Schedule

PRE-CONFERENCE EVENING SEMINARS– 17/10/2016

Pre-Conference Evening Seminar Agenda		
06.00pm (150 mins) **Two Sessions Available**	**Session one:** Pre-Conference Evening Seminar: Implementing a Robust Strategy for Managing eSubmissions in a Diverse Global Environment **Suzie Henderson,** Takeda Development Centre Europe, UK **Carolline Petersen,** Novo Nordisk A/S, Denmark	**Session two:** Best Practice for Conducting Multi-Regional Clinical Trials in the Emerging Markets **Roger Joby,** 1to1to1, UK

Schedule

DAY 1- 18/10/2016

Global Pharma Regulatory Affairs
18 – 20 October 2016
Maritim proArte Hotel
Berlin

Emerging Markets Stream 1 Russia, CIS, Turkey, Middle East & Africa	Emerging Markets Stream 2 Latin America & Asia-Pacific	Global eSubmissions	Pharmaceutical Labelling
08.00 - Registration	**08.00 -** Registration	**08.00 -** Registration	**08.00 –** Registration
09.00 – Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks
Morning Sessions **09.10** – Overview of Russian National and EEU registration process **Alexander Borisov**, Teva LLC, Russia	**Morning Sessions** **09.10** – Exploring the latest regulatory environment in Brazil and best strategies for product registration **Stefano Accorsi**, CHIESI FARMACEUTICI S.p.a., Italy	**Morning Sessions** **09.10** – Flash update: The EU eSubmissions Roadmap – what is upcoming, timelines and impact on industry? **Melanie Ruppel**, Boehringer Ingelheim Pharma GmbH & Bo. KG, Germany	**Morning Sessions** **09.10** – Interactive discussion session: improving communication between pharmacovigilance, labelling, regulatory affairs and risk management to ensure compliant, relevant and timely labelling updates **Patricia Lefebvre**, Sanofi **Matthias Boedding,** Merck Serono **Frederic Bouder,** Maastricht University **Simon Ashworth,** Takeda Development Centre Europe Ltd.
09.45 – Exploring the new and upcoming Russian GMP inspection requirements for foreign drugs **Tina J Narendra-Nathan,** Consultant CMC Regulatory & GMP Process Development, UK	**09.45 –** Brazil extended session **Stefano Accorsi**, CHIESI FARMACEUTICI S.p.a., Italy	**09.25 –** EXTENDED ROUND TABLES SESSION: Update and experiences with EU Ectd Module 1 Specification v3.0 becoming mandatory from 1st October 2016 **Alastair Nixon,** GlaxoSmithKline Research & Development Limited, UK	
10.20 – TROUBLESHOOTING SESSION: Russia GMP requirements	**10.20 –** Exploring the new regulation for variations in Brazil and third party reviews and the recognition model in Mexico **Antonio Trejo Diaz**, TEVA, USA	**10.20 –** Practically implementing strategies for ETCD only DCP, MRP and National Procedure Submissions **Maike Diepen-Engisch**, Teva, Germany	**10.10 –** Risk minimisation: Examining strategies to reduce medication errors through effective labelling **Dr Michael Forstner**, Acino Pharma AG

