & Africa **16:50** - The Big Picture Panel: Looking Ahead – What's Next for Pharmaceutical Regulatory Affairs?	

eCTD Submissions

09:00 - 17:30
TRAINING COURSE: eCTD Submissions | April 19-20

Day 1

Introduction and expectations

Clarifying the impact of the eCTD on the regulatory submission process (part 1)

- Introduction – from CTD to eCTD, electronically from applicant to agency
- Tracking the progress and success of the eCTD around the globe

Clarifying the impact of the eCTD on the regulatory submission process (part 2)

- Examining the eCTD validation and review process
- Assessing the impact on eCTD submission review for both agency and applicant?
- What are the challenges of using the eCTD?

Clarifying the impact of the eCTD on the regulatory submission process (part 3)

- Organising your eCTD – Options for structure and design
- Reusability of eCTDs across regions
- Overcoming Module 1 issues

Preparing for your e-submissions (part 1)

- Transforming documents into electronic dossier
- Creating PDFs from word documents
- Examining the use of hyperlinks – when, where and how many
- Discussing common pitfalls and how to avoid them

Preparing for your e-submissions (part 2)

How to move from paper to eCTD?

Summary and Q&A

Day 2

Harmonized procedures in the EU

- Overview of electronic submission in Europe
- Evaluating the challenges towards technical harmonisation
- European Heads of Medicines Agencies' eSubmission roadmap
- Online submissions – through gateways and portals

Practical exercise: Lifecycle management

- Effective eCTD lifecycle management
-
    - eCTD lifecycle operators
    - eCTD lifecycle challenges and management
    - Validation
- Tracking and reporting on how previously submitted documents are affected by variations and amendments.
- Maintaining control of an evolving dossier
- Ensuring you capture all lifecycle documents, including responses to questions, variations/ amendments and Renewals
- Managing document obsolescence efficiently
- Managing an eCTD lifecycle through single or multiple agencies

Building and submitting an eCTD

- eCTD creation and assembly
    - Creating file/folder structure and assigning documents
    - Hyperlinks and eCTD attributes
    - Building the required XML backbone and regional XML

Regulatory requirements for product lifecycle

- Time management and project planning for eSubmissions

Practical exercise

- eSubmission Strategy & eSubmission project management

CTD in depth - XML

- What is XML and where is it used in the eCTD?
- Understanding the general concepts, terms and "Util" directory
- Examining the role of XML in the future

Discussion and Q&A

Participants

Frank Dickert - Senior Business Consultant, EXTEDO

Introduction to EU Pharmaceutical Regulatory Affairs

09:00 - 16:30
TRAINING COURSE: Introduction to EU Pharmaceutical Regulatory Affairs | April 27-29

Module 1:

Legal basis of EU pharmaceutical regulation

- Identify European Regulatory Institutions
- European legislation - where are we now?
- Analyse the development and scope of Regulations, Directives, and guidelines
- Identify sources of useful information to allow you to prepare a successful submission
- Assess the influence of ICH

Working effectively with the EMA

- Identify the structure and function of the EMA
- Understand EMA operating procedures
- Clarify the role of the EMA committees and working parties
- Analyse communication with the pharmaceutical industry
- Review communication with the public, including EPARs

Module 2:

Understand and select the most appropriate European registration procedure for your Marketing Authorisations Applications (MAAs)

- The Centralised Procedure (CP)
- The DeCentralised Procedure (DCP)
- The Mutual Recognition Procedure (MRP)
- The National Procedure

The Centralised Procedure

- Criteria for selecting the CP
- Principal aspects of this procedure
- Timing of the various procedural stages
- Advantages and disadvantages of the CP
- Examining experience to date

The Decentralised Procedure and Mutual Recognition Procedure

- What are the principle aspects of these procedures
- Timing of the various procedural stages
- Advantages and disadvantages of these procedures
- Examining experience to date

Making the DCP or MRP work for you

Participants will be able to:

- Select the best products for submission through the DCP or MRP
- Analyse decision criteria for selecting the DCP or MRP procedure
- Identify realistic time-frames and monitor the progress of their application
- Apply best-practice dossier preparation to help gain speedy regulatory approval

Understand Clinical Trials applications in the EU

- Review the implementation of the Clinical Trials Directive
- Data requirements for clinical trials
- Role of ethics committees and their influence on the approval of the trial
- Clinical trials supplies
- Future changes in clinical trial application procedures in the EU

Summary session

Time has been reserved in the day to allow participants to summarise the main points learned in the morning session. The following points will be covered:

- Discuss common formats and develop an understanding of the CTD structure
- Data requirements for different types of application

Module 3:

Compile a drug registration dossier: An overview of what information is needed and how to present it

A review and analysis of each part of the registration dossier. Participants will take part in interactive exercises and discussions during the day that will give them the tools and techniques to understand how to successfully compile the drug registration dossier.

