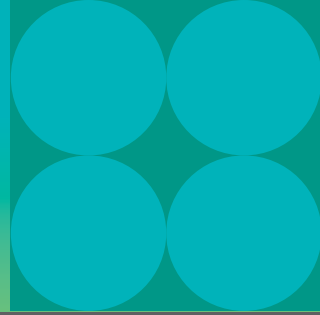


Global Regulatory Affairs Summit

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



**ACCELERATE GLOBAL EXPANSION.
MINIMISE TIME TO MARKET.
TRANSFORM YOUR GLOBAL
REGULATORY STRATEGY.**

Connect with regulators and industry peers from around the world to discuss the latest global requirements and swap registration top tips



lifesciences.knect365.com/global-regulatory-affairs/

#GLOBALRA

KNect365
Life Sciences

DAY ONE: MONDAY 8 APRIL 2019

	TRACK 1: Regulatory Affairs in Emerging Markets	TRACK 2: Telematics & Regulatory Information Management	TRACK 3: Global eSubmissions
08.00	Registration		
	Regulatory Affairs in APAC	RIM/IDMP	Regulatory Management
09.00	Chairperson's Opening Remarks	Chairperson's Opening Remarks	Chairperson's Opening Remarks
09.10	China's Regulatory Reform and Impact on the Pharmaceutical Industry Michael Gebauer, Senior Expert, Established Products, Bayer AG, Germany	Feedback on EMA's IDMP Implementation Guidelines Laurent Desqueper, XEVMPD & IDMP Business System Owner, MSD Europe Inc, Germany	CASE STUDY: Implementing eCTD within National Procedures Daniel Verrall, Senior Team Manager, Pfizer, UK
09.45	Practical Guidance for Drug Registration Compliance in China Stefano Accorsi, Head of Regulatory Affairs "Rest of the World", Chiesi Farmaceutici S.p.A., Italy	Lessons Learned from Data Migration Danielle Beaulieu, Director, Global Regulatory Business Capacities, Bristol-Myers Squibb, USA	Regulatory Agency Perspective: Feedback, Plans and Practical Advice for eCTD Submissions Jaana Pohjonen, Specialist of Record Management and Archives, Quality Manager, FIMEA, Finland
10.20	Understanding the Regulatory Environment and Practical Considerations for Market Entry in South Korea Alan Chalmers, Director, Pharma International, Switzerland	Improving Data Integration Across the Business Representative from Navitas Marty Boom, Global Head of Regulatory and Safety, Navitas Life Sciences, Germany	An Update on Clinical Trial Applications in the EU Speaker to be Announced
10.55	Morning coffee		
11.20	Updates on Regulatory Harmonization Efforts for Pharmaceutical Products in ASEAN Asmaa Asim, Head of Regulatory Affairs, Boehringer Ingelheim, Singapore	Data Modelling for Regulatory Affairs Dr. Jörg Stüben, Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim International GmbH, Germany	Best Practice for Implementing the EU Falsified Medicines Directive Johan Verhaeghe, National Policy Liaison, Medicines for Europe, Belgium
11.55	Fast-Tracking Approvals & GMP Guidelines Updates in Taiwan Speaker to be Announced	Utilizing AI and Data Analytics to Optimise your Regulatory Strategy Representative from Cunesoft	Experiences of Submitting Dossiers in China Speaker to be Announced
12.30	Networking Lunch		

	TRACK 1: Regulatory Affairs in Emerging Markets	TRACK 2: Telematics & Regulatory Information Management	TRACK 3: Global eSubmissions
	Regulatory Affairs in APAC	RIM/IDMP	Regulatory Management
14.00	Marketing Authorizations and Latest Regulatory Updates in India Arun Mishra, Senior Director EMAP Region, GSK, India	INDUSTRY CASE STUDY: Cross Functional Collaboration - Data Integration Across the Business Patrick Middag, Associate Director, Regulatory IT, Bristol-Myers Squibb, Belgium Deborah McCloskey, Global Regulatory Business Capabilities Director, Bristol-Myers Squibb, USA	Assessing the Latest Developments Towards eCTD in Singapore Speaker to be Announced
14.35	Strategies for Successful Product Registration in India Arun Mishra, Senior Director EMAP Region, GSK, India	Industry Feedback on the Falsified Medicines Directive: Post Implementation Quentin Grignet, IDMP – Project Lead, GSK, Belgium	Guidance from South East Asia on the Harmonisation and Implementation of CTD Speaker to be Announced
15.10	Understanding Product Requirements and Expectations in Japan Speaker to be Announced	Spotlight Session by Amplexor Representative from Amplexor	CASE STUDY: Implementing a Successful eSubmissions Strategy at a SME Representative from Veeva Systems with a guest client
15.45	Afternoon tea		
16.15	Updates from Australia: Current Regulatory Landscape and Opportunities for the Pharmaceutical Industry Speaker to be Announced	Designing an End-to-End RIM System Costas Mistrellides, R&D Business Lead, Johnson & Johnson Consumer, UK Chris Dunn, IDMP Specialist, Johnson & Johnson, UK	Outlining Current Regulatory Submission Status in Jordan Representative from Jordan FDA
16.45	APAC PANEL DISCUSSION: Regulatory Feedback and Industry Experiences Alan Chalmers, Director, Pharma International, Switzerland Justyna Kwiatkowska, Regulatory Affairs Specialist, Adamed Group, Poland	PANEL DISCUSSION: The Future of Information Management - Shifting the Mindset from Tactics to Strategy Dr. Jörg Stüben, Head of Regulatory Information Management and Senior Expert, Boehringer Ingelheim Frits Stulp, Project Manager EU-SRS, Medicines Evaluation Board, The Netherlands	Updates on Submissions in Australia Henrietta Dehmlow, Head of Submission Management, Roche, Switzerland
17.20	Chairman's Closing – End of Day 1 and Networking Drinks		