Tina J Narendra-Nathan, Consultant CMC Regulatory & GMP Process Development, UK			**10.45 –** Question and answer session
10.55 – Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking
11.25 – Assessing how drug interchangeability is defined and established according to amendments introduced by Federal Law No. 429-FZ **Edelgard Rehak,** Dr. Edelgard Rehak Consulting, Germany	**11.25** – Navigating the regulatory framework for registration in Chile **Cathie Gongora,** Sanofi Pasteur, France	**11.25 –** Flash perspective: Industry perspective on the practical use of the new PSUR repository **Chantal Le Floch,** Servier, France	**11.25 –** Examining the latest updates from PRAC **Frederic Bouder,** Maastricht University
12.00 – FLASH UPDATE: Implementing the Russian CTD format for registration dossiers under amendments introduced by the Federal Law No.429-FZ **Anna Harrington Morozova,** Regem Consulting	**12.00 –** Evolving regulatory landscape in Latin America – comparison of regulatory requirements in Chile, Brazil and Caribbean markets **Rohit Kulkarni,** Regulex Consulting Ltd., UK	**12.00 –** Latest update on EMA Policy 0070 on publication and access to clinical trial data, and how this will impact Regulatory Operations functions **Alastair Nixon,** GlaxoSmithKline Research & Development Limited, UK	**12.00 –** Practically meeting the authority expectations regarding PRAC implementation timelines **Simon Ashworth,** Takeda Development Centre Europe Ltd.
12.15 – Quickfire Q&A Session			
12.35 - Networking Lunch	**12.35 -** Networking Lunch	**12.35 -** Networking Lunch	**12.35 -** Networking Lunch
<u>Mid Afternoon Session</u> **14.00** – Latest regulatory updates in Ukraine including the recently adopted Ministry of Health's Order No 452 which came into force September 2015 **Mariana Novozheniuk,** Bayer Pharma AG, Germany	**<u>Mid Afternoon Session</u>** **14.00** – Examining and implementing pharmacovigilance and risk management activities in Latin America **Diana Guarin,** AbbVie Inc., USA	**<u>Mid Afternoon Session</u>** **14.00** - Regulatory agency perspective: Feedback, plans and practical advice for ECTD submissions **Triin Maesalu,** State Agency of Medicines, Estonia	**<u>Mid Afternoon Session</u>** **14.00 –** Regulatory feedback: Assessing the regulatory landscape for pharmaceutical labelling

14.35 – EXTENDED Q&A SESSION: Sharing experiences with registration in Ukraine and questions on the latest regulatory updates **Mariana Novozheniuk,** Bayer Pharma AG, Germany	**14.35** – Working globally and adapting to requirements in emerging markets with a focus on Latin America **Andrea Herrmann,** Merck KGaA, Germany	**14.35 –** Document Management – A critical lynchpin in regulatory information management success **Lena Shafir,** EMC**,** USA	**14.35 –** Examining and implementing pharmacovigilance and risk management activities in Latin America **Diana Guarin,** AbbVie Inc., USA
15.10 – Networking and afternoon tea	**15.10 –** Afternoon Coffee & Networking	**15.10 –** Afternoon Coffee & Networking	**15.10 –** Afternoon Coffee & Networking
15.40 – Exploring the regulatory framework and best strategies for product registration in Kazakhstan **Anna Harrington Morozova,** Regem Consulting, UK	**15.40** – LATAM COLLABORATION ZONE **Stefano Accorsi,** CHIESI FARMACEUTICI S.p.A., Italy **Cathie Gongora,** Sanofi Pasteur, France **Andrea Herrmann,** Merck KGaA, Germany **Rohit Kulkarni,** Regulex Consulting Ltd., UK	**15.40** – IDMP and the impact on eSubmissions **Remco Munnik,** Asphalion S.L., Spain	**15.40** – The Need for Quality Management and Process Control in a Pharma Artwork Studio **Suzanne Ivory,** Perigord
16.15 – Latest updates and practical experiences with the Eurasian Union **Galina Senchukova,** Sanofi Pasteur Eurasia, Russia		**16.15** – Building a regulatory publishing team and defining processes for electronic submissions **Magda Andrițoiu,** Alvogen, Romania	**16.15**– Managing the end to end labelling process: optimising internal processes and oversight for efficient and compliant labelling **Lynsey Flitton,** AbbVie
16.50 – Sharing experiences with the upcoming Eurasian Union regulatory requirements **Nadezda Abramova,** Merck KGaA, Germany	**16.50 -** End of conference day 1 and networking drinks	**16.50** – Mergers & Acquisitions: Implications and challenges on global regulatory operations **Claudia Pyne,** Allergan Limited, UK	
17.25 – End of conference day 1 and networking drinks		**17.25 -** Case study: Successfully outsourcing regulatory publishing and overcoming key challenges – one year on **Richard Knowles,** Ipsen Biopharm Limited, UK **18.00 –** End of conference day 1 and networking drinks	**17.25 –** End of conference day 1 and networking drinks