Format and content of the dossier: CTD

- Identify administrative data required to be presented in Module 1
- Understand the key importance of the Summary of Product Characteristics (SmPCs)
- Proposals for packaging, labelling and package inserts
- Requirements for Overviews and Summaries

Chemical, pharmaceutical, and biological documentation

- The function of the Quality Overall Summary (QOS)
- Data requirements
- Using an ASMF or COS
- Understand the need for GMP inspections

Exercise

Non-clinical or toxico-pharmacologial documentation

- Function of the Non-clinical Overview and Summaries
- Identify relevant guidelines
- Review of the data requirements and literature data for constructing CTD

Clinical documentation

- Function of the Clinical Overview and Summaries
- Understanding the terms used in clinical trials
- Identify the relevant guidelines
- Review of the data requirements

Summary session

- Discuss common formats and develop an understanding of the CTD structure
- Data requirements for different types of application

Module 4:

Mastering specific regulatory areas: Post-approval obligations, lifecycle management, variations, and renewals

The specific regulatory areas you need to master in order to successfully perform in both your short and long-term regulatory affairs strategy.

Understanding abridged applications

- Understand the legal basis for abridged applications
- Identify various types of application and the corresponding data requirements
- Determine essential similarity
- Consider data exclusivity
- Look at SmPCs: Identifying guidelines and pinpointing obstacles to achieving a harmonised SmPC
- Clarify the post-approval obligations of the marketing authorisation holder and the competent authority

Successfully filing variations

- Understand the variations legislation
- Identify the types of variations
- Criteria that define each type of variation
- Pinpoint what documentation/data is required for each type of variation
- Identify the procedural steps and time-lines for filing the variations
- Variations vs Extensions (New Marketing Authorisations)

Determine obligations for renewals

- Understand renewal legislation
- Analyse data requirements for renewal
- Understand the 'Sunset Clause' and implications for not marketing a product

Pharmacovigilance obligations

- Continuous pharmacovigilance requirements
- Periodic Safety Reports
- Risk management plans

Examine the importance of intra-company interactions for regulatory affairs

- Making good use of project team for increased efficiency in the regulatory team
- Co-ordinating information collection processes
- The importance of manufacturing/analytical interface

Module 5:

Proposing a registration strategy for a product

Participants will develop a strategy for effective product registration and learn best practice dossier preparation to gain speedy regulatory approval. Participants will have the opportunity to summarise and apply what they learned throughout the course and raise any outstanding questions.

Participants

Sumaiya Patel - Director of Regulatory Consultancy, Independent

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Filing Variations

09:00 - 16:30
TRAINING COURSE: Filing Variations | June 29-30

Introduction to the Course

- Introduction to the Course
- Outlining the aims and objectives of the course
- Introducing the course leaders and delegates
- Identifying individual training needs

Module 1

Basis of Regulations 1234/2008 and 712/2012 in Europe

- Classification in accordance with the legislation
- Understand the differences between Type IA, Type IB and Type II variations
- Clarify foreseen and unforeseen Variations
- Sharing practical experience with European and national procedures
- Assessing how pharmaceutical companies are operating in this evolving regulatory environment
- Working with Regulators: Lessons learnt

Module 2

Learning Outcomes

- Analysing and classifying the different changes
- Analyse different changes
- Consider the conditions and documentation requirements
- Practice classifying the changes

Grouping and worksharing

- Understanding when grouping is appropriate
- Clarifying what types of Variations may be grouped
- Guidance on assembling a grouped submission
- Understanding when work sharing is appropriate
- Discussion of example cases

CMC case

- Identify the Variation
- Learn what to consider eligible for grouping
- Draft submission strategy

Module 3

Learning Outcomes

- Submitting Type IA, IB and Type II applications
- Understand how to ensure that your dossier is complete
- Learn how to get it right first time
- Find out what to do when your application is rejected
- Plan the timelines and project management of a Variation submission
- Differences in national EU requirements
- Identify and understand strategic considerations

Other procedures:

- Article 5
- Urgent safety restrictions
- Understanding when to use extension applications

Module 4

Learning Objectives

- Submitting Type IA, IB and Type II applications
- Understand how to ensure that your dossier is complete
- Learn how to get it right first time
- Find out what to do when your application is rejected

Submission Planning

- Identify and understand strategic considerations Special topics in Variations
- Handling active ingredient master files as Variations
- Submission of new clinical data

Module 5

Variations through National procedures and differences from Centralised Procedure

- Understand the procedures
- Languages and translations
- Explore the Linguistic review process
- Learn about the role of the EMA and EU Commission

Mutual Recognition and Decentralised Procedures for Variations

- Understand the procedures
- Understand the responsibilities of the MAH, RMS, and CMS
- Learn how to efficiently plan for and run an MR Variation procedure

Module 6

Data requirements for Type II Variations

- Learn how to identify a Type II change
- Understand how to support Type II changes to ensure regulatory approval
- Gain an appreciation of the complexities of Type II applications

Practical session

- Data requirements for more complex changes
- Assess the data requirements for Type II Variations
- Consider extending use into a new patient population
- Integrating new safety information

Case study exercise

- Work through an example potential changes in an MRP authorised product
- Plan the timelines for and project management of a Variation submission

Impact of referrals on Variations and lifecycle management

Participants

Sumaiya Patel - Director of Regulatory Consultancy, Independent

SCHEDULE

TRAINING COURSES -

TIME	TRAINING COURSE: FILING VARIATIONS	JUNE 29-30	TRAINING COURSE: INTRODUCTION TO EU PHARMACEUTICAL REGULATORY AFFAIRS	APRIL 27-29	TRAINING COURSE: ECTD SUBMISSIONS	APRIL 19-20
09:00	**09:00** - Filing Variations		**09:00** - Introduction to EU Pharmaceutical Regulatory Affairs		**09:00** - eCTD Submissions	