

VIRTUAL EVENT

Global Pharmaceutical Regulatory Affairs Summit

20TH - 22ND APRIL 2021

Presented in Central European Time (CET)

IDMP, ESUBMISSIONS, GLOBAL REGULATIONS: CRITICAL UPDATES DIRECTLY TO YOUR SCREEN.

Break into Global Markets, Discover the Future of RIM & IDMP, Obtain a Comprehensive Understanding of Telematics Policy, and Prepare for Submissions and eCTD v4.0.

Learn from Government Agencies, IDMP Taskforce Members, and Pioneers in the Pharmaceutical Industry.

TUESDAY 20TH APRIL 2021	WEDNESDAY 21ST APRIL 2021	THURSDAY 22ND APRIL 2021
Regulatory Affairs in Asia-Pacific	Regulatory Affairs in Latin America	Regulatory Affairs in Russia & CIS, MENA & Turkey
Telematics Policy	Global eSubmissions	Global eSubmissions
	IDMP	RIM

VIRTUAL EVENT

**Global Pharmaceutical
Regulatory Affairs
Summit**

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DAY ONE

TUESDAY, APRIL 20th, 2021



09:00		Platform Tutorial	
Regulatory Information Management and eSubmissions: Telematics Policy Day		Global Markets in Regulatory Affairs: APAC	
12:15		Session: Telematics Updates and Timelines	
Opening Remarks from Chair		Session: Chinese Regulatory Requirements	
Opening Remarks from Chair		Opening Remarks from Chair	
9:55 - 10:20	Feedback on the Telematics Roadmaps: Timelines and Next Steps <ul style="list-style-type: none"> Looking at the new roadmaps by EU Commission and EMA/HMA Regulatory process optimisation at EMA Understating the timelines Assessing the requirements and changes for industry Rodrigo Palacios, Lead Regulatory Technology Policy, Roche	ASEAN regulatory updates and push for harmonization <ul style="list-style-type: none"> Opportunities and challenges for entering the ASEAN market Key regulatory updates in the region Exploring the key differences in ASEAN countries Regulatory differences among ASEAN members Understanding the requirements for further harmonization in the region Aziza Ahmed, Executive Director APAC CMC Regulatory Affairs, Merck	
10:25 - 10:50	Connecting the Pieces: How does the Individual Telematics Projects Fit together? <ul style="list-style-type: none"> Assessing the overall goal for the telematics plan Understanding the benefits for business for the success of the telematics plan The impact of telematics on the patient Nikolai Brun, Director of Division, Danish Medicines Agency	10:25 - 11:05 - Panel Sharing experiences for product registrations in ASEAN <ul style="list-style-type: none"> Discussing the registration process and best practices for MAA submissions Practical advice on overcoming key challenges faced with drug registrations in ASEAN Update on ASEAN Joint Assessment Procedure for MAA submission Pakhi Rusia, Head of Regulatory Affairs, APAC, Glenmark Pharmaceuticals Gaelle Richer, Adjunct Professor, National University of Singapore Deepak Jain, Senior Manager, Global Regulatory Affairs, Macleods	
10:55 - 11:20	Optimising Variation Management through digitalisation strategies Katrin Spaepen, Director Strategy, Vault RIM, Veeva Systems Emma Forrest, Global Operations R&D, Recordati	11:10 - 11:35 Delving into China's Drug Administration Law (DAL): Drug Registration Rules (DRR) and Administrative Measures for Monitoring Drug Production (AMMDP) <ul style="list-style-type: none"> Aligning the new and previous guidelines Impact on review and approval processes Evaluating the lessons learnt so far What developments can we expect? Jacopo Francalanci, Global Regulatory Affairs Rest of World Regulatory Affairs Manager, Menarini Ricerche SpA	
11:25 - 11:50	Medicine for Europe Telematics Strategy <ul style="list-style-type: none"> How to connect the dots with EU Telematics projects - establishing a long term vision to comply and achieve business benefits Remco Munnik, Regulatory Information Director, Medicines for Europe	Networking time An opportunity to connect with your peers, speakers and sponsors.	
11:50 Networking Break <i>Meet our speakers and an opportunity to connect with your peers.</i>			
Session: IDMP Policy			
12:50 - 13:15	IDMP, Key Engine to a Regulatory Strategy Wim Cypers, Senior Vice President, Product Innovation, ArisGlobal Kevin Cooper, Product Marketing Management, ArisGlobal	Updates to Drug Serialisation Requirements in China <ul style="list-style-type: none"> Clarifying the current requirements of serialisation Defining a drug traceability code generation strategy Future developments in serialisation Geraldine Lissalde-Bonnet, Director Public Policy, GS1 Global	
13:20 - 13:45	Feedback and requirements for Substances for IDMP Jean-Gonzague Fontaine IDMP Sustainability Strategy Lead GSK Vaccines, Belgium	Clinical Trials for the Chinese Market <ul style="list-style-type: none"> Understanding the clinical trial regulatory landscape Outlining clinical trial requirements Local clinical data requirements The impact of Covid-19 on patients, trial processes, and outcomes on clinical trials Alan Chalmers Director, Pharma International	
13:50 - 14:15	Using Control Vocabularies for Substances Gary Wilson, Director, Corrlt	13:50 - 14:20 Multi-Speaker: Sharing Experiences on Regulatory Strategies in China <ul style="list-style-type: none"> Advice on entering the Chinese market Outlining the registration process and best practices How to work with the NMPA Addressing common pitfalls that hinder approval 	

