eRegulatory Summit

8 - 10 April 2019
Crowne Plaza Fira Center
Barcelona, Spain

MEET THE INNOVATORS CHANGING THE FACE OF INFORMATION MANAGEMENT AND ESUBMISSIONS

Telematics, RIM, eCTD, IDMP and Filing Variations: Actionable insights to improve your regulatory strategy

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Day 1: Monday 8th April

	Global Submissions	Telematics & RIM
08.00	*Registration*	
09.00	**Opening Remarks**	**Opening Remarks**
09.10	**CASE STUDY: Implementing eCTD within National Procedures** • Pain points from industry during the implementation of eCTD in National Procedures • Understanding the value in creating a baseline submission • Best practice for harmonising dossiers **Daniel Verrall,** Senior Team Manager, **Pfizer**	**Feedback on EMA's IDMP Implementation Guidelines** • Reviewing EMA's implementation guide, the defined items and timelines • Understanding the importance of the IDMP Implementation Guidelines for successful transition to IDMP • Designing a strategic implementation plan **Laurent Desqueper,** XEVMPD & IDMP Business System Owner, **MSD Europe Inc.**
09.45	**Regulatory Agency Perspectives: Feedback, plans and practical advice for eCTD submissions moving forward** • Exploring current regulatory timelines • Discussing common pitfalls during eSubmissions process and how they can be avoided • Examples of handling industry data submissions **Jaana Pohjonen,** Specialist of Record Management and Archives, Quality Manager, **FIMEA**	**Lessons Learned from Data Migration** • Case study: end-to-end execution of data migration • How best to maintain data quality during migration? • Common problems faced during the migration process **Danielle Beaulieu,** Director, Global Regulatory Business Capacities, **Bristol-Myers Squibb**
10:20	**An Update on Clinical Trial Regulation in the EU** • Current and projected timelines for the EU CTA • Working through the Clinical Trial Regulation and submissions portals • Discussing best practice for the incorporation of clinical trial submissions into eCTD **Abby Cottage,** Regulatory Operations Manager, **Amgen**	**Improving Data Integration Across the Business** • Discussing the significance of information integration • Data integration implementation best practice • Current challenges in cooperation across departments • Leveraging cross-functional expertise to strengthen relationships **Marty Boom,** Global Head of Regulatory and Safety, **Navitas Life Sciences**
10.55	*Morning Coffee & Networking*	
11.20	**Best Practice for Implementing the EU Falsified Medicines Directive** • EU-Falsified Medicines Directive What is required? Timeline and implications • How to implement the unique identifier and the tamper verification feature? • Effects and consequences for the pharmaceutical and packaging industry **Johan Verhaeghe,** National Policy Liaison, **Medicines for Europe**	**Data Modelling for Regulatory Affairs** • Exactly know what you have • Understand the end to end relationship within the lifecycle of those data • Avoid data redundancies • Improve data quality • Form the prerequisite for any proper digitalization activities. **Dr. Jörg Stüben,** Head of Regulatory Information Management and Senior Expert, **Boehringer Ingelheim International GmbH**
11.55	**Experiences of Submitting Dossiers in China** • Industry experience of submitting in China • Reflection on the changes in the regulatory environment • Updates on eCTD adoption status and trends **Sophie Huang,** Head of Regulatory Submission Management & Planning Beijing, **Bayer**	**Utilizing AI and Data Analytics to Optimise your Regulatory Strategy** • How you can use AI to get more out of your existing data • Exploring the impact of AI on the regulatory submissions process • Defining and understanding the main challenges for stakeholders Representative from **Cunesoft**
12.30	*Networking Lunch*	

