Global Regulatory Affairs Summit

23-25 October 2018
Hotel Palace Berlin
Berlin, Germany

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DAY ONE: TUESDAY 23 OCTOBER 2018

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	Regulatory Data Management and Submissions
08.00	*Registration*		
	Regulatory Affairs in Russia, Ukraine and the Eurasian Economic Union	**European Regulatory Affairs Forum**	**Regulatory Management**
09.00	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**
09.10	**CASE STUDY: Successfully undergoing a Russian GMP inspection of manufacturing sites** **Edelgard Rehak, Dr. Edelgard Rehak Consulting,** *Russia*	**Brexit: Implications for Regulatory Affairs professionals and the pharmaceutical industry as a whole** **Aimad Torqui,** Director Global Regulatory Policy, **MSD,** *The Netherlands*	**Understanding IDMP and SPOR Timelines in the EU and beyond** **Andrea Herrman,** Head of IDMP Office – GRA Operations, **Merck**
09.45	**INTERACTIVE TROUBLESHOOTING SESSION: Practical advice on Russian GMP inspections** **Alex Dranov,** Senior Regulatory & Scientific Affairs Manager, Dr. Willmar Schwabe, **GmbH & Co. KG,** *Germany*	**The EU Paediatric Regulation: Latest updates including the EU Commission's roadmap for the joint evaluation of the Paediatric and Orphan Regulations** **Mette Due Theilade Thomsen,** Founder, **PIP Adviser,** *Denmark*	**Debate discussion: To continue with IDMP or not?** **Jean-Michel Cahen,** IDMP Project Lead, **Novartis Pharma AG,** *Switzerland*
10.20	**The Eurasian Economic Union (EEU) by 2025: Implications for the pharmaceutical industry and practical experiences so far** **Olga Kravtsova,** Head of Regulatory Affairs, **BIOCAD,** *Russia*	**Orphan medicinal products: Current challenges and opportunities and the latest regulatory landscape** **David King,** Director, Regulatory Policy & Intelligence, **Shire,** *UK*	**SPOTLIGHT PRESENTATION: Paraxel**
10.55	*Morning coffee*		
11.25	**INTERACTIVE DISCUSSION FORUM: Preparing for changes with the new EEU procedures** **Mariana Novozheniuk,** Regulatory Affairs CMC Manager, **Bayer AG,** *Germany*	**ATMPs in the light of precision (personalised) medicine** **Hanneke Later-Nijland,** Attorney-at-Law | Counsel, **Axon Lawyers, Law Firm focused on Life Sciences,** *The Netherlands*	**Best practices to handle Data migration from XEVMPD to IDMP** **Laurent Desqueper,** XEVMPD & IDMP Business System Owner, **MSD Europe Inc** *(Pending)*
12.00	**Overview of requirements and practical requirements for creating labels for the EEU** **Giovanna Ferrari,** Regional Labelling Lead, **Pfizer,** *UK*	**Challenges and opportunities in developing ATmPs such as Allogeneic CAR-T cells** **Stéphan Reynier,** Chief Regulatory and Compliance Officer, **Cellectis,** *France*	**PANEL DISCUSSION: Sharing experiences of data migration** **Patrick Middag,** Lead IT Business Partner for Regulatory EU and Data Capabilities, **Bristol-Myers Squibb**
12.35	**Exploring serialisation requirements in Russia and implications for industry** **Olesya Mertsalova,** Regulatory Affairs Cluster Head, **EEU, GSK,** *Russia*	**EU pharmacovigilance: Updates on the activities of the PRAC** **Doris Stenver,** Chief Medical Officer and Member, Pharmacovigilance Risk Assessment Committee (PRAC), **Danish Medicines Agency,** *Denmark*	**SPOTLIGHT PRESENTATION/CASE STUDY: Best practices for data mining and converting**
13.10	*Networking Lunch*		