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13:50 - 14:50	<p>Dual Dialogue: Exploring the Role of IDMP in Digital Transformation of the Regulatory Process.</p> <ul style="list-style-type: none"> • Product data quality/availability as prerequisites to more advanced capabilities in regulatory assessments, underlying operational processes and downstream benefits. • Interoperability across regulatory and healthcare communities • Use cases for IDMP based on policy documents • scientific assessment through structured information builds a foundation for accelerated access to medicines • Transition from unstructured, paper based regulatory submissions to a data-driven sponsor/HA exchange to improve the efficiency/speed of regulatory processes • Investigation of quality or supply chain issues. • dissemination of information to stakeholders in public health and digital healthcare. • Challenges, opportunities and future steps to reap the benefits from implementations of IDMP <p>Patrick Middag, IT Business Partner for Regulatory EU, Canada and IDMP, Bristol-Myers Squibb Rodrigo Palacios, Lead Regulatory Technology Policy, Roche</p>	
14:45 - 15:50	<p>Networking Break <i>including speed networking</i></p>	
	<p>Session: Clinical Trial Regulation Portal and Electronic Product Information</p>	<p>Session: ASEAN</p>
15:40-16:05	<p>Regulatory Data Update on Clinical Trial Regulation Portal (CTIS)</p> <ul style="list-style-type: none"> • Updates on the portal • Data requirements for CTIS • User management • Experience with <p>Stéphanie Kromar, Senior Regulatory Affairs Manager, EORTC</p>	<p>Building a Strategy for Market Access in Japan</p> <ul style="list-style-type: none"> • Best practices for Market Access Authorisation (MAA) submissions, renewals and variations • Understanding the key obstacles for accessing the Japanese market • Sharing experiences within Japan <p>Arturo Martinez Gonzalez, Senior Regional Regulatory Affairs Expert Japan and LATAM, GSK</p>
16:10-16:35	<p>Update on the Electronic Product Information (EPI)</p> <ul style="list-style-type: none"> • Understanding the aims and goals for EPI • Assessing the requirements on industry • Outlining the timelines for requirements <p>Aimad Torqui, EMEA Lead, Global Regulatory Policy, MSD</p>	
16:35-16:50	<p>Follow up Question time on EPI</p> <ul style="list-style-type: none"> • Nathalie Lambot, Expert Clinical trials & Regulatory Affairs, Pharma.Be • Aimad Torqui, EMEA Lead, Global Regulatory Policy, MSD 	
16:40 - 17:05	<p>The Electronic Patient Leaflet Project (e-PIL): APioneer Pilot in Belgium and Luxembourg</p> <ul style="list-style-type: none"> • The e-PIL pilot project is a collaboration between the pharma industry and the regulatory authorities in Belgium and Luxembourg, which has been approved by the European Commission, and which is supported by the hospital pharmacist associations at national level. • In this pilot launched in 2018, the paper leaflet of a selection of medicines restricted to hospital use and marketed in Belgium and in Luxembourg is no longer included in its paper version but can be consulted online via trusted websites. • The objective is to demonstrate that the electronic format provides sufficient, adequate and tailored information on the use of medicines to healthcare professionals and patients in hospital setting. • The interim results after 12 months and after 24 months have shown that for 98% of the pharmacists, the absence of the paper leaflet in the packaging has not generated any inconvenience in their daily practice, nor it has affected the request from other healthcare professionals in the hospital. 98% of the responding pharmacists would agree the paper patient leaflet being removed from all hospital-only medicines. • Based on these positive results, the pilot, initially intended for a duration of 24 months, has been extended to a duration of 48 months with the authorization of the European Commission, allowing further consolidation of the results. <p>Nathalie Lambot, Expert Clinical trials & Regulatory Affairs, Pharma.Be</p>	

