6th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR

September 29-30, 2016
Orlando, USA

Hosting Organizations: Conference Series LLC
2360 Corporate Circle., Suite 400 Henderson, NV 89074-7722, USA
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30</td>
<td>Registrations</td>
<td></td>
</tr>
<tr>
<td>09:30</td>
<td>Opening Ceremony</td>
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<tr>
<td>09:55-10:00</td>
<td>Keynote Forum Introduction</td>
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<tr>
<td>10:00-10:40</td>
<td>Title: Regulatory requirements and filing considerations for Type II master files</td>
<td>Ramnarayan Randad, Food and Drug Administration, USA</td>
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<tr>
<td>10:40-11:20</td>
<td>Title: Localization of foreign medicinal products manufacturing in Russia</td>
<td>Jelena Gankina, NPF Materia Medica Holding, Russia</td>
</tr>
<tr>
<td>11:40-12:20</td>
<td>Title: Pharmaceutical regulatory environment with perspective on the International GMP's</td>
<td>Mohammed R Khan, Synergex Consulting, Canada</td>
</tr>
<tr>
<td>12:20-13:00</td>
<td>Title: Future medical applications in 3-D printing: Clinical benefits, regulatory issues &amp; manufacturing challenges™</td>
<td>Michael Drues, Vascular Sciences, USA</td>
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<tr>
<td>13:00-13:45</td>
<td>Lunch Break 11:20-11:40</td>
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<tr>
<td>13:45-14:10</td>
<td>Title: Risks of inadequate regulatory intelligence</td>
<td>Priya Bhutani, RegDesk, Inc., USA</td>
</tr>
<tr>
<td>14:10-14:35</td>
<td>Title: Evaluating a novel drug delivery system for oral amoxicillin</td>
<td>Nadeem Ahmad, Advanced Product Design Services, Canada</td>
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<tr>
<td>14:35-15:00</td>
<td>Title: Communication with FDA: What do we say and how do we say it?™</td>
<td>Michael Drues, Vascular Sciences, USA</td>
</tr>
<tr>
<td>15:00-15:25</td>
<td>Title: The regulatory affairs as a bridge between government regulatory authorities and pharmaceutical companies</td>
<td>Elene Chikobava, Quadrium Pharmhouse Ltd., Georgia</td>
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</tbody>
</table>
Conference Day Two  | Friday September 30, 2016

Salon 3 & 4

Session Chair: Jelena Gankina, NPF Materia Medica Holding, Russia
Session Chair: Mohammed R Khan, Synergex Consulting, Canada

<table>
<thead>
<tr>
<th>Time</th>
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</tr>
</thead>
<tbody>
<tr>
<td>10:00-10:25</td>
<td>Title: ABC-VEN matrix analysis of pharmaceutical inventory management in Tikur Anbessa specialized hospital for the years 2009 to 2013, Addis Ababa, Ethiopia</td>
<td>SefineW Migbaru, Addis Ababa University, Ethiopia</td>
</tr>
<tr>
<td>10:25-10:50</td>
<td>Title: SWOT analysis of the Addis Ababa city administration food, medicine and health care administration and control authority</td>
<td>Meshesha Solomon Getnet, Addis Ababa University, Ethiopia</td>
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<tr>
<td>10:50-11:10</td>
<td>Title: Food additives and health</td>
<td>Mercy Robert Ekwere, Cross River College of Education, Nigeria</td>
</tr>
</tbody>
</table>

Refreshments and Networking Break 11:10-11:30

B2B Meetings and Networking

Award Ceremony

Lunch Break
Organizing Committee Members

Kenneth Christie
VTS Consultants, Inc.,
USA

Elene Chikobava
Quadrium Pharmhouse
Georgia

Boyd L Summers
BL Summers Consulting LLC
USA

Mark Kindy
University of South Florida
USA

David Amor
Medgineering Inc.,
USA

Mohammed R Khan
Synergex Consulting
Canada
Mohammed R Khan
Synergex Consulting, Canada
Title: Pharmaceutical regulatory environment with perspective on the international GMP's