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	Regulatory Management
	Regulatory Affairs in Russia, Ukraine and the Eurasian Economic Union	**European Regulatory Affairs Forum**	**Regulatory Management**
14.30	**CASE STUDY: Best practice for normative document preparation** **Yuliana Purysheva,** Regulatory Affairs Specialist**, R-Pharm Group,** *Russia*	**The registration dossier: Best practice for European submissions and comparisons to the emerging markets** **Anna Roznovska,** Head of Global Regulatory Affairs**, PRO.MED.CS Praha a.s.,** *Czech Republic*	**Demonstrating a successful RIM system** **Fidaa F. Odetallah,** RIMS Specialist**, HIKMA**
15.05	**Best practices for filing new registrations and CMC variations in Russia** **Alessandra Leone,** Global CMC Sr. Manager, **Pfizer,** *Italy*	**A patient-centric approach to labelling: Communicating risks to the patient and exploring usability and readability of the SmPC and PIL** **Patricia Lefebvre,** Director Regulatory Labeling, **Sanofi-Aventis,** *France*	**SPOTLIGHT PRESENTATION: Best practices for data mapping**
15.40	*Afternoon tea*		
16.10	**Reviewing the dynamic regulatory environment in Ukraine and practical advice on product registration** **Anna Altshuler,** Head of Regulatory Affairs, **Pfizer,** *Ukraine*	**CASE STUDY: Exploring codes on packaging, including QR codes and 2d data matrix codes** **Viktoria Grahnen,** Labeling Strategist Manager, Global Labeling, Europe, **AbbVie AB,** *Sweden*	**Designing an innovative RIM system** **Laurent Lefebvre,** Regulatory CMC Associate Director, **Novartis** **Jean-Michel Cahen,** IDMP Project Lead, **Novartis Pharma AG,** *Switzerland*
16.45	**Examining latest regulatory updates and best strategies for product registration in Ukraine and Moldova** **Alla Sorokoletova,** Director of Medical and Regulatory Affairs Department, PV, QA, Ukraine & CIS, **Acino Pharma AG,** *Ukraine*	**Exploring the evolution of E-Labelling in Europe: Latest regulatory requirements and expectations** **Rüdiger Faust,** Director, Regulatory Strategy & Intelligence Lead, **Grünenthal GmbH,** *Germany*	**Ensuring successful RIM system prepared for the Falsified Medicines Directive (FMD)**
17.20	**Exploring cross-functional leadership for regulatory professionals for market access of pharmaceuticals in emerging markets: Focusing on Ukraine, Russia, Kazakhstan, Belarus, CIS** **Mariia Govorukha,** Manager Regulatory Affairs CIS, **Atrium Innovations Inc.,** *Germany*	*End of Day One*	*End of Day One*
17.55	*End of Day One*		

DAY TWO: WEDNESDAY 24 OCTOBER 2018

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	ESubmissions and IDMP
08.00	*Registration*		
	Regulatory Affairs in Latin America	**European Regulatory Affairs Forum**	**RIM/Submissions**
09.00	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**
09.10	**ANVISA: Exploring the latest regulatory updates** **Letícia Cafruni,** Regulatory Affairs Coordinator, **AbbVie,** *Brazil*	**Comparing regulatory requirements and expectations between Europe and the US** **Paulina Komorowska,** Regulatory Affairs Director EMEA, **Valeant Pharma,** *Poland*	**Understanding the long term telematic strategy** **Remco Munnik,** Regulatory Information Director, Asphalion S.L., *Spain*
09.45	**CASE STUDY: Practical experience with product registration in Brazil** **Letícia Cafruni,** Regulatory Affairs Coordinator, **AbbVie,** *Brazil*	**Exploring comparisons between European and US regulatory requirements and expectations** **Claudia Hey,** Senior Director, Head Europe Global Regulatory and Scientific Policy (GRASP), **Merck KGaA,** *Germany,* **focused on Life Sciences,** *The Netherlands*	(9:55) **The impact of SPOR on Regulatory affairs** **Vada Perkins,** Head, Regulatory Intelligence, **Bayer**
10.20	**Examining specific requirements for variations in Brazil** **Darius-Jean Namdjou,** International Regulatory Project Lead, **Grünenthal GmbH,** *Germany*	**The registration dossier: Best practice for European submissions and comparisons to the emerging markets** **Anna Roznovska,** Head of Global Regulatory Affairs, **PRO.MED.CS Praha a.s.,** *Czech Republic*	(10:40) **Question and Answer Panel on the Telematic Strategy and SPOR** **Remco Munnik,** Regulatory Information Director, **Asphalion S.L.,** *Spain* **Vada Perkins,** Head, Regulatory Intelligence, **Bayer**
10.55	*Morning coffee*		
11.25	**CASE STUDY: Navigating the regulatory environment for product registration in Mexico** **Stefano Accorsi,** Head of Regulatory Affairs "Rest of the World", **Chiesi Farmaceutici S.p.A.,** *Italy*	**SPOTLIGHT PRESENTATION**	**SPOTLIGHT PRESENTATION:** **SPOR Taskforce Feedback: Understanding the Substance Management Service**
12.00	**CASE STUDY: Examining Chile's regulatory environment and successfully registering a product** **Samuel Bautista,** Manager Global Regulatory Affairs, **Grünenthal GmbH,** *Germany*	**EU pharmacovigilance: Updates on the activities of the PRAC** **Doris Stenver,** Chief Medical Officer and Member, Pharmacovigilance Risk Assessment Committee (PRAC), **Danish Medicines Agency,** *Denmark*	**FDA feedback on the SRS system and a comparison to SPOR** **Larry Callahan,** Substance Registration System, **FDA,** *USA*
12.35	**Discussing the regulatory pathways for registration of biologics (Vaccines) in LATAM** **Arturo Gonzalez-Martinez,** Senior Regulatory Expert Japan and LATAM, **GSK,** *Belgium*	**Case study: Implementing successful global variation strategies** **Dr. Meike Vanhooren, Senior Director, Pfizer,** *Germany*	**Feedback on the implementation of RMS and OMS** **Dr. Jörg Stüben,** Head of Regulatory Information Management and Senior Expert, **Boehringer Ingelheim International**
13.10	*Networking Lunch*		

