Scientific Program

OMICS Group Conferences
Accelerating Scientific Discovery

International Summit on

GMP, GCP, QA, QC and Validation

December 3-5, 2012 DoubleTree by Hilton Philadelphia, USA

"Organize your Events at OMICS Group Conferences"

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

OMICS Group Conferences
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Email: gmp-gcp2012@omicsonline.com

18:00-19:00 **Registrations** December 2, 2012

Day 1 December 3, 2012

08:30-09:30 **Registrations**

Breakout 1

OMICS Group Conferences
Accelerating Scientific Discovery

09:30-10:00 **Opening Ceremony**

Keynote Forum

10:00-10:05 Introduction

10:05-10:30 **D J Christopher**
Devine Guidance International Inc., USA

10:30-10:55 **Brett Vengroff**
ComplianceLogix, USA

Coffee Break 10:55-11:10

11:10-11:35 **James R Bruno**
CAP Solutions, USA

11:35-12:00 **Igho Onakpoya**
University of Oxford, UK

Track 1: Current GMP Guidelines for Pharmaceuticals
Track 2: Current Regulations and Quality Standards
Track 3: GLP, GCP, and cGMP

Chair: Antonella, PharmaScience, Canada

Session Introduction

12:00-12:20 **Title: Strategy for effective quality management of clinical trial good manufacturing practice**
Margery Ross, Development QA - Biologics Early Phase GMP, USA

12:20-12:40 **Title: Managing global GMP training records - best practices and standards among life science companies**
Ellen Leinfuss, UL EduNeering, USA

12:40-13:00 **Title: Reforming GDX for today and tomorrow**
Demet Sag, Duke University, USA

Lunch Break 13:00-14:00

14:00-14:20 **Title: The role of safety evaluation as part of the process of drug in-licensing**
Ashraf Youssef, AYPharma Safety Consulting, USA

14:20-14:40 **Title: Critical success factors to sustaining quality management systems within a continuous improvement framework**
Antonella A. Maggio, PharmaScience, Canada

14:40-15:00 **Title: Sourcing APIs, generic formulations & OTC drugs from Indian pharmaceutical manufacturers: A GMP fiasco waiting to happen?**
Ram Balani, FDASmart Inc., USA

15:00-15:20 **Title: The FDA's quality system regulation**
Christopher Joseph Devine, Devine Guidance International, USA

15:20-15:40 **Title: Recent trends in FDA warning letters**
Linda Biava, Regulatory Compliance Associates, USA

Coffee Break 15:40-15:55

15:55-16:15 **Strategic view on ocular drug delivery: Opportunities and challenges**
Tina Guanting Qiu, Sucsmpo Pharma Americas Inc., USA

16:15-16:35 **Title: The challenges of designing and implementing cGMP manufacturing in the academic research institute/ hospital setting**
Terry D. Schuenemeyer, The Methodist Hospital Research Institute, USA

16:35-16:55 **Title: The GCP responsibilities of the investigator in clinical research studies to insure subject safety**
Charles H Pierce, Medpace, USA

16:55-17:15	**Title: Batch recall activities in marketing affiliate** **Walid Sellem,** Eli Lilly Company, France
17:15-17:35	**Title: Speed, cost and quality in clinical research** **Cheryl D Spencer,** CQMS, USA
17:35-17:55	**Title: Current issues and challenges in the implementation of GMP and GCP regulations** **Masuma Anwar,** Healthcare Pharmaceuticals Limited, Bangladesh
17:55-18:15	**Title: Clinical Research Coordinators: A key role in hematology research. Explorative study to analyze the presence of Clinical Research Coordinators in Italian hematology centers and their relevance in coordinating clinical trials and supporting the research team; on behalf of the Italian Group of Data Managers** **Laura McMahon,** Ospedale Ca Foncello, Italy
18:15-19:15	**Cocktails Sponsored by Outlook on Developing Drugs: Open Access**

Day 2 December 4, 2012

Breakout 1

Track 4: Clinical Trial Regulations
Track 5: Computational Strategies in GMP/GCP
Track 6: Legal Requirements for Medical Devices
Track 10: Technology Transfer for Biopharmaceuticals

Chair: Igho Onakpoya, University of Oxford, UK
Co-Chair: Chitra Edwin, University of Cincinnati, USA