END OF CONFERENCE DAY 1



09:00	Platform Tutorial		
	IDMP focus Day	Global eSubmissions	Regulatory Affairs in Global Markets
	Session: IDMP Updates and requirements	Session: eCTD v4.0	Session: Brazilian Regulatory Framework Chair: Silvia Bendiner, Executive Partner - WESSX, Inc
10:00-10:40	Interview with Members of IDMP Taskforce <ul style="list-style-type: none"> Discussing timelines and milestones for IDMP delivery Comparing V1 to V2 Understanding the content of three modules in IDMP How will IDMP data be sent? Impact on eCTD <p>Laurent DESQUEPER, Regional Business Lead XEVMPD-IDMPGRACS Innovation, Quality & Strategic Execution (IQSE) – EMEA, Merck Sharp & Dohme, Inc</p>		LATAM – Access to Innovation, Harmonization, Convergence, Reliance <ul style="list-style-type: none"> Access to Innovation: The Cuban Regulatory Agency (CECMED) Office of Innovation Latest updates on harmonization, convergence and reliance across the LATAM region Mutual recognition initiatives; GMP inspections, other relevant Accelerated regulatory pathways, early access programs for life-saving drugs, etc. <p>Lawrence Liberti, Adjunct Assistant Professor, Temple University School of Pharmacy Ana Padua, Associate Director for Global Regulatory Affairs, Merck Group Mario Alanis, Senior Consultant, Centre for Innovation in Regulatory Science (CIRS) Moderator: Silvia Bendiner, Executive Partner, WESSX</p>
10:45-11:10	IDMP More than a Requirement: Business Benefits. <ul style="list-style-type: none"> Outlining the biggest impacts to the day to day running of a business Exploring the true value of having one single version of the truth <p>Quentin Grignet, Director – Master Data Strategy & Analytics IDMP Program Sponsor</p>		11:45 - 11:35 CET - Brazil: Key Regulatory Strategies Pharmaceuticals & biologics: key challenges & opportunities <ul style="list-style-type: none"> Accelerated regulatory pathways Advice on working with ANVISA Brazilian harmonization of regulatory requirements: pharmaceuticals & biologics Comparison with USA, Canada and EU <p>Arturo Martinez Gonzalez, Senior Regional Regulatory Affairs Expert Japan and LATAM, GSK Pedro Franco, Director for Europe in Global Regulations & Scientific Policy, Merck Group Priscilla Rodrigues, Regulatory Affairs Director, Merck Group Ana Padua, Associate Director for Global Regulatory Affairs, Merck Group</p>
11:15-11:45	Interactive Session: Preparing for IDMP Implementation <ul style="list-style-type: none"> Hear different approaches to IDMP preparation Outlining the strategies implemented and the timelines required for this Discussing pitfalls and how these could have been overcome Assessing the budget requirements for IDMP, both finically and manpower <p>Margo Tyler-McWilliams, Associate Director, Regulatory Informatics and Analytics, Global Regulatory Operations Takeda Patrick Middag, IT Business Partner for Regulatory EU, Canada and IDMP, BMS Paul Attridge, Sr Director Strategy Veeva Systems, UK</p>	Responding to a Pandemic, the Regulatory As the Regulatory Operations submission manager for Gilead's rapid COVID-19 conditional marketing authorisation application to the EMA, Jack will share insights into the operational side of the process and what was learned from the experience. Jack Daley, Manager, Regulatory Operations Gilead Sciences, UK	
11:50-12:15	Session from Calyx Karen Harry, Director, Regulatory Implementation, Calyx	eCTD 4.0 with EXTEDO <ul style="list-style-type: none"> Abstract Pending <p>Frank Dickert, Business Consultant, EXTEDO</p>	11:40 - 12:05 - Brazil: Regulatory Framework - APIs <ul style="list-style-type: none"> Harmonized regulatory approach/filing strategy Market application refusals: Reasons & Remediate Action GMP certificates ICH Harmonization – benefits for Brazil <p>Erika Diago Rufino, Senior Manager Regulatory Affairs, Janssen</p>
12:15-13:15	Networking Break including IDMP Platform Solutions		
	Session: Strategies to Prepare for IDMP	Session: Data and eCTD	Session:
13:15-13:40	IDMP, where to start <ul style="list-style-type: none"> Identifying key stakeholders for IDMP implementation Their data, your data, where to start Redefinition of company processes <p>Ramón Hernández Moratinos, Senior Regulatory Information Specialist Asphalion</p>	Understanding how the Submission of More Product Data as Structured Data could Impact eCTD Dossier Process' <ul style="list-style-type: none"> Addressing where eCTD and IDMP meet Long term aims with eCTD and IDMP <p>Dr. Andreas Franken, Data Protection Officer B.A.H</p>	Brazil: Orphan Drug Registration - Strategic Regulatory Pathway <ul style="list-style-type: none"> Clinical Trials, GMPs and Market Authorizations accelerated review procedure New indications accelerated review procedure <p>Telma Rocha, Senior Regulatory Affairs Manager, Janssen</p>