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	ESubmissions and IDMP
	Regulatory Affairs in Latin America	**European Regulatory Affairs Forum**	**RIM/Submissions**
14.30	**CASE STUDY: Sharing best strategies for clinical trial submissions in Latin America** **Sol Yates,** Associate Director, Global Regulatory Affairs, **Grünenthal GmbH,** *Germany*	**CASE STUDY: Demonstrating an effective grouping strategy for filing variations** **Anna Krusińska,** Regulatory Manager, **AbbVie,** *Poland*	**Feedback on the Products of SPOR** **Vada Perkins, Head, Regulatory Intelligence Director, Regulatory Policy & Intelligence, Bayer**
15.05	**Practically implementing pharmacovigilance and risk management activities in LATAM** **Cristina de Irala,** Pharmacovigilance Consultant, *Spain*	**CASE STUDY: Exploring successful worksharing strategies for filing variations** **Şebnem Türkes Hartwig, S**enior Regulatory Affairs Manager, **F. Hoffmann-La Roche Ltd.,** *Switzerland*	**An introduction to CESSP programme** **Alastair Nixon,** Director Publishing, **GlaxoSmithKline** *(Pending)*
15.40	*Afternoon tea*		
16.10	**OPEN FLOOR Q&A DISCUSSION: LATAM** Joined by speakers from the day	**OPEN FLOOR Q&A DISCUSSION: Europe** **Tânia Veiga,** Regulatory Affairs Europe, **Orexigen Therapeutics Ireland Ltd.,** *Ireland*	**Outlining the status and timelines of ECTD 4.0** **Leigh Sandwell, Pfizer**
16.45			**ELabelling**
17.20	*End of day two*		**The future of submission and data management through Automated Intelligence** **Olga Alfieri,** Director, Global Submission Management, **Eisai**
18.30			*End of day two*

DAY THREE: THURSDAY 25 OCTOBER 2018

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	ESubmissions and IDMP
08.00	*Registration*		
	Regulatory Affairs in Asia-Pacific	**Regulatory Affairs in the Middle East and Africa**	**Submissions**
09.00	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**
09.10	**Major regulatory changes China: Staying on top of a turbulent environment** **Ziqun Han,** Director, **Zen Medical Science Consultancy,** *UK*	**Exploring latest regulatory updates in Oman** **Dr. Mohammed Hamdan Al Rubaie,** Director General of Pharmaceutical Affairs & Drug Control, Ministry of Health, **Sultanate of Oman**	**Overcoming hurdles with submissions in multiple** **Anna Sahl,** Submission Manager, **Bayer**
09.40	**CASE STUDY: Practically complying with the rapidly evolving regulatory landscape in China** **Ching Li,** Manager International, Corporate Regulatory Affairs, **Biotest Pharma GmbH,** *Germany*	**Regulatory update and practical advice for successful generics' registration in Saudi Arabia** **Syndie Messager,** Market Access and International Regulatory Affairs Coordinator, **Laboratorios Cinfa,** *Spain*	**Member state feedback from Thai FDA** **Thai FDA representative,** *Awaiting final confirmation*
10.10	**CASE STUDY: Marketing authorizations and latest regulatory updates in India** **Andrey Mladenov,** Senior Manager Regulatory Affairs, **Tillotts Pharma AG,** *Switzerland*	**Practical advice for product registration and regulatory updates from the Gulf Cooperation Council (GCC)** **Abdul Mateen,** Regulatory Affairs Consultant, **AstraZeneca,** *UK*	**Experiences in Submitting Dossiers in Thailand** **Jagraj Sangha,** International Regulatory Publishing, **Gilead Sciences International Ltd**
10.40	*Morning coffee*		
11.10	**Exploring practical considerations for market entry and the latest regulatory environment in South Korea** **Eric Ducamp,** Associate Director, Global Regulatory Affairs, **Ipsen,** *France*	**Regulatory update and complying with requirements for registration in Iran** **Abid Hussain,** Senior Manager Regulatory Affairs, **Emcure Pharmaceuticals Ltd.,** *UAE*	**Exploring submissions in Brazil** **A speaker from ANVISA,** *awaiting confirmation*
11.40	**Outlining latest regulatory updates in the ASEAN countries and status of the ACTD format** **Silvia Nita,** Global Regulatory Affairs CMC Manager, **Roche,** *Switzerland*	**Outlining the regulatory environment and practical advice for product registration in Lebanon** **Ayad Azzi,** Regulatory Affairs Manager – Emerging Markets, **Boehringer Ingelheim,** *Germany*	**Outlining latest regulatory updates in the ASEAN countries and status of the ACTD format** **Silvia Nita,** Global Regulatory Affairs CMC Manager, **Roche,** *Switzerland*
12.10	**Japan: Examining the latest regulatory environment and practical experiences with MAA submissions** **Martine Zimmermann,** Global Head of Regulatory Affairs, **Alexion Pharma GmbH,** *Switzerland*	**Exploring regulatory requirements and overcoming challenges across Francophone Africa** **Marta Abascal,** International Market Access & Regulatory Affairs Specialist, **Laboratorios Cinfa,** *Spain*	**Sharing experiences of successful submissions in GCC** **Satish Mahajan,** Manager, Regulatory Operations – Publishing, **GSK**
12.40	*Networking Lunch*		

