215th OMICS Group Conference

Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control

September 25-26, 2014 Valencia Convention Centre, Spain

Exhibitor

Telstar
We make it possible

Collaborations

AEFI

FEBiotec
Federación Española de Biotecnologías

Media Partners

EFMC European Federation for Medicinal Chemistry
eventogo
conferencehound
nanoTECHNOLOGY
iptechex pharmalicensing
Lanyrd.com the social conference directory
PharmaManufacturing.com
MEDtube sharing medical knowledge
MIDEAST CLINICS DIRECTORY
PharmaVOICE
PharmaVision
Medical News TODAY

"Organize your Events at OMICS Group Conferences"

Proposals are invited for organizing Symposia/Workshops at OMICS Group Conferences or OMICS Group will sponsor small events at your universities in related areas under the title of your own. These proposals can be sent to respective conference mail ids or to *symposia@omicsonline.org*

OMICS Group Conferences
5716 Corsa Ave., Suite 110, Westlake Los Angeles, CA 91362-7354, USA
Phone: +1-650-268-9744, Fax: +1-650-618-1414, Toll free: +1-800-216-6499
Email: *gmpsummit2014@omicsgroup.us*

Day 1 September 25, 2014

08:00-09:00 Registrations

Committee Room 5

09:00-09:25 **Opening Ceremony**

Keynote Forum

09:25-09:30 **Introduction**

09:30-09:55 **Victor Sanchez**
Pharma-Bio Serv S.L., Spain

09:55-10:20 **Sundar Chellamani**
SysComm Project Management Limited, Ireland

10:20-10:45 **Maria Pellin Amoros**
Laboratoires Quinton International S.L., Spain

Coffee Break 10:45-11:00 @ Auditorium 3 Foyer

11:00-11:25 **Rama K Pidaparti**
Wipro Technologies, USA

Track 1: Good Manufacturing Practices: The Gap within
Track 2: Current Regulations and Quality Standards
Track 3: Current GMP Guidelines
Track 5: Good Clinical Practices & Good Laboratory Practices

Session Introduction

Session Chair: Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden
Session Co-Chair: Rama K Pidaparti, Wipro Technologies, USA

11:25-12:25 Workshop on **Natural Health Products site licensing in Canada: How to meet the GMPs regulations**
Jalal Mokhalalati, Quality Medical Regulations Services, Canada

12:25-12:45 **Title: Regulatory requirements and benefits converting to continued process verification**
Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden

12:45-13:05 **Title: Greening the pharmaceutical industry to afford Good Laboratory Practice**
Salwa Elmeligie, Cairo University, Egypt

Lunch Break 13:05-14:00 @ Multi Purpose Hall 2

14:00-14:20 **Title: Effective methods for software and systems integration for software companies and institutions**
Boyd L Summers, BL Summers Consulting, LLC., USA

14:20-14:40 **Title: Reflections about quality control and quality assurance in clinical trials**
Fernando Geijo, Telstar, Spain

14:40-15:00 **Title: Role of Good Laboratory Practice in Good Clinical Practice**
Salwa Elmeligie, Cairo University, Egypt

15:00-15:20 **Title: Quality excellence through benchmarking quality improvement models**
Kamran Atif, Arwan Pharmaceuticals Industries, Lebanon

Track 6: Quality Assurance
Track 7: Quality Control

Session Chairs: Dharmi Trivedi, University of Phoenix, USA
Magnus Jahnsson, Pharmadule Morimatsu AB, Sweden

15:20-15:40 **Title: Ensure quality assurance for software companies and institutions**
Boyd L Summers, BL Summers Consulting, LLC., USA