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13:45-14:10	<p>Sharing Experiences with Integrating Different Systems for IDMP</p> <ul style="list-style-type: none"> • Feedback on how to integrate multiple departments data • Experiences with maintaining data integrity during this process • Feedback on overcoming the common challenges with integrating systems: • How to ensure the same value/names is used across departments? • How to change/update data to ensure you have one single source of truth ? • How to ensure this is done in a timely fashion ? <p>Laurent Lefebvre, Regulatory CMC Director, NovaRIM System Delivery Business Lead, Novartis</p>	<p>Data vs Documents: Regulatory Affairs Impact</p> <ul style="list-style-type: none"> • Discussing the new requirements of publishers and regulatory affairs professionals • Outlining the data workflow from IDMP to eCTD • Do we need to submit this data twice? • Will industry need to maintain multiple individual IDMP datasets per product in the same way that eCTDs are managed today? How much XML will need to be submitted and maintained? <p>Alistair Nixon, GSK</p>	<p>Colombia: Regulatory Overview and Drug Registration</p> <ul style="list-style-type: none"> • INVIMA – Overview of Regulatory requirements & market access • Pharmaceuticals, Biologics and Biosimilars • Pitfalls for Registration refusals & remediate action • Colombian regulatory requirements within the global harmonization context <p>Johanna Garcia, Consultant, Udelá</p>
14:15-14:55	<p>Implementing IDMP on a Time Crunch</p> <ul style="list-style-type: none"> • Best practices for preparing for IDMP to be ready for December 202 • Avoiding common bottlenecks with IDMP • Overseeing what data requirements to be prepared for <p>Costas Mistredllides, Senior Regulatory Data Manager, Merck Group</p>	<p>IDMP/ eCTD Interactive Surgery</p> <ul style="list-style-type: none"> • Bring your concerns with eCTD and IDMP and have them addressed by experts • Raising your issues and worries <p>Joel Finkle, Associate Director, Regulatory Information Management, BeiGene, Ltd</p>	<p>14:15 - 14:40</p> <p>Mexico: Overview of the Regulatory landscape</p> <ul style="list-style-type: none"> • Pharmaceuticals, Biologics and Biosimilars • Pitfalls for Registration refusals & remediate action • Mexican regulatory requirements within the global harmonization context <p>Rivolino Flores, Director of Regulatory Affairs and Innovation, Canifarma</p>
14:35-14:55	<p>IDMP uses/strategies representing Medicines for Europe's use case on Availability of Medicines based on the use of ISO IDMP and TOM</p> <p>Remco Munnik, Regulatory Information Director Medicines for Europe</p>		
15:00 - 15:50	<p>Roundtables: Implementing IDMP Feedback additional question time Roundtables: LATAM common regulatory concerns</p>		