	Regulatory Affairs in Emerging Markets	Regulatory Affairs in EMEA	ESubmissions and IDMP
	Regulatory Affairs in Asia-Pacific	Regulatory Affairs in the Middle East and Africa	Submissions
14.00	**Understanding orphan drug designation requirements and expectations in Japan** **Lamine Messaoudi,** Co-Founder, **RegArise,** *USA*	**Understanding the prioritisation of local production in Turkey and implications for industry** **Figen Kabadas Oge,** Head of Regulatory Affairs, **Delpharm,** *France*	**Roundtables: Question and Answer around the world**
14.30	**Outlining Australia's latest regulatory requirements for product registration** **Mahir Karababa,** Head Regulatory Affairs RoW, **Santhera Pharmaceuticals AG,** *Switzerland*	**Latest regulation on the registration of medicinal product and overcoming the challenge of GMP inspections by the Turkish Health Authority** **Figen Kabadas Oge,** Head of Regulatory Affairs, **Delpharm,** *France*	**CASE STUDY: Preparing for the Mandate of National submissions** **James Hendry,** Head of Global Regulatory Affairs Operations, **GE**
15.00	**Discussing regulatory requirements for labelling and package inserts across APAC** **Wei Way, Kok,** Manager Regulatory Competency Center APAC, **Hexal AG/Sandoz,** *Germany*	**Practical experiences of labelling in Africa and Middle East – An Overview** **Ronnie Mundair,** Regional Labelling Head- Director, **Pfizer,** *UK*	**CASE STUDY: Preparing for the Mandate of National submissions** **Daniel Verrall,** Senior Team Manager, **Pfizer**
15:30	*Afternoon tea*		
16.00	**OPEN FLOOR Q&A DISCUSSION: APAC** **Ching Li,** Manager International, Corporate Regulatory Affairs, **Biotest Pharma GmbH,** *Germany* **Ziqun Han,** Director, **Zen Medical Science Consultancy,** *UK* **Justyna Kwiatkowska,** Junior Regulatory Affairs Specialist, **Adamed Group,** *Poland* **Alan Chalmers,** Director, **Pharma International,** *Switzerland*	**Latest regulatory updates and best practice for biosimilars registration in Turkey and MENA** **Parminder Kaur,** Founder and RA/PV Consultant, **RegPak BioPharma Consulting,** *The Netherlands*	**Ensuring industry are prepared for Policy 0070** A representative from **PPP Solutions**
16.30		**Exploring latest status and updates of 'fast track' approvals and priority reviews conducted in Turkey and MENA** **Edmar Campos,** Intercontinental Coordinator, Global Regulatory Affairs, **Ipsen,** *France*	**Defining the right level of RA technical checks of regulatory files** **Caroline Petersen,** Project Manager, **Novo Nordisk**
17.00	*End of day three*	**OPEN FLOOR Q&A DISCUSSION: Middle East and Africa** **Dr Salah Chettibi, Regulatory Affairs Manager, Kyowa Kirin Services Ltd, UK**	*End of day three*
18:00		*End of day three*	

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