Day 1: Monday 8th April *(continued)*

	Global Submissions	Telematics & RIM
14.00	**Assessing the Latest Developments Towards eCTD in Singapore** • Outlining the current regulatory review process and good review practices • Updates on eCTD adoption in Singapore • Discussing common submission pitfalls **Speaker to be Announced**	**INDUSTRY CASE STUDY: Cross Functional Collaboration – Data Integration Across the Business** • Discussing the significance of information integration • Data integration implementation best practice • Current challenges in cooperation across departments • Leveraging cross-functional expertise to strengthen relationships **Patrick Middag,** Associate Director, Regulatory IT, **Bristol-Myers Squibb** **Deborah McCloskey,** Global Regulatory Business Capabilities, **Bristol-Myers Squibb**
14.35	**Guidance from South East Asia on the Harmonisation and Implementation of eCTD** • Where do we stand with the ASEAN Pharmaceutical Harmonisation Standard? • Discussing the latest eCTD updates and expectations in Thailand • Updates and timelines from around the region **Speaker to be Announced**	**Industry Feedback on the Falsified Medicines Directive: Post Implementation** • Feedback from industry on the implementation best practice • Pragmatic advice on strategies for departmental data coordination • Case study on minimising risk and data alignment to fill potential data gaps **Quentin Grignet,** IDMP Project Lead, **GSK**
15:10	**eSubmissions Strategy at a SME** • Best practice for implementing an efficient eCTD strategy • Deciding factors: in-house or outsourcing? The best options for your regulatory submissions process • Outlining challenges and sharing experience of overcoming them Representative from **Veeva**	**Spotlight Session** Representative from **Amplexor**
15.45	*Coffee & Networking Break*	
16.15	**Outlining Current Regulatory Submission Status in Jordan** • Latest updates from the JFDA including new eCTD specification • Outlining the current regulatory review process and good review practices • Discussing common pitfalls during submissions process and how they can be avoided Representative from **Jordan FDA**	**Designing an End-to-End RIM System** • Understand the increasing importance and roles of RIM systems within organizations • Formulating a foundational RIM strategy • Operational hurdles for smaller companies **Costas Mistrellides,** IDMP Regulatory Affairs Coordinator, **Johnson & Johnson** **Chris Dunn,** IDMP Specialist, **Johnson & Johnson**
16.50	**Updates on Submissions in Australia** • Discussing regulation changes out of the TGA in Australia • Sharing practical experiences of successful submissions • Outlining challenges and sharing experience of overcoming them **Henrietta Dehmlow,** Head of Submission Management, **Roche**	**PANEL DISCUSSION: The Future of Information Management - Shifting the Mindset from Tactics to Strategy** The separation between eSubmissions and Data Management is fairly pronounced now, but in a few years' time we will see the two areas intersect. What is the 5-year plan? Where do we see the industry going? **Joerg Stueben,** Senior Expert in Global Regulatory Operations, **Boehringer Ingelheim International GmbH** **Frits Stulp,** Project Manager EU-SRS, **Medicines Evaluation Board,** *The Netherlands*
17:20	*Chairman Closing – End of Day 1 and Networking Drinks*	

Day 2: Tuesday 9th April

Plenary Session

08.00	*Registration*
09.00	**Opening Remarks**
09.10	**Telematics Landscape and Implementation Feedback** • An overview of the current regulatory landscape and projected timelines for implementation • Feedback on current progress • Implications for industry: what is expected and how to achieve this **Remco Munnik,** Regulatory Information Director, **Asphalion S.L.**
09.45	**Best Practice for Successful Implementation of OMS & RMS** • A detailed look at the operation of OMS & RMS implementation processes • Discussing the triumphs and hurdles for successful implementation • Integration of SPOR into the Application Dataset Management module in CESSP **Dominik Gigli,** Senior Manager IDMP Office, **Merck KGaA**
10:20	**A Systematic Approach to PMS Preparations** • What is the current outlook for product implementation? • Hit the ground running: discussing techniques and methodology for successful integration in the first instance • Potential challenges and how best to avoid them **Kelly Hnat,** Principal, **K2 Consulting**
10.55	*Morning Coffee & Networking*
11.25	**The IDMP Substance Management System** • An update on the FDA's progress with the implementation of G-SRS • Discussing the status of SMS implementation in the EU • Examining the differences between systems and the impact of the HMA endorsement of an EU G-SRS project **Frits Stulp,** Project Manager EU-SRS, **Medicines Evaluation Board,** *The Netherlands*
12.00	**CESSP Essentials: What to Expect from Phase 1** • Discussing the timelines for submission roll out and implications for the future • Exploring the interaction of current telematics strategies and CESSP • Preparing a system integration plan to control your master data **Leigh Sandwell,** Director, UK Publishing Hub Lead, Global Regulatory Operations, **Pfizer**
12.30	*Networking Lunch*

	Global Submissions	Telematics & RIM
14:00	**Outlining the Latest Updates from Canada and the Implications for Industry** • Examining the latest results from the eCTD pilot for CTAs • Covering all requirements for 2019 • Case study on common submission errors and troubleshooting challenges	**How eCTD and IDMP Will Work Together** As, strategically, Brexit will impact parts of the telematics strategy (in Europe). My part is mainly looking at how the two worlds should fuse together to form a company's future RIM programme. The presentation will be more strategic as it's making sure customers foresee how their processes will look in the future when IDMP and eCTD do fuse. **Anjana Pindoria,** Director Product Strategy, **Extedo**
14:35	**GCC Experiences with eCTD Transitions and Timelines** • Discussing regulation changes across the GCC region • Sharing practical experiences of successful submissions • Comparing the GCC eCTD submissions process with the EU **Richard Knowles,** Senior Manager GRAAS Operations, **Amgen**	**Label and Artwork Management Systems: Transitions and Sustainability** • How to create a fool-proof plan based on market regulations, products and packaging needs • Best practice for preventing costly delays • Success stories: improving data quality in your tracking database **Bas van Heijst,** Associate Director Regulatory Affairs, **Astellas**