15:55-16:20	<p>IDMP Roadmap to Success</p> <p>Agnes Cwieneczek, Head of Product Management and Consulting, Amplexor Life Sciences</p> <p>David Gwyn, Vice President, Amplexor Life Sciences</p>	<p>The SPOR Target Operating Model (TOM) – Understanding the impact on your Submissions and Processes”</p> <p>This session will provide an overview of the TOM, and clarify topics discussed in Chapter 3 of the SPOR Implementation Guide.</p> <ul style="list-style-type: none"> • Understand what the TOM is its importance for SPOR • What are the impacts to your submission planning and management processes? • What are the impacts to your eCTD submissions? • How should you prepare? <p>Kelly Hnat, Principal, K2 Consulting USA</p>	<p>15:50 - 16:15 - Pharmacovigilance and Risk Management in LATAM</p> <ul style="list-style-type: none"> • EMA and FDA risk management framework • LATAM region risk management landscape • Comparing LATAM's requirements to those of the EU and FDA • Understanding the challenges for implementation and next steps <p>Josue Bautista Arteaga - President, The Mexican Drug Safety Society</p>
16:25-16:50	<p>Practical Advice on Being Prepared to Migrate from EVMPD to IDMP</p> <ul style="list-style-type: none"> • Verifying EVMPD data's accuracy and IDMP reusability • Best practices to ensure a smooth migration • Turning EVMPD bottlenecks into IDMP opportunities <p>Mandy Mason, Associate Director, Data Stewardship & Compliance, BMS</p>	<p>Automation for Submissions</p> <ul style="list-style-type: none"> • Options for speeding up submission processed by removing the mundane • Underlining the time savings that can be brought by automation for submissions • Understanding the data quality needed for automation with submissions <p>Katharina Schmitz, Head of Automator Solutions, LORENZ Life Sciences Group</p>	<p>16:20 - 17:00 - How has COVID-19 Affected the LATAM Region and the Regulatory Landscape?</p> <ul style="list-style-type: none"> • What has been the pandemic response in LATAM? • The Cuban Prophylactic and Algorithm Model – An Example of Successful Case Study • What to expect soon? Other Developments? <p>Lawrence Liberti, Adjunct Assistant Professor, Temple University School of Pharmacy</p> <p>Mario Alanis, Senior Consultant, Centre for Innovation in Regulatory Science (CIRS)</p> <p>María de la Luz Lara Méndez, CEO, Udelá</p> <p>Moderator: Silvia Bendiner, Executive Partner, WESSX</p>
16:55	<p>Ensuring data compliance for 'Legacy' Products under IDMP and other telematic programmes</p> <ul style="list-style-type: none"> • Understanding why on market products are never "legacy" • Feedback from working group on 'legacy' data collection • Highlighting the impact on industry • Argha Nag, Global Regulatory Systems & Data <p>Argha Nag, Global Regulatory Systems & Data Governance Lead, AstraZenca</p>		
16:55	<p>END OF CONFERENCE DAY 2</p>		

