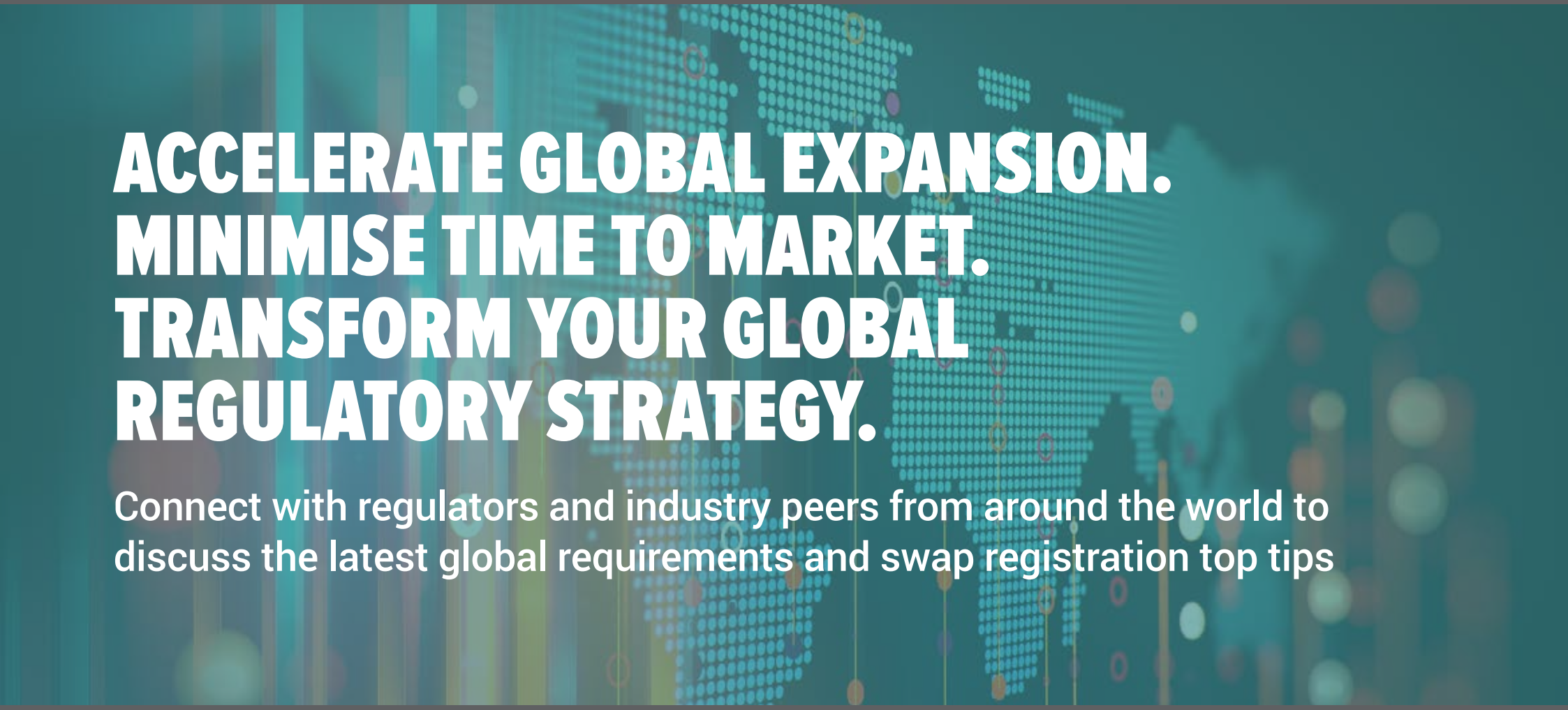
Global Regulatory Affairs Summit

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



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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*		

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	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,** EU-SRS Project Manager, **Medicines Evaluation Board**	**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*		

DAY TWO: TUESDAY 9 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 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,** EU-SRS Project Manager, **Medicines Evaluation Board,** *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*		

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	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*		

DAY THREE: WEDNESDAY 10 APRIL 2019

	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,** Global Regulatory Affairs CMC Manager, **Roche**	**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*	

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- 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

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- Wifi Sponsor
- Registration Sponsor
- Mobile App Sponsor

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- Networking Lunch Sponsor
- Coffee Break Sponsor

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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