OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on GMP, GCP & Quality Control

September 25-26, 2014 Valencia, Spain

Tentative Scientific Program

Day 1	
25-09-2014	
08:00-09:00	**Registrations**
09:00-09:30	**Opening Ceremony**
Keynote Forum	
09:30-09:35	**Introduction**
09:35-10:00	**Title:** Current directions for process validation according FDA and EMA
	Victor Sanchez, Pharma-Bio Serv, S.L., Spain
10:00-10:25	**Title:** Planning to outsource manufacturing: Have you done your homework?
	Mohammed R Khan, Synergex Consulting,Canada
10:25-10:50	**Title:** Essentials in Quality by Design
	Thomas A. Little, Thomas A. Little Consulting, USA
10:50-11:05	**Networking and Refreshment Break**
11:05-11:30	**Title:** *In-Vitro* release testing and IVIVC of complex parenteral products
	Diane J. Burgess, University of Connecticut, USA
Track 1: Good Manufacturing Practices: The Gap within Track 2: Current Regulations and Quality Standards Track 3: Current GMP Guidelines	
Session Introduction	
11:30-11:50	**Title:** Regulatory requirements and benefits converting to continued process verification
	Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden
11:50-12:10	**Title:** Quality excellence through benchmarking quality improvement models
	Kamran Atif, Arwan Pharmaceuticals Industries, Lebanon SAL
12:10-12:30	**Title:** Training and education the WHYs of cGMP to operators can make a huge difference in meeting CQV standards inside pharmaceutical manufacturing facilities
	Susan Stipa, McDay LLC, USA

12:30-12:50	**Title:** Effective methods for software and systems integration for software companies and institutions
	Boyd L. Summers, BL Summers Consulting LLC., USA
12:50-13:10	**Title:** From a training perspective: What does the FDA look for during an inspection?
	David Gallup, Training and Communications Group, Inc., USA
	Speaker Opportunity Available
13:10-14:00	**Lunch Break**
Track 4: The Role of "C" in cGMP Track 5: Good Clinical Practices & Good Laboratory Practices	
14:00-14:20	**Workshop:** "Natural health products site licensing in Canada: How to meet the GMPs regulations"
	Jalal Mokhalalati, QMRS, Canada
14:20-14:40	**Title:** GMP compliance for inspections, sampling and testing of packaging components in pharmaceuticals
	Sarma R Donepudi, SCITECHSOLUTIONS Inc., Canada
14:40-15:00	**Title:** Industrial process validation of metformin tablets to facilitate the scale up of commercial production: A GMP and validation perspective
	Gannu Praveen Kumar, Sahasra Institute of Pharmaceutical Sciences, India
15:00-15:20	**Title:** The regulatory inspection & audits
	Neeraj Srivastava, Consultant, India
15:20-15:40	**Title:** Greening the pharmaceutical industry to afford good laboratory practice
	Salwa Elmeligie, Cairo University, Egypt
	Speaker Opportunity Available
15:40-16:00	**Networking and Refreshment Break**
16:00-16:20	**Title:** Reflections about quality control and quality assurance in clinical trials
	Fernando Geijo, Azbil Telstar, Spain
16:20-16:40	**Title:** A guide to an effective clinical trial protocol in CGMP & CGCP as a tool for sustenance of ethical principles and regulatory requirements in the pharmaceutical and
	Peter Odeh, SNBL Clinical Pharmacology Center, USA
16:40-17:00	**Title:** Role of Good Laboratory Practice in Good Clinical Practice
	Salwa Elmeligie, Cairo University, Egypt
	Speaker Opportunity Available
Panel Discussion	