DAY THREE

THURSDAY 22nd, APRIL 2020



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	Regulatory Information Management	Global eSubmissions	IDMP focus Day Regulatory Affairs in Global Markets: MENA
10:05-10:30	<p>Best Practices to having an End to End RIM System</p> <ul style="list-style-type: none"> Understanding the key requirements to have a successful end to end system Successful strategies to implement changes Creating a strong notification process for manufacturing <p>Akash Palia, Senior Associate Regulatory Information Management, Alexion</p>	<p>Feedback on eCTD Submissions with China</p> <ul style="list-style-type: none"> Industry feedback on the first eCTD Submissions in China Lessons learnt from submissions in China Avoiding common pitfalls <p>Cecilia Sirichoke, Novartis</p>	<p>Understanding MENA's Regulatory Landscape</p> <ul style="list-style-type: none"> Overview MENA region Organisation and structure of the Health Authorities General Requirements in MENA Regulatory procedures Regulatory strategy <p>Ilona Putz, Consultant, PULONA Emerging Markets FZE</p>
10:35-11:00	<p>Best practices to having an end to end RIM system</p> <ul style="list-style-type: none"> Guiding principles Understanding the key requirements to have a successful end to end system Successful strategies to implement changes <p>Matthias Glatz, IT-Manager Regulatory Affairs, Novartis Pharma AG</p>	<p>Update on Japan eCTD</p> <ul style="list-style-type: none"> Understanding the timelines of Japan eCTD Assessing the requirements for eCTD in Japan <p>Takeshi Adachi, President, PPG Inc</p>	<p>10:35 - 11:15 - Interactive: Shared Experiences for Product Registration for the Gulf Cooperation Council (GCC)</p> <ul style="list-style-type: none"> Updated on the recent developments in the region The Gulf Health Council and Central Drug Registration Shared experiences on registering products for the GCC Challenges in accessing GCC markets and how to overcome them <p>Abdul Mateen, Associate Regulatory Project Director, AstraZeneca Khaled Rozza, Regional Regulatory Affairs Manager, GCC, Acino</p>
11:05-11:30	<p>Robust RIM Systems: Meeting regulatory challenges with digital transformation and tech-enabled services</p> <p>Cecile Riboud, Senior Director Europe Integrated Global Compliance, IQVIA Jens-Olaf Vanggaard, Director, Global Regulatory and Safety Solutions, IQVIA</p>	<p>APAC eCTD Roundtable</p> <p>Ziqun Han, Director, Zen Medical Science Consultancy</p>	<p>11:20 - 11:45 - Pharmacovigilance and risk management activities in MENA</p> <ul style="list-style-type: none"> Latest updates in pharmacovigilance measures and new requirements Quality challenges for safety reporting activities resulting from the COVID-19 pandemic <p>Manal Younus -Head of Iraqi Pharmacovigilance Centre, Iraqi Ministry of Health</p>
12:20-12:45	<p>Spotlight Session</p> <ul style="list-style-type: none"> Looking for vendor companies to share their experiences with data management <p>Please contact Dylan Smith</p>	<p>Feedback from Saudi Arabia on eCTD</p> <ul style="list-style-type: none"> Updated on requirements for eCTD Addressing timelines for submissions Using the eSDR Portal Best practices for submitting products to SFDA <p>Nadeen Al Dibsi, Senior Manager Regulatory Affairs - SFDA,GCC & JFDA, AlSafa, Jordan</p>	<p>Evaluating the Biosimilars Landscape in Turkey and MENA</p> <ul style="list-style-type: none"> The status on the biosimilars market in MENA Latest regulatory updates of biosimilars What can be learnt from Europe to improve uptake? Key challenges to the future of the biosimilars market in Turkey and MENA <p>Dr Khalid Al-Kinani, Head of the Biologics and Biosimilars Registration Committee, Iraqi Ministry of Health</p>
12:50-13:15	<p>Case Study : Strategies to Enable Our Regulatory Department to Accelerate Submissions of Medicines Globally</p> <ul style="list-style-type: none"> The opportunity to transform our company to deliver faster submissions and how we have connected our regulatory departments across product development, manufacturing and affiliates The three key strategies we have developed to drive and enable this change across Roche Designing and executing our portfolio which includes RIM, IDMP, RPA, digital labelling, etc to meet these strategies Some of the challenges and opportunities when transforming and sustaining these changes. <p>Vijay Reddi, Regulatory Transformation Lead, Roche</p>		<p>Regulatory Updates for Turkey: Prioritisation and Localisation - High Impacts for Foreign Investors</p> <ul style="list-style-type: none"> Understanding the Turkish regulatory requirement of local production and its impacts for foreign investors Assessing the technology transfer requirements and localisation rationale What are the prioritisation submissions and criteria for MA and GMP audit submissions in the place? <p>Figen Kabadas, Head of Regulatory Affairs - Delpharm</p>