15:40-16:00	**Title: Effective CAPA program, A valuable tool in quality improvement** **Dharmi Trivedi,** University of Phoenix, USA
	Coffee Break 16:00-16:15 @ Auditorium 3 Foyer
16:15-16:35	**Title: Evaluation of bacterial contamination of clean room clothing** **Noelle H O Driscoll,** Robert Gordon University, Scotland
16:35-16:55	**Title: Optimization solutions for validation procedures in the quality control of enantiomers; Chirality tests for antidepressants Citalopram and Venlafaxine** **Ivanka Pencheva,** Sofia Medical University, Bulgaria
16:55-17:15	**Title: How to improve quality and consistency of legacy products applying QbD/Six Sigma methodology** **Alicia Tebar,** Telstar, Spain
17:15-17:35	**Title: Maintain the effectiveness of a QMS by using Lean Six Sigma approach** **Peter Jehander,** AF Technology AB, Sweden
17:35-17:55	**Title: Analytical method lifecycle management** **Gerald de Fontenay,** Amatsi Group, France
	Panel Discussion
	B2B Meetings

Day 2 September 26, 2014

Committee Room 5

Keynote Forum

10:00-10:25	**David L Chesney** Parexel International, USA
10:25-10:50	**Wael Ebied** SEDICO Pharmaceuticals-Merck & Co., Egypt
10:50-11:15	**Aziz Chraibi** Pharma Bio Expert Inc., Canada
	Coffee Break 11:15-11:30 @ Auditorium 3 Foyer

11:30-12:30	Workshop on **Best practices for internal and supplier auditing** **David L Chesney,** Parexel International, USA

Track 8: Validation
Track 9: Contract Manufacturing, Sterile/Aseptic Manufacturing
Track 11: Medical Devices

Session Chair: Aziz Chraibi, Pharma Bio Expert Inc., Canada
Session Co-Chair: Jixing Wang, Dalton Pharma Services, Canada

12:30-12:50	**Title: Managing equipment validation using ASTM approach for optimum cost and aggressive schedule** **Sundar Chellamani,** SysComm Project Management Limited, Ireland
12:50-13:10	**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
	Lunch Break 13:10-14:00 @ Multi Purpose Hall 2
14:00-15:00	Workshop on **ICH Q9 risk management applied to the compliance challenges between cGMP & safety design issues in manufacturing pharmaceutical & biotechnology facilities** **3 Case Studies: High Potent (HP1@5) Plants, Bio-safety containment (BSL1@4) facilities and explosive environment (ATEX 1@3)** **Aziz Chraibi,** Pharma Bio Expert Inc., Canada

15:00-15:20	**Title: GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality** **Maria Pellin Amoros,** Laboratoires Quinton International S.L., Spain
15:20-15:40	**Title: DHF, DMR and DHR - The three Ds of Medical devices** **Rama K Pidaparti,** Wipro Technologies, USA
15:40-16:00	**Title: Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)** **Mootaz El Halawani,** Pharmaceutical Quality Expert, Egypt
	Coffee Break 16:00-16:15 @ Auditorium 3 Foyer
16:15-16:35	**Title: Challenges of cGMP implementation at different CMO's - role of quality agreements** **Rivka Zaibel,** Advanced Regulatory Services Ltd. (ADRES), Israel
16:35-16:55	**Title: CMO's challenges and strategies in sterile manufacturing** **Jixing Wang,** Dalton Pharma Services, Canada
16:55-17:15	**Title: Production of biosimilars in developing countries: Challenges and opportunities: SEDICO case Study** **Wael Ebied,** SEDICO Pharmaceuticals - Merck & Co., Egypt
17:15-17:35	**Title: The relevance of training in supply chain management of pharmaceutical products** **Ibelema Emeh,** Setax Training & Consultancy Limited, United Kingdom
	Closing Ceremony
	B2B

OMICS Group Inc.
2360 Corporate Circle, Suite 400
Henderson, NV 89074-7722, USA
Ph: +1-888-843-8169
Fax: +1-650-618-1417
contact@omicsgroup.com

OMICS Publishing Group
5716 Corsa Ave., Suite 110, Westlake
Los Angeles, CA 91362-7354, USA
Ph: +1-650-268-9744
Fax: +1-650-618-1414
contact.americas@omicsonline.org

OMICS Group
SEZ Unit, Building No. 20, 9th Floor
APIIC Layout, HITEC City
Hyderabad-500081, Telangana, INDIA
Ph: 040-40131823, 040-47482222
contact.asiapacific@omicsonline.org

Toll free
USA & Canada: +1-800-216-6499
Australia: +1-800-651-097
Europe: 0805-080048