Schedule

DAY 2- 19/10/2016

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Berlin

Emerging Markets Stream 1: Russia, CIS, Turkey, Middle East & Africa	Emerging Markets Stream 2: Latin America & Asia-Pacific	Global eSubmissions	Pharmaceutical Labelling
09.00 – Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks
9.10 – Clinical trials of medicines: Current regulatory environment and updated local regulations in Ukraine **Nataliia Bogdan,** Bogdan Independent Speaker (previously – Central Regulatory Authority), Ukraine	**9.10** – Product registration and latest regulatory updates in China: Challenges and opportunities **Joe Zhou,** Genor BioPharma, China	**9.10** – Ministry of Health perspective: Latest updates and progress for eCTD submissions in Oman **Ph. Nissreen Nassr,** Ministry of Health, Oman	**9.10** – Industry case study: Practically implementing labelling updates to achieve global level approval **Bas Van Heijst,** Astellas
9.45 – INTERACTIVE ROUNDTABLES: Sharing experiences with conducting local clinical trials in Russia and CIS **Alex Dranov,** Dr. Willmar Schwabe GmbH & Co. KG, Germany	**9.45 –** China extended session **Joe Zhou,** Genor BioPharma, China **Kamani Gopalakrishna**, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany **Ching Li,** Biotest Pharma GmbH, Germany	**9.45 –** Saudi FDA perspective: Latest updates and progress for ECTD submissions in Saudi Arabia **Abdullah Abdulaziz,** Saudi FDA, Saudia Arabia	**9.45 –** Assessing the importance of translation and readability when updating labelling globally **Paul Soul-Williams,** AbbVie
10.20 – Reviewing labelling requirements and overcoming challenges in Russia and the CIS markets **Giovanna Ferrari,** Pfizer, UK	**10.20 –** Case study: Best strategies for successful product registration in India **Kamani Gopalakrishna,** Boehringer Ingelheim Pharma GmbH & Co. KG, Germany	**10.20 –** Latest updates and progress for eSubmissions in Jordan **Wesal Haqaish,** Jordan FDA, Jordan	**10.50 –** Pharmaceutical Labelling presentation delivered by Schlafender Hase
10.55 – Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking
11.25 – RUSSIA AND CIS COLLABORATION ZONE	**11.25 –** Exploring the regulatory framework and considerations for		**11.25 –** Panel discussion: Overcoming the challenges of implementing global level

Alex Dranov, Dr. Willmar Schwabe, GmbH & Co. KG, Germany **Edelgard Rehak,** Dr. Edelgard Rehak Consulting, Germany **Mariana Novozheniuk,** Bayer Pharma AG, Germany **Anna Harrington Morozova,** Regem Consulting **Galina Senchukova,** Sanofi Pasteur Eurasia, Russia **Nadezda Abramova,** Merck KGaA, Germany	successful product registration in South Korea **Eric Ducamp,** Ipsen, France	**11.25 –** Examining latest updates and sharing experiences with submitting ECTD in Australia **Nathalie Mueller-Andriamboavonjy,** Incyte, Switzerland	updates – improving communication and cooperation
	12.00 – Clarifying Taiwan's regulatory framework and practical advice for product registration **Cecile Vareilles,** Ipsen, France	**12.00 –** China: Latest updates and sharing experiences with submitting ECTD **Carolline Petersen,** Novo Nordisk A/S, Denmark	**12.00 –** Reviewing labelling requirements and overcoming challenges in Russia and the CIS markets **Giovanna Ferrari,** Pfizer, UK
12.35 - Lunch	**12.35 -** Lunch	**12.35 -** Lunch	**12.35 –** Lunch
14.00 – Navigating regulatory requirements and exploring successful marketing strategies for biosimilars in Russia and CIS countries **Roman Ivanov,** BIOCAD, Russia	**14.00 –** Reviewing latest regulatory progress in the ASEAN countries and impact on industry **Ines Pinto,** Actelion Pharmaceuticals Ltd., Portugal	**14.00 –** Examining the latest progress towards ECTD submissions in Thailand **Jens Pantke,** F. Hoffmann-La Roche Ltd. Switzerland	**14.00** – Examining the current status of the Falsified Medicines Directive and the current challenges being faced by industry **Johan Verhaeghe,** Medicines for Europe
14.35 – Emerging Markets: regulators could be delaying access to vaccines **Malika Almansouri,** GSK Vaccines, Belgium	**14.35 –** Case Study: Successful product registration and latest regulatory requirements in Japan **Lamine Messaoudi**, International Regulatory Consult Group, USA	**14.35 –** Outlining latest updates on the news US Module 1 v2.3 and practical implications for industry **Olga Alfieri**, Eisai, USA	**14.35 –** GS1 Standards – a tool for fighting counterfeiting? **Glen Hodgson**, GS1, UK
15.10 – Networking and afternoon tea	**15.10 –** Networking and afternoon tea	**15.10 –** Networking and afternoon tea	**15.10 –** Networking and afternoon tea
15.40 – Implementing a revised ICH GCP in Emerging Markets: Developing EU & FDA Risk Management Plans Appropriate to Emerging Markets **Francis P. Crawley,** Good Clinical Practice Alliance – Europe (GCPA), Belgium		**15.40** – Presentation to be delivered by AMPLEXOR **Romuald Braun**, AMPLEXOR, Switzerland	**15.40** – Serialisation workshop: Examining strategies to overcome labelling challenges resulting from increasing serialisation and coding requirements