Day 2: Tuesday 9th April *(continued)*

	Global Submissions	Telematics & RIM
15.10	**Presentation to be Delivered by Accenture**	**Towards Regulatory 2025 – The Building Blocks of the Future** • Emerging change in technology innovation spending - from discrete projects to a strategy driven building blocks • The paradigm shift - From systems integration to cross-department platform unification • Cusp of maturity - Regulatory automation use cases using structured authoring • Systemic approach to Regulatory Intelligence **Mallika Rajasekaran,** Director – Regulatory Product Management, **ArisGlobal**
15:40	*Coffee & Networking Break*	
16.10	**Creating a Global Dossier Plan for Fast-tracking Approvals** • Guidelines and updates on global systems • Overview and case studies for expedited approvals • Regulatory hurdles and creating a plan to overcome them **Olga Alfieri,** Director, Global Submission Management, **Eisai**	**Digital Transformation of Novartis' Regulatory Processes** • Novartis' strategic digital roadmap to transform Regulatory processes • Technology enablers • Gain operational efficiency through automation • Using data insights and predictive analytics to support better decisions • Key takeaways **Wolfgang Schleifer,** Service Delivery Lead Regulatory, **Novartis** **Nicole Armstrong,** IT Service Delivery Project Manager for Regulatory Intelligence, **Novartis**
16.45	**PANEL SESSION: Sharing Experiences of Global eCTD Submissions** • Global eCTD adoption status, trends and v4.0 outlook • Sharing experiences of confusion and conflicts from SME and large pharma standpoint • Q&A: answering best practice questions	**Developing a Robust Data Archiving System** • Constructing a flexible long-term data archiving system • Reviewing options for maintaining data integrity in you archive system • Looking at current automation initiatives and how to use them **Michel Mikhail,** Expert in International Regulatory Affairs and Biosimilars
17:20	*Chairman's Closing Remarks*	

Day 3: Wednesday 10th April

	Filing Variations Focus Day	US FDA Workshop
08.30	*Registration*	
09.00	**Led by:** **Gry Agapitos,** Senior Regulatory Affairs Professional, **ALK Abello** **Justyna Kwiatkowska,** Regulatory Affairs Specialist, **Adamed Group** **Monique Mendel Ott,** Manager Global Regulatory Affairs, **Grünenthal GmbH** **Sophie Nageotte,** Regulatory CMC Consultant	**Speaker** **Andrew Willis,** Regulatory Consultant & PTI Trainer, **A Willis Consulting**
09.10	**An Update on ICH Q12**	(09.15) **Reviewing the Organisation of the US Food and Drug Administration (FDA) and How this May Impact Future Regulation**
09.45	**A Detailed Look at the Variation Classification Guideline**	
10:20	**Demonstrating an Effective Grouping and Work Sharing Strategy**	(10.00) **Examining Drug Development Regulations in the US and Implications for the Industry** • What are the types of IND's? • Analysing the manufacture of Drug Substance and Drug Product • Preclinical testing requirements • Clinical testing requirements • Identifying phases of clinical development as they relate to regulatory restrictions
10.55	*Morning Coffee & Networking*	

Day 3: Wednesday 10th April *(continued)*

	Filing Variations Focus Day	US FDA Workshop
11.25	**Troubleshooting your EU Filing Variation Plan**	**Key Topics** • Understanding the options: • Fast track: *> Breakthrough status > Accelerated review > Priority review* • Consider eligibility requirements • Paediatrics • Refusal to file
11.55	**Comparing Requirements: Filing Variation Differences between EU and USA**	(12.10) **Analysing the Investigational New Drug Application (IND) and Defining the Regulatory Requirements** • Organisation of the IND • Requirements for submitting an IND • Understand the FDA review process for INDs • Identifying and understanding FDA actions on INDs
12.35	**Outlining the Everchanging Requirements in Asia**	
13.10	*Networking Lunch*	
14:30	**Designing a Successful Global Variation Strategy**	**Identifying the Various Categories of NDAs** • Defining full NDAs • Explaining abbreviated NDAs and 505 (b) (2) • Understanding 'paper' NDAs • Understanding NDA's in the CTD Format • Defining differences in Agency review approaches • The US Regional requirements • Generic submissions
15:05	**Q&A – Variations Around the World**	(15.00) **Key Differences between EU and US**
15:30	**Chairman's Closing Remarks**	**Meetings with the FDA** • Access the Federal Register • The Freedom of Information Act (FOIA) • Optimising the use of the FDA home page • Exploring useful URL's • How to understand FDA's, SOP's and use them to your advantage
16:00	*End of Day 3 and Close of Conference*	