	TRACK 1: Regulatory Affairs in Emerging Markets	TRACK 2: Telematics & Regulatory Information Management	TRACK 3: Global eSubmissions
08.00	Registration		
	Regulatory Affairs in CIS	European Regulatory Affairs Forum	RIM/Submissions
09.00	Opening Remarks from the Chairperson	Opening Remarks from the Chairperson	
09.10	Navigating the Russian Regulatory Landscape Natalia Morgunova, Head of Regulatory Affairs & PV, Novo Nordisk A/S, Russia	SPOR Regulatory Landscape and Implementation Feedback Remco Munnik, Regulatory Information Director, Asphalion S.L., Spain	
09.45	Case study: Best Practice for Normative Document Preparation Irina Krasnokutskaya, Regulatory Affairs Manager, Novo Nordisk, Russia	Best Practice for Successful Implementation of OMS & RMS Dominik Gigli, Senior Manager IDMP Office, Merck KGaA, Germany	
10.20	Sharing Experiences of Russian GMP Inspections: Success & Failure Alex Dranov, Senior Regulatory & Scientific Affairs Manager, Dr. Willmar Schwabe, GmbH & Co. KG, Germany Edelgard Rehak, Dr. Edelgard Rehak Consulting, Germany	A Systematic Approach to PMS Preparations Kelly Hnat, Principal, K2 Consulting, USA	
10.55	Morning coffee		
11.25	Registration Strategies and Best Practices for Dossier Preparation for Successful Product Registrations in Russia Edelgard Rehak, Dr. Edelgard Rehak Consulting, Germany	The IDMP Substance Management System Frits Stulp, Project Manager EU-SRS, Medicines Evaluation Board, The Netherlands	
12.00	Reviewing the Regulatory Environment in Ukraine Ebru Guzel, Regulatory Affairs Director, Regional Liaison MEA, MSD Europe Inc.	CESSP Essentials: What to Expect from Phase 1 Speaker to be Announced	
12.30	Networking Lunch		

	TRACK 1: Regulatory Affairs in Emerging Markets	TRACK 2: Telematics & Regulatory Information Management	TRACK 3: Global eSubmissions
	Regulatory Affairs in CIS	European Regulatory Affairs Forum	RIM/Submissions
14.00	Reviewing the Regulatory Environment in Ukraine Ebru Guzel, Regulatory Affairs Director, Regional Liaison MEA, MSD Europe Inc.	How eCTD & IDMP Will Work Together Anjana Pindoria, Director Product Strategy, EXTEDO	GCC Experiences with eCTD Transitions and Timelines Richard Knowles, Senior Manager GRAAS Operations, Amgen, UK
14.35	Latest Status Update of the Eurasian Economic Union (EEU) and Implications for Industry Speaker to be Announced	Label and Artwork Management Systems: Transitions and Sustainability Bas Van Heijst, Associate Director Regulatory Affairs, Astellas	Outlining the Latest Updates from Canada and the Implications for Industry Susanne Picard, President/General Manager, SPharm Inc., Canada
15.10	Reviewing the Regulatory Environment and Best Strategies for Product Registration in Kazakhstan Speaker to be Announced	Spotlight Session by Aris Global	Creating a Global Dossier Plan for Fast-Tracking Approvals Olga Alfieri, Director, Global Submission Management, GRO, Eisai, USA
15.40	Afternoon tea		
16.10	PANEL DISCUSSION: Sharing Practical Experience of Submissions in Russia & the CIS Countries Ebru Guzel, Regulatory Affairs Director, Regional Liaison MEA, MSD Europe Inc. Natalia Morgunova, Head of Regulatory Affairs & PV, Novo Nordisk A/S	Digital Transformation of Novartis’ Regulatory Processes Wolfgang Schleifer, Service Delivery Lead for Regulatory, Novartis	Creating a Common Clinical Trials Submission Format Speaker to be Announced
16.45	Regulatory Affairs for Submissions in Turkey (key updates in turkey; ministry of health, GMP inspections, traceability) Figen Kabadas Oge, Head of Regulatory Affairs, Delpharm, France	Developing a Robust Data Archiving System Michel Mikhail, Expert in International Regulatory Affairs and Biosimilars, Independent	PANEL DISCUSSION: Sharing Experiences of Global eCTD Submissions
17:10	Creating a Global Dossier. Comparing European and Emerging Market Registration Requirements Speaker to be Announced	End of day two	
17.40	End of day two		

