154th OMICS Group Conference

Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on

GMP, GCP & Quality Control

November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, IL, USA



Exhibitor

ADVANCED ·TESTING· LABORATORY
"The Science of Testing- The Art of Serving"

Media Partners

Scholars Central | SciTechnol | OMICS eBooks Group

"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: *gmp2013@omicsonline.us*

Day 1 November 12, 2013

09:00-10:00 Registrations

Berlin

OMICS Group Conferences
Accelerating Scientific Discovery

10:00-10:25 Opening Ceremony

Keynote Forum

10:25-10:30 Introduction

10:30-10:55 Gerard Pearce
SQA Services, Inc., USA

10:55-11:20 Ashraf Youssef
AYPharma Safety Consulting, USA

Coffee Break 11:20-11:35 @ Foyer

11:35-12:00 Patricia Henley
London School of Hygiene & Tropical Medicine, UK

12:00-12:25 James Huang
Forest Laboratories, Inc., USA

Track 1: Current Regulations and Quality Standards
Track 2: Current GMP Guidelines for Pharmaceuticals
Track 7: Quality Control, Quality Assurance and Validation

Session Chair: James Huang, Forest Laboratories, Inc., USA

Session Co-Chair: M. S. Lourdes Sanchez, Sintenovo SA de CV, Mexico

Session Introduction

12:25-12:45 Maintaining your laboratory in a state of Control - The data integrity challenge
Jacqueline McCulloch, Clarkston Consulting, USA

12:45-13:05 Case study: Quality assurance and quality control partnering to drive compliance, science, and innovation
Jason Ruckert, Advanced Testing Laboratory, USA

13:05-13:25 Quality assurance on a budget from a non-commercial perspective
Lucy H H Parker, St George's Healthcare NHS Trust, UK

Lunch Break 13:25-14:10 @ Athens

14:10-14:30 Automation in validated environments
Abitha Sundararajan, Med Manage Systems, USA

14:30-14:50 Quality accreditation for medical research at Universities?
Brigitte von Rechenberg, University of Zurich, Switzerland

14:50-15:10 Risk assessment
M.S. Lourdes Sanchez, Sintenovo SA de CV, Mexico

15:10-15:30 Modern quality systems & Risk management approaches
Naveen Kumar Venkatesham, Laurus Labs Private Limited, India

15:30-15:50 Diverting from traditional validation approaches - Beefing up and speeding up validation, while minimizing vulnerabilities to new regulatory inspection foci
Constance E. Curts, FDA and EU Regulatory Validation Consultant, USA

Coffee Break 15:50-16:05 @ Foyer

16:05-16:25	**Data integrity issues** **Mohammad Iqbal Hossain,** Novartis Ltd., Bangladesh
16:25-16:45	**Challenges in benefit-risk evaluations during co-development among partnerships and alliances** **Ashraf Youssef,** AYPharma Safety Consulting, LLC, USA
16:45-17:05	**Is your company in a state of control?** **Brian Hill,** Brian Hill & Associates, USA
17:05-17:25	**Prior knowledge assessments: A knowledge compilation process that can be used to bring about more focused process characterization and development studies for platform products** **Jim Seely,** Bioprocessing Consultant, USA
17:25-17:45	**Mitigating the environmental impact of cleaning processes in GMP regulated facilities** **Elizabeth Rivera,** STERIS Corporation, USA
18:30-19:30	Cocktails Sponsored by **Journal of Developing Drugs @ Athens**

Day 2 November 13, 2013

Berlin

Track 3: The role of "C" in cGMP
Track 8: Legal Requirements for Medical Devices
Track 10: Computational Strategies in GMP/GCP

Session Chair: Pejman Parhami, Hyland's, Inc., USA

Session Co-Chair: Brian Hill, Brian Hill & Associates, USA

Session Introduction

09:30-09:50	**The role of "C" in cGMP** **Naveen Kumar Venkatesham,** Laurus Labs Private Limited, India
09:50-10:10	**The evolution of the medical device 510 (k) process and impending changes** **Jacqueline McCulloch,** Clarkston Consulting, USA
10:10-10:30	**Supplier management-Key components of managing suppliers in a cGMP environment** **Pejman Parhami,** Hyland's, Inc., USA
10:30-10:50	**Bridging the cultural divide: Supplier auditing in a global economy** **Jennifer Leny,** American Society for Quality, USA

Coffee Break 10:50-11:05 @ Foyer

11:05-11:25	**A risk based scientific approach to analytical method development and validation activities for regulated laboratories** **Shib Mookherjea,** ValQual International, USA
11:25-11:45	**Moving beyond part 11; Quality assurance considerations for translating cGMP compliance into electronic batch record initiatives** **Heather Schwalje,** Emerson Life Sciences Industry Solutions Group, USA
11:45-12:05	**Leaderships role in change management** **Myriam Ochart,** Lean Compliance Partners, USA

Lunch Break 12:05-12:50 @ Athens

Workshops

12:50-15:20	**Zippy Lean Workshop (Production Line Simulation) by** **Myriam Ochart,** Lean Compliance Partners, USA & **Jennifer Leny,** American Society for Quality, USA

Coffee Break 15:20-15:35 @ Foyer

15:35-18:05	**Highlights of Process Analytical Technology (PAT) & FDA Directives Workshop** **Shib Mookherjea,** ValQual International, USA

Athens

16:20-17:20	**Poster Presentations**
18:30-19:30	Cocktails Sponsored by **Advances in Pharmacoepidemiology & Drug Safety @ Athens**

Day 3 November 14, 2013

Berlin

Track 4: Good Clinical Practice
Track 5: Good Laboratory Practices and Clinical Trials
Track 6: Quality Inspections and Auditing
Track 9: Contract Manufacturing
Track 12: Microbiology, Food and Nutraceuticals

Session Chair: Anthony Grilli, Focus Scientific Solutions, USA

Session Introduction

10:00-10:20	**Performing microbial risk analysis on a standard compounding pharmacy aseptic fill process** **Anthony Grilli,** Focus Scientific Solutions, USA
10:20-10:40	**The effect of L-arginine on mice placenta** **Mohanad AbdulSattar Ali Al-Bayati,** University of Baghdad, Iraq
10:40-11:00	**Cleaning challenges in the dietary supplement industry** **Elizabeth Rivera,** STERIS Corporation, USA

Coffee Break 11:00-11:15 @ Foyer

11:15-11:35	**Myrica rubra fruit drink sub-chronic toxicity and hepatoprotective effect in rats** **Mohamed AlAjmi,** King Saud University, Saudi Arabia
11:35-11:55	**The informed consent form process: A basic contemporary standpoint for medical research professionals** **Peter Odeh,** SNBL Clinical Pharmacology Center, USA
11:55-12:15	**DHF, DMR and DHR-The three Ds of medical devices** **Rama K. Pidaparti,** Wipro Technologies, USA
12:15-12:35	**Immunosuppressive effects of mesenchymal stem cells versus corticosteroid in experimental model of arthritis** **Marwa Elhussiny Younnis,** Cairo University, Egypt
12:35-12:55	**Comparative pharmacokinetics and compliance issues to optimize art- The Indian scenario** **Princy Louis Palatty,** Father Muller Medical College, India
12:55-13:15	**A new cGMP bioassay involving electrophysiological recordings of CFTR currents** **Antonio Lacerda,** ChanTest Corporation, USA

Lunch Break 13:15-14:00 @ Athens

Bookmark your dates

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia, Spain