	Session Introduction
10:00-10:20	**Title: Adverse effects of commonly used weight loss supplements: A critical review** **Igho Onakpoya,** University of Oxford, UK
10:20-10:40	**Title: Determinants of metabolic syndrome among Thai people** **Aporn Deenan,** Burapha University, Thailand
10:40-11:00	**Title: Effects of acute and chronic maternal separation and alcohol intake on adolescent rats** **Gabriela Beatriz Acosta,** University of Buenos Aires (UBA), Argentina
	Coffee Break 11:00-11:15
11:15-11:35	**Title: The significance of immunogenicity to biologic therapeutics: Understanding applicable regulatory guidelines, and defining risk management strategies** **Chitra Edwin,** University of Cincinnati, USA
11:35-11:55	**Title: Embedding quality into your clinical trials** **Patricia Santos-Serrao,** MasterControl Inc., USA
11:55-12:15	**Title: FDA guidance & risk-based monitoring** **Moe Alsumidaie,** Annex Clinical, USA
12:15-12:35	**Title: Getting ready for the new active post market surveillance focused on safety for medical devices** **Rama K Pidaparti,** Wipro Technologies, USA
12:35-12:55	**Title: Mobile health applications and biomedical software requirements globally** **Kosta Makrodimitris,** Advisor & Author, USA
	Lunch Break 12:55-13:55
13:55-14:15	**Title: A quality systems approach for validation and maintenance of a global ERP system** **James Carron,** Flatirons Pharmaceuticals, USA
14:15-14:35	**Title: Surviving the audit: An IRB/HRPP perspective** **W. Parker Nolen,** Indiana University Office of Research Administration, USA
14:35-14:55	**Title: Building a live and science based GMP system at WuXi AppTec in China** **Jerry Xu,** WuXi AppTec, China
14:55-15:15	**Title: Usability testing as part of design control risk management - The Taiwan experience** **Christopher Chan,** Industrial Technology Research Institute, Taiwan
15:15-15:35	**Title: Essential oils of *Myrtus communis L.* produce a non-sedating anxiolytic effect in mice model of anxiety** **Eyob Hailu,** Addis Ababa University, Ethiopia
	Coffee Break 15:35-15:50
15:50-16:10	**Title: Comprehensive and cost effective just right validation** **Rama K Pidaparti,** Wipro Technologies, USA
16:10-16:30	**Title: Driving technology innovation for lifecycle products and technology transfers, and avoid interruption in the supply chain** **Joeh Biehl & Robert,** Propharma, USA
16:30-16:50	**Title: Quantitative indicators of quality in clinical research** **Fernando Geijo,** Development Team Consulting, Spain
16:50-17:10	**Title: Medical device quality management requirement in Taiwan and its global harmonization strategy** **Christopher Chan,** Industrial Technology Research Institute, Taiwan
17:10-17:25	**Panel Discussions**

Breakout 2

10:00-12:00	B2B Meeting
17:00-18:30	Poster Presentations
18:00-19:00	Cocktails Sponsored by Journal of Clincial Research & Bioethics

Day 3 December 5, 2012

Breakout 1

Track 7: Quality Management and Quality Improvement in Research
Track 8: Analytical Method Development and Validation for Therapeutic Proteins
Track 9: GMP meets GCP

Chair: Kaitlin B, Iowa State University, USA

Session Introduction

10:00-10:20	**Title: Enabling and supporting antibiotic stewardship quality assurance programs with rapid microbiology diagnostics** **Philip Onigman,** Independent Bio Technology Consultant, USA
10:20-10:40	**Title: Keys to creating accountability in a quality management system** **Cynthia Juncosa,** Lean compliance Partners, USA
10:40-11:00	**Title: Management's role & responsibility** **Myriam Ochart,** O-CHART Management Consultants, USA

Coffee Break 11:00-11:15

11:15-11:35	**Title: The 7th system: Integrating clinical systems into a comprehensive quality audit program** **Brett Vengroff,** ComplianceLogix, USA
11:35-11:55	**Title: A lifecycle approach to process validation** **Ravi Samavedam,** BioSPEQ Inc, USA
11:55-12:15	**Title: Quality risk management in a lean six sigma culture** **Debbie W. Hinton,** Hinton Consulting Services, USA
12:15-12:35	**Title: Systematic approach to cleaning requirements** **Nayaz Ahmed,** PrimaPharm Inc., USA
12:35-12:55	**Title: *In vivo* fluorescence imaging of cathepsin and macrophage activity for determining biocompatibility of implanted biomaterials** **Kaitlin Bratlie,** Iowa State University, USA

Lunch Break 12:55-13:55

13:55-14:15	**Title: Establishing quality indicators to assure GMP/GCP compliance** **J. Lawrence Stevens,** One Way Consultants, USA
14:15-14:35	**Title: Cognitive dysfunction in bipolar disorder: A guide for clinicians and non clinicians** **Pierrette J. Oge-Cazeau,** Palm Beach State College, USA
14:35-14:55	**Title: Placing the "Good" Back into GCP for Informed Consent** **Julie Blasingim,** Schulman Associates IRB, USA
14:55-15:15	**Title: Antigen identification in *Neisseria meningitidis B* based serum and monoclonal antibodies: Shooting moving targets** **Elizabeth N De Gaspar,** Adolfo Lutz Institute, Brazil
15:15-15:35	**Title: Implementation of GMP in Albania** **Melisa Troshani,** University of Tirana, Albania
15:35-15:55	**Title: Implementation of new technologies in a regulated environment** **James R Bruno,** CAP Solutions, USA

15:55-16:10 Panel Discussions

Coffee Break 16:10-16:25