	TRACK 1: Regulatory Affairs in LATAM	TRACK 2: Filing Variations Day
08.00	Registration	
09.00	Opening Remarks from the Chairperson	Opening Remarks from the Chairperson
09.10	Updates on the Regulatory Landscape in Brazil Representative from ANVISA	An Update on ICH Q12
09.45	Industry Experiences of Bringing Products to Market in Brazil	The European Variations Procedure
10.20	Examining the Product Registration Landscape in Mexico Dr. Ana Silvia Nita, Director, Regulatory Affairs CMC Biologics, MSD BioPharma, Lucerne, Switzerland	Demonstrating an Effective Grouping and Work Sharing Strategy
10.55	Morning Coffee & Networking	
11.25	CASE STUDY: Successfully Registering Products in Argentina Alejandra Blanc, Regulatory Affairs & Quality Assurance Director, AbbVie S.A.	Troubleshooting your EU Filing Variation Plan
12.00	Biosimilars: Current Status in the Development of Biosimilar Market in LatAm Lisa Ruiz, Latin America Area Head, Regulatory International, AbbVie Inc., USA	Comparing Requirements: Filing Variation Differences Between the EU and USA
12.35	Practically Complying with the Regulatory Landscape in Colombia Laura Galvis Morales, Head of Regulatory Affairs Colombia, Boehringer Ingelheim, Colombia	Outlining Requirements and Best Practice for Filing Variations in Asia
13.10	Networking Lunch	
14.30	Designing an Effective Labelling Strategy for Product Registrations in LatAm	Designing a Successful Global Variation Strategy
15.05	PANEL DISCUSSION: Latin America Pain Points	Q & A: Around the World
15.30	Afternoon Coffee & Networking	
16.00	Exploring the Current Efforts for Pharmaceutical Regulation and Harmonisation in Africa	Focus Day Speakers Include: Gry Agapitos, Senior Regulatory Affairs Professional, ALK Abello, Denmark Justyna Kwiatkowska, Regulatory Affairs Specialist, Adamed Group, Poland Sophie Nageotte, CMC Regulatory Consultant Monique Mendel Ott, Manager Global Regulatory Affairs, Grünenthal GmbH, Germany
16.30	Strategies for Successful Registrations in the Middle East Abid Hussain, Senior Manager Regulatory Affairs, Emcure Pharmaceutical Ltd., UAE	
17.00	End of Day 3 and Close of Conference	

PROMOTE NEW AND EXISTING PRODUCTS AND SERVICES TO OUR HIGH LEVEL DELEGATION

We can provide flexible and tailored solutions to optimise your investment. Below are some examples of how you can get involved at the event.

Speaking Opportunities

- Demonstrate your thought leadership to the most senior level audience. Raise your profile, share your experiences and position yourself as one of the go-to companies in your business area.
- Deliver a keynote address or presentation
- Participate in a high level panel discussion and interact with the audience
- Moderate or present during a breakout session

Branding Packages

- Create greater awareness of your brand and ensure your company stands out in the crowd. Branding sponsorship options include:
- Conference Bag Sponsor
- Delegate Badge/Lanyard Sponsor
- Wifi Sponsor
- Registration Sponsor
- Mobile App Sponsor

Hospitality Packages

- Ensure your company or product is the talk of the conference by hosting social functions including drinks receptions, lunch breaks, coffee breaks, a networking dinner, evening entertainment, and more
- Networking Drinks Sponsor
- Networking Lunch Sponsor
- Coffee Break Sponsor

Exhibition Packages

- Join the exhibition where all refreshments and lunch is served. This offers extensive networking and helps delegates and speakers to connect with relevant suppliers. Showcase your expertise, build new contacts and demonstrate your products and services.
- Sponsorship and exhibition opportunities are limited - book now to avoid disappointment. Email Alexander Zenonos to find out more - Alexander.zenonos2@informa.com or call +44 (0) 20 7017 7742

1 to 1 Meetings & Networking

With access to 200+ industry professionals the event provides the ultimate opportunity to meet current and prospective clients. Use the event networking app to arrange 1 to 1 meetings with key decision makers ahead of the event to optimise your time on site.



To learn more about available sponsorship & exhibition opportunities, contact Brad Hoyland: T: +44 (20) 337 73522 • Brad.Hoyland@Knect365.com

For speaking opportunities, contact Sophie Roberts: T: +44 (20)75519668 • sophie.roberts@knect365.com