13:05-13:30	Data usage without responsibility? <ul style="list-style-type: none"> Data ownership and governance in RA Experiences with data maintenance workflows <p>Jörg Stüben, Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH</p>	EFPIA recommendations for eCTD <ul style="list-style-type: none"> Overview of global eCTD implementation progress by regulators Recommended timelines & considerations for new regions considering to adopt eCTD Benefits of eCTD for agencies, and examples from existing regions How industry can support and influence locally, including latest information on recent EFPIA engagements <p>Tim Powell, Associate Director, Submission Sciences, Biogen</p>	13:20 - 13:45 - Guidance on Launching Products in Russia/ EAEU and CIS Countries <ul style="list-style-type: none"> Key considerations to ensure successful market entry Clarifying the accelerated procedures in both Russia and CIS Challenges in bringing a product to market in the region <p>Dr Edelgard Rehak, Consultant, Edelgard Rehak Consulting</p>
13:45 - 14:45	Networking Break		
14:45 - 15:10	The Future of RIM with CLOUD <ul style="list-style-type: none"> Understanding the cloud trend and the impact it might have on RIM and data management Discussions around safety and data ownership while using cloud <p>Rodrigo Palacios, Lead, Regulatory Technology Policy, Roche</p>	eCTD in Brazil <ul style="list-style-type: none"> Latest updates Feedback on the latest technology <p>Patrícia Kott Tomazett, Health Regulation Specialist, General Management of Drugs - GGMed, Brazilian Health Surveillance Agency (ANVISA), Brazil</p>	Spotlight from Biomapas
15:15 - 15:40			The Eurasian Economic Union (EAEU): Evaluating the Regulatory Landscape <ul style="list-style-type: none"> EAEU requirements compared to EU requirements Mutual recognition of drug registrations in EAEU countries What are the differences in national requirements? How to successfully implement a transition to a single set of requirements across the Union Understanding need for EAEU GMP inspections <p>Alex Dranov, Senior Regulatory & Scientific Affairs Manager, Dr. Willmar Schwabe GmbH</p>
15:45 - 16:10	Using Innovative Technologies to Generate IDMP Dataset for Qualification – Usage of Machine Learning & Robotic <p>Argha Nag, Independent</p>	Global eCTD Updates <ul style="list-style-type: none"> Exploring ROW timelines and updates for ECTD Understanding the current on-going initiatives globally <p>Olga Alfieri, Director, Global Submission Management, Eisai Inc.</p>	Product Labelling Under the EAEU and CIS Markets <ul style="list-style-type: none"> Harmonising product information across Russia and the EAEU markets: requirements and learnings so far An overview of product information requirements and trends across other CIS markets <p>Rebecca Jackson, Team Leader, Worldwide Safety & Regulatory - Pfizer</p>
16:15 - 16:30	Closing Remarks	Closing Remarks	Closing Remarks

End of Conference

Looking for sponsorship opportunities?

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Dylan.Smith@informa.com | +44 (0)20 3377 3237