			Horst Kastrup, MEDA Pharma GmbH & Co. KG
16.15 – Health agency interactions in emerging markets across the globe; available possibilities, timings of advice and its impact on overall regulatory strategy **Ayaz Khan,** Grunethal GmbH, Germany		**16.15 –** GLOBAL ESUBMISSIONS COLLABORATION ZONE **Wesal Haqaish,** Jordan FDA, Jordan **Mohanned El Khider,** Ministry of Health, Oman **Abdualmajeed Saad Binjumayah,** Saudi FDA, Saudi Arabia **Nathalie Mueller-Andriaboavonjy,** Incyte, Switzerland **Jens Pantke,** F. Hoffmann-La Roche Ltd. Switzerland **Carolline Petersen,** Novo Nordisk A/S Denmark	
16.50 – Out of industry perspective: Developing a common corporate culture across established and emerging markets **Chie Misumi**, Intercultural Communication Specialist			[redacted]
17.25 – End of Conference day two	**17.25 –** End of Conference day two	**17.25 –** End of Conference day two	**17.25 –** End of Conference day two

Schedule

DAY 3- 20/10/2016

Global Pharma Regulatory Affairs
18 – 20 October 2016
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Berlin

Emerging Markets Stream 1: Russia, CIS, Turkey, Middle East & Africa	Emerging Markets Stream 2: Latin America & Asia-Pacific	Global eSubmissions	Pharmaceutical Labelling
09.00 – Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks	**09.00 –** Chairpersons Opening Remarks
9.10 – Practical advice for product registration and regulatory updates from the Gulf Cooperation Council (GCC) **Abid Hussain,** Saudi Pharmaceutical Industries - SPI, Saudi Arabia	**9.10** – Ensuring specific stability data requirements are met in Latin America **Meike Vanhooren,** Pfizer, Germany	**9.10** – Understanding the updated EMA timelines for IDMP Iteration 1 and impact of a phased implementation approach on industry **Andrew P Marr,** Marr Consultancy Ltd., UK	**9.10** – WORKSHOP: Best practices for creating a CCDS suitable for global implementation **Barbara Lachmann,** Lachmann Consulting
9.45 – Latest regulatory updates and practically registering in Jordan **Syndie Messager,** Laboratorios Cinfa	**9.45 –** Regulatory requirements and challenges for biosimilars registration in Latin America **Thomas Kirchlechner,** Sandoz GmbH, Austria	**9.45 -** Flash case studies – successfully preparing for IDMP implementation irrespective of the delay Representative speaker from **Roche** **10.00 - Quentin Grignet**, GSK, Belgium	
10.20 – Reviewing current Africa regulatory harmonisation initiatives and practical advice on product registration **Merce Caturla,** Janssen Pharmaceutica N.V., Belgium	**10.20 –** Reviewing labelling and packaging requirements and overcoming challenges in Asia-Pacific **Ching Li,** Biotest Pharma GmbH, Germany	**10.20 –** Flash presentation: Case study – successfully preparing for IDMP implementation irrespective of the delay **Costas Mistrellides**, Regulatory Affairs Executive, UK	

