# 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


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

## Day 1 December 3, 2012

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

**Breakout 1**

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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

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| 16:55-17:15 | **Title: Batch recall activities in marketing affiliate**<br>**Walid Sellem,** Eli Lilly Company, France |
| 17:15-17:35 | **Title: Speed, cost and quality in clinical research**<br>**Cheryl D Spencer,** CQMS, USA |
| 17:35-17:55 | **Title: Current issues and challenges in the implementation of GMP and GCP regulations**<br>**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**<br>**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

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| | **Session Introduction** |
| 10:00-10:20 | **Title: Adverse effects of commonly used weight loss supplements: A critical review**<br>**Igho Onakpoya,** University of Oxford, UK |
| 10:20-10:40 | **Title: Determinants of metabolic syndrome among Thai people**<br>**Aporn Deenan,** Burapha University, Thailand |
| 10:40-11:00 | **Title: Effects of acute and chronic maternal separation and alcohol intake on adolescent rats**<br>**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**<br>**Chitra Edwin,** University of Cincinnati, USA |
| 11:35-11:55 | **Title: Embedding quality into your clinical trials**<br>**Patricia Santos-Serrao,** MasterControl Inc., USA |
| 11:55-12:15 | **Title: FDA guidance & risk-based monitoring**<br>**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**<br>**Rama K Pidaparti,** Wipro Technologies, USA |
| 12:35-12:55 | **Title: Mobile health applications and biomedical software requirements globally**<br>**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**<br>**James Carron,** Flatirons Pharmaceuticals, USA |
| 14:15-14:35 | **Title: Surviving the audit: An IRB/HRPP perspective**<br>**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**<br>**Jerry Xu,** WuXi AppTec, China |
| 14:55-15:15 | **Title: Usability testing as part of design control risk management - The Taiwan experience**<br>**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**<br>**Eyob Hailu,** Addis Ababa University, Ethiopia |
| | **Coffee Break 15:35-15:50** |
| 15:50-16:10 | **Title: Comprehensive and cost effective just right validation**<br>**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**<br>**Joeh Biehl & Robert,** Propharma, USA |
| 16:30-16:50 | **Title: Quantitative indicators of quality in clinical research**<br>**Fernando Geijo,** Development Team Consulting, Spain |
| 16:50-17:10 | **Title: Medical device quality management requirement in Taiwan and its global harmonization strategy**<br>**Christopher Chan,** Industrial Technology Research Institute, Taiwan |
| **17:10-17:25** | **Panel Discussions** |

**Breakout 2**

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| 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**

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

**Coffee Break 11:00-11:15**

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| 11:15-11:35 | **Title: The 7th system: Integrating clinical systems into a comprehensive quality audit program**<br>**Brett Vengroff,** ComplianceLogix, USA |
| 11:35-11:55 | **Title: A lifecycle approach to process validation**<br>**Ravi Samavedam,** BioSPEQ Inc, USA |
| 11:55-12:15 | **Title: Quality risk management in a lean six sigma culture**<br>**Debbie W. Hinton,** Hinton Consulting Services, USA |
| 12:15-12:35 | **Title: Systematic approach to cleaning requirements**<br>**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**<br>**Kaitlin Bratlie,** Iowa State University, USA |

**Lunch Break 12:55-13:55**

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| 13:55-14:15 | **Title: Establishing quality indicators to assure GMP/GCP compliance**<br>**J. Lawrence Stevens,** One Way Consultants, USA |
| 14:15-14:35 | **Title: Cognitive dysfunction in bipolar disorder: A guide for clinicians and non clinicians**<br>**Pierrette J. Oge-Cazeau,** Palm Beach State College, USA |
| 14:35-14:55 | **Title: Placing the "Good" Back into GCP for Informed Consent**<br>**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**<br>**Elizabeth N De Gaspar,** Adolfo Lutz Institute, Brazil |
| 15:15-15:35 | **Title: Implementation of GMP in Albania**<br>**Melisa Troshani,** University of Tirana, Albania |
| 15:35-15:55 | **Title: Implementation of new technologies in a regulated environment**<br>**James R Bruno,** CAP Solutions, USA |

**15:55-16:10 Panel Discussions**

**Coffee Break 16:10-16:25**