Day 2	
26-09-2014	
Track 6: Quality Assurance Track 7: Quality Control Track 8: Validation	
	Session Introduction
09:00-09:20	**Title:** Analytical method development and validation for therapeutic proteins
	Robert Zoubek, Granzer Regulatory Consulting & Services, Germany
09:20-09:40	**Title:** Analytical method lifecycle management
	Gerald de Fontenay, Amatsi Group, France
09:40-10:00	**Title:** Application of a risk analysis method to different technologies for producing a monoclonal antibody employed in Hepatitis B vaccine manufacturing
	Lorely Haidee, Center for Genetic Engineering and Biotechnology, Cuba
10:00-10:20	**Title:** Quality control and lean management: A holistic concept of building quality and cost reduction in a manufacturing enterprise
	Akintunde A. Sowunmi, Manufacturing engineer at Olympus KeyMed, UK
10:20-10:40	**Title:** A risk based scientific approach to analytical method development and validation activities for regulated laboratories
	Alicia Tebar, Project manager QA & QbD en Azbil Telstar, Spain
10:40-11:00	**Networking and Refreshment Break**
11:00-11:20	**Title:** Toxicological assessment of degradation products: Is it relevant as a complementary approach during stability testing of pharmaceuticals?
	Daniele Rubert Nogueira, Universidade Federal de Santa Maria, Spain
11:20-11:40	**Title:** Evaluation of bacterial contamination of clean room clothing
	Noëlle H. O'Driscoll, Robert Gordon University, Scotland
11:40-12:00	**Title:** Optimization solutions for validation procedures in the quality control of enantiomers chirality tests for antidepressants Citalopram and Venlafaxine
	Ivanka Pencheva, Medical University – Sofia, Bulgaria
12:00-12:20	**Title:** Quality by design for complex parenteral products
	Diane J. Burgess, University of Connecticut, USA
12:20-12:40	**Title:** Comparative evaluation of biomarker Psoralen in antioxidant active extracts of different species of genus Ficus by validated HPTLC method
	Perwez Alam, King Saud University, Saudi Arabia

12:40-13:00	**Title:** Pharmaceutical quality system
	Lothar Hartmann, Crucell, Switzerland
	Speaker Opportunity Available
13:00-13:40	**Lunch Break**
Track 09: Contract Manufacturing, Sterile/Aseptic Manufacturing Track 10: GMP in Microbiology, Biotechnology and Food Industry	
13:40-14:40	**Workshop:** Best practices for internal and supplier auditing
	David L. Chesney, PAREXEL International, USA
14:40-15:00	**Title:** DHF, DMR and DHR – the three Ds of medical devices
	Rama K Pidaparti, Wipro Technologies, USA
15:00-15:20	**Title:** Maintain the effectiveness of a QMS by using lean six sigma approach
	Peter Jehander, ÅF Technology AB, Sweden
15:20-15:40	**Title:** Good distribution practices
	Javier Franch, Warehouse & Distribution EMEA at Edwards Life sciences, Spain
15:40-16:00	**Title:** GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality
	María Pellín Amorós, Quinton International, Spain
16:00-16:20	**Title:** Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)
	Mootaz El Halawani, Pharmaceutical Quality Expert, Egypt
16:20-16:40	**Title:** Sterile/Aseptic manufacturing: Additional challenges in production of radiopharmaceuticals
	Valentina Ferrari, GE Healthcare, UK
16:40-17:00	**Title:** Ensure Quality Assurance for Software Companies and Institutions
	Boyd L. Summers, BL Summers Consulting LLC., USA
	Speaker Opportunity Available
Track 11:Medical Devices Track 12:Computational Strategies in GMP/GCP Track 13:Storage, Distribution, Transportation	
	Speaker Opportunity Available
	Speaker Opportunity Available
	Speaker Opportunity Available
Breakout 2	
Poster Presentations	
B2B	
Editorial Board Meeting	

Please note that this is a tentative program. Timings in this program may subject to change

Workshop on

Natural Health Products site licensing in Canada: How to meet the GMPs regulations

by

Dr. Jalal Mokhalalati

Principal, Quality Medical Regulations Services

Workshop on

Best Practices for Internal and Supplier Auditing

by

David L. Chesney

Vice President and Practice Lead
Strategic Compliance Services
PAREXEL Consulting