6th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs and IPR

September 29-30, 2016
Orlando, USA





Hosting Organizations: Conference Series LLC
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Conference Day One | Thursday September 29, 2016

Salon 3 & 4

08:30-09:30	Registrations
09:30-09:55	Opening Ceremony

Keynote Forum

09:55-10:00	**Introduction**
10:00-10:40	**Title:** Regulatory requirements and filing considerations for Type II master files **Ramnarayan Randad,** Food and Drug Administration, USA
10:40-11:20	**Title:** Localization of foreign medicinal products manufacturing in Russia **Jelena Gankina,** NPF Materia Medica Holding, Russia

Refreshments and Networking Break 11:20-11:40

11:40-12:20	**Title:** Pharmaceutical regulatory environment with perspective on the International GMP's **Mohammed R Khan,** Synergex Consulting, Canada
12:20-13:00	**Title:** Future medical applications in 3-D printing: Clinical benefits, regulatory issues & manufacturing challenges ™ **Michael Drues,** Vascular Sciences, USA

Lunch Break 13:00-13:45

Session Introduction

Session Chair: Mohammed R Khan, Synergex Consulting, Canada
Session Chair: Ramnarayan Randad, Food and Drug Administration, USA

13:45-14:10	**Title:** Risks of inadequate regulatory intelligence **Priya Bhutani,** RegDesk, Inc., USA
14:10-14:35	**Title:** Evaluating a novel drug delivery system for oral amoxicillin **Nadeem Ahmad,** Advanced Product Design Services, Canada
14:35-15:00	**Title:** Communication with FDA: What do we say and how do we say it? ™ **Michael Drues,** Vascular Sciences, USA
15:00-15:25	**Title:** The regulatory affairs as a bridge between government regulatory authorities and pharmaceutical companies **Elene Chikobava,** Quadrium Pharmhouse Ltd., Georgia

Refreshments and Networking Break 15:25-15:45	
15:45-16:10	**Title:** Recently developments for regulatory clinical trial approvals in Brazil **Charles Schmidt,** FCMSCSP, Brazil
16:10-16:35	**Title:** Cleaning validation in pharmaceuticals **Rashid Mahmood,** Surge Laboratories Private Limited, Pakistan
B2B Meetings	

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

	Session Introduction
10:00-10:25	**Title:** ABC-VEN matrix analysis of pharmaceutical inventory management in *Tikur Anbessa* specialized hospital for the years 2009 to 2013, Addis Ababa, Ethiopia **Sefinew Migbaru,** Addis Ababa University, Ethiopia
10:25-10:50	**Title:** SWOT analysis of the Addis Ababa city administration food, medicine and health care administration and control authority **Meshesha Solomon Getnet,** Addis Ababa University, Ethiopia
10:50-11:10	**Title:** Food additives and health **Mercy Robert Ekwere,** Cross River College of Education, Nigeria
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





Ramnarayan Randad

Food and Drug Administration, USA

Title: Regulatory requirements and filing considerations for type II master files

Biography

R. S. Randad, Ph.D. (Ram) is Quality Assurance Leader and Master Review Chemist in the office of Life Cycle API, ONDP. In addition to the CMC reviews, he has served on number of working group such as Risk-Based Review, Complex Drug Substance, Question based Review (QbR), Quality by Design based QbR revision, the Office of Generic drugs Education and Training committee, DMF Completeness assessment team, Center for Science and advancement, and US Pharmacopeia monograph development committees. He has frequently represented Agency on CMC issues and regulatory science in public speaking engagements. He is an author of "FDA Drug Review and Regulation" to the "Burger's Medicinal Chemistry, Drug Discovery and Development". Prior to joining FDA, Ram worked in the private sector for 15 years as a Research Chemist, Principal Investigator, Group Leader, and Director of Chemistry. Randad has authored more than 25 scientific papers in the peer reviewed journals and has > 10 US patents to his credit. His work has led to the design and development of a drug lead. He received Ph.D. from National Chemical laboatory, Poona University, India in 1985. Soon after, he came to US as a Postdoctoral Associate of Prof. Herbert C Brown, Nobel Laureate, Purdue University..



Mohammed R Khan

Synergex Consulting, Canada

Title: Pharmaceutical regulatory environment with perspective on the international GMP's

Biography

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

Biography

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 & completive 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 Medicare 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..



Jelena Gankina

NPF Materia Medica Holding, Russia

Title: Localization of Foreign Medicinal Products Manufacturing in Russia

Biography

Jelena Gankina has extensive experience in the pharmaceutical industry. Having graduated as a pharmacist in Moscow, she started her professional career as a scientist in R&D (Scientific Research Institute of Pharmacology, Moscow) and got her Ph.D. in molecular pharmacology. She has presented her scientific results during professional events and in scientific press in Russia and abroad. Since 1994, Jelena has been working in the regulatory field, where she has gathered experience in generic (LEK Pharmaceuticals, PLIVA Hrvatska d.o.o., Polpharma), innovative (Bristol-Myers Squibb) and Russian domestic companies (Akrikhin) in Russia, CIS and the EU in different areas: registration (APIs, medicinal products, medical devices, para-pharmaceuticals), quality, pharmacovigilance and clinical operations.



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 mediun 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 wholesaler “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.