Mohammed Khan is a Quality Management Consultant and Principal Synergex Consulting in Ontario, Canada. He has earlier served as Director QA, QC & Regulatory Compliance with DuPont Pharmaceuticals, Canada, and on the Board of the Pharmaceutical Manufacturers Association of Canada, Plant Operations Section. He has also served on the DIA's Advisory Council of North America and chaired the DIA's Canadian Programming Steering Committee and is the recipient of the DIA Outstanding Service Award. He has served as Program Coordinator, Program Committee Member, Session Chair and Speaker at numerous national and international DIA events, as well as Presenter for the PDA, OMICS Group, IQPC, PSG Canada, UK based International Society of Ethnopharmacology, and the Indian Pharmaceutical Congresses.

Michael Drues
Vascular Sciences, USA
Title: Future medical applications in 3-D printing: clinical benefits, regulatory issues & manufacturing challenges

Michael Drues is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programing, brain-storming sessions, prototype design, product development, benchtop & animal testing, innovative regulatory strategy & competitive regulatory intelligence, clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment. Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development.
Charles Schmidt  
FCMSCSP, Brazil  
**Title:** Recently Developments for Regulatory Clinical Trial Approvals in Brazil  

**Biography**  
Pediatrician with Master and Doctorate degree. He has been practicing and teaching while working in the biopharma for the past 25 years. He had developed and managed successfully big and medium size CROs in Latin America and at their global level for more than 15 years. His experience also includes leadership roles in Medical Affairs, Pharmacovigilance, and Medical Monitoring in Pharmaceutical companies. Charles has an extensive background in clinical development efforts in many therapeutic areas in LatAm. He is an attending physician in coordinating the post-graduation program in clinical research at Santa Casa Medical School in Sao Paulo - Brazil since 2007. Also, he is the medical manager of the central institute of clinical research at Hospital de Clínicas - Sao Paulo. Charles was the founder and ex-president of the Brazilian Association of CROs and director of Brazilian Association of Pharmaceutical Physicians - SBMF.

Elene Chikobava  
Quadrium Pharmhouse Ltd., Georgia  
**Title:** The Regulatory Affairs as a bridge between Government Regulatory Authorities and Pharmaceutical Companies  

**Biography**  
Elene Chikobava is a Master Chemistry, with 10 years of working experience as a biochemist in the Scientific-Research Centre of Biophysics and Biotechnology, where she has completed her PhD in Biologic Science. She became a senior specialist of the Pharmacopoeia Committee of Drug Agency of the Ministry of health, Labor and Social affairs of Georgia after its creation in 2003. After being actively involved in renovation of the Pharmacopoeia Committee, where she worked as a senior specialist of Pharmacopoeia Department. Then she started to work as a Head of Regulatory Affairs specialist for the domestic manufacturer of generic and herbal products - “Biopolus” Ltd (Georgia), along with it she was consulting Georgian wholesalers “GPC” about pharmaceutical products registrations of pharmaceutical products in Georgia and different companies; clinical researches and manufacturing technology. Dr. Chikobava had been a participant of numerous scientific conferences, including those conducted by WHO, she has published more than 20 scientific papers.

Rashid Mahmood  
Surge Laboratories Private Limited, Pakistan  
**Title:** Cleaning validation in pharmaceuticals  

**Biography**  
Rashid Mahmood has 13 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, NDA, ANDA, BLA, GMP Requirements, Drugs Laws, Statistical Methodology, Method Validation, Process & Cleaning Validation, Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, ISO/IEC 17025:2005, 14001-2004, OHSAS 18001:2007, SA 8000 and 9001:2008 with strong scientific, analytical, statistical, planning, managerial and training skills, have written several articles and attended many international conferences as a speaker and presented various speeches in USA & China on Clean ing Validation, cGMP Guidelines, Quality Risk Management etc.