		10.35 – Flash presentation: Case study – understanding how the updated IDMP timelines can be leveraged to improve business operations **Jakob Juul Rasmussen**, Independent Consultant, Denmark	
10.55 – Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking	**10.55 –** Morning Coffee & Networking
11.25 – Outlining the regulatory framework in North Africa and practical advice for market entry **Abdul Mateen,** AstraZeneca, UK	**11.25 –** ASIA-PACIFIC COLLABORATION ZONE **Joe Zhou,** Genor BioPharma, China **Alan Chalmers,** Pharma International, Switzerland **Kamani Gopalakrishna,** Boehringer Ingelheim Pharma GmbH & Co. KG, Germany **Eric Ducamp**, Ipsen, France **Cecile Vareilles,** Ipsen, France **Ines Pinto,** Actelion Pharmaceuticals Ltd., Portugal	**11.25 –** Flash presentation: Case study – understanding how the updated IDMP timelines can be leveraged to improve business operations **Patrick Middag,** Bristol-Myers Squibb, Belgium **11.40 –** Flash Case Studies Q&A Session	**11.25 –** WORKSHOP: PART TWO: Best practices for creating a CCDS suitable for global implementation **Barbara Lachmann,** Lachmann Consulting
12.00 – Case study: Overcoming the challenge of GMP inspections in Turkey **Figen Kabadas Oge,** Senior Regulatory Affairs Consultant, Turkey		**12.00 –** Where is Regulatory Affairs headed? – how IDMP shapes your organization, processes and regulatory IT strategy **Niels Buch Leander**, NNIT, Denmark	**12.00 –** Company Core Data Sheet Industry case study **Aaron Barzey**, ADB Medical, UK
12.35 - Lunch	**12.35 -** Lunch	**12.35 -** Lunch	**12.35 –** Lunch
14.00 – Exploring regulatory requirements for registration of biosimilars in MENA **Helmet Brunar,** PassionBio – Creating Ventures, Austria	**14.00 –** Best practice for filing a variation and gaining approval in Asia-Pacific **Judith Rupprecht,** Mundipharma Research GmbH & Co KG, Germany	**14.00 –** FDA perspective: Update on the GSRS and its use at FDA **Larry Callahan,** FDA**,** USA	**14.00** – Effective labelling as a tool for patient safety **Souzi Makri,** EUPATI Fellow

14.35 – Case study: Practical advice for successful generics registration in MENA **Anna Roznovska,** PRO.MED.CS, Czech Republic	**14.35 –** Case Study: Best practice for filing a variation and gaining approval in Asia-Pacific **Ching Li**, Biotest Pharma GmbH, Germany	**14.35 –** SME perspective: Understanding the strategies and key challenges associated with getting an IDMP project started **Sue Metz**, PAREXEL, USA	**14.35 –** Examining the patient perspective: Improving pharmaceutical labels **Anne Lenihan**, Pfizer
15.10 – Networking and afternoon tea	**15.10 –** Networking and afternoon tea	**15.10 –** Networking and afternoon tea	**15.10 –** Networking and afternoon tea
15.40 – Turkey and Mena Collaboration Zone **Abid Hussain**, Saudi Pharmaceutical Industries – SPI, Saudi Arabia **Wesal Hawaish**, Jordan FDA, Jordan **Tine Vermeulen**, PLANPHARMA, Belgium **Abdul Mateen**, AstraZeneca, UK **Merce Caturla**, Janssen Pharmaceutica N.V., Belgium **Ozedemir Sengoren**, UCB Pharma A.S., Turkey **Erhan Bas**, Bilim Pharmaceuticals, Turkey	**15.40** – Evolving regulatory requirements for biosimilar registrations in Asia-Pacific **Rodeina Challand,** Challand Biosimilar Consulting, UK	**15.40** – Practically implementing a Master Data Governance approach to overcome IDMP challenges **Will Foster**, Eisai Limited., UK	**15.40** – Examining readability and usability of the PIL and SmPC **Em Stevens,** B.Braun Melsungen AG
	16.15 – End of Conference	**16.15** – Latest updates and progress on controlled vocabularies for successful IDMP implementation **Andrew P Marr**, Marr Consultancy Ltd., UK	**16.15 –** An update on the EC report on readability of the SmPC Dominique Westphal, Paul Ehrlich Institute, Germany
16.50 – End of Conference		**16.50 –** End of Conference	**Please feel free to move into conference stream 1 or 3**
			18.00 – End of Conference