**Tentative Program**

8th International Conference and Exhibition on

**GMP, GCP & Quality Control**

June 08-09 2018, Philadelphia, Pennsylvania, USA

Theme: “Meeting standards of drug regulations & achieving GxP compliance”

**For Available Speaker Slots**
gmpsummit@pharmaceuticalconferences.org

19+ Interactive Sessions  15+ Keynote Lectures  75+ Plenary Lectures  5+ Workshops

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Email: gmpsummit@pharmaceuticalconferences.org

http://gmp-gcp-quality-control.pharmaceuticalconferences.com
# Tentative Program

## 8th International Conference and Exhibition on GMP, GCP & Quality Control

**June 08-09 2018, Philadelphia, Pennsylvania, USA**

### SCIENTIFIC PROGRAM

#### DAY 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Talk</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:45-09:15</td>
<td>Keynote Session</td>
</tr>
<tr>
<td>09:15-09:45</td>
<td>Keynote Talk 1</td>
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<tr>
<td>09:45-10:15</td>
<td>Keynote Talk 2</td>
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<tr>
<td>10:15-10:45</td>
<td>Keynote Talk 3</td>
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<tr>
<td>10:45-11:00</td>
<td>Coffee/Tea Break</td>
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#### Pre-Lunch Session

<table>
<thead>
<tr>
<th>Time</th>
<th>Sessions/Tracks</th>
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</thead>
<tbody>
<tr>
<td>11:00-12:40</td>
<td>Good Manufacturing Practices, Current Regulations and Quality Standards, Current GMP Guidelines</td>
</tr>
</tbody>
</table>

#### Networking Lunch 12.40-13.30

#### Post Lunch Sessions

<table>
<thead>
<tr>
<th>Time</th>
<th>Sessions/Tracks</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.30-13.50</td>
<td>Good Laboratory Practices, Quality Control, Quality Assurance</td>
</tr>
<tr>
<td>13.50-14.00</td>
<td>Panel Discussions, Extended Networking</td>
</tr>
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#### Evening Sessions

<table>
<thead>
<tr>
<th>Time</th>
<th>Sessions/Tracks</th>
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<tbody>
<tr>
<td>15.45-18.00</td>
<td>GMP in Food Industry, Best Industry Practices, GMP in Microbiology and Biotechnology, Supply Chain Controls</td>
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#### DAY 2

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>09:00-09:45</td>
<td>Keynote Session</td>
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<tr>
<td>09:45-10:15</td>
<td>Keynote Talk 5</td>
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<tr>
<td>10:15-10:45</td>
<td>Keynote Talk 6</td>
</tr>
<tr>
<td>10:45-11:00</td>
<td>Coffee/Tea Break</td>
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<tbody>
<tr>
<td>11:00-12.40</td>
<td>Validation, Contract &amp; Sterile Manufacturing, Formulation Development</td>
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</table>

#### Networking Lunch 12.40-13.30

#### Post Lunch Sessions

<table>
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#### Evening Sessions

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<tr>
<td>15.45-18.00</td>
<td>Softwares in GMP and GCP, Clinical Affairs and Regulatory Strategies, Implementation, Excipient Qualification, Panel Discussions, Extended Networking</td>
</tr>
</tbody>
</table>

**Closing and Award Ceremony**
Glimpses of GMP Summit Series Conferences
Glimpses of GMP Summit Series Conferences
Major Scientific Sessions

- Good Manufacturing Practices: The Gap within Current Regulations and Quality Standards
- Current GMP Guidelines (cGMP) & GxP in Pharmaceuticals
- The Role of c in cGMP
- Good Clinical Practices & Good Laboratory Practices
- Quality Control
- Quality Assurance
- Validation
- Contract & Sterile/Aseptic Manufacturing
- Storage, Distribution, Transportation
- Formulation Development
- GMP in Food Industry
- GMP in Microbiology and Biotechnology
- Softwares in GMP and GCP
- Clinical Affairs and Regulatory Strategies Implementation
- Excipient Qualification and Supply Chain Controls
- Entrepreneurs Investment Meet

Best Poster Award

- You will be given about 5-7 minutes to present your poster including questions and answers. Judges may pose questions during the evaluation of the poster
- Judges will even evaluate the student’s enthusiasm towards their study, interest and knowledge in the area of their research
- The winners will be announced at the closing ceremony of the conference. The decision of the winner will be withdrawn if the winner/winners is/are not present at the time of announcement
- Apart from the judging time you may also be present at the poster to share your research with interested delegates

Conference Venue

Philadelphia, Pennsylvania, USA

General Queries

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Liberty_Bell

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5th International Summit on

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Quality Control

August 12-13, 2016
Toronto, Canada

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Email: gmpsummit@conferenceseries.net

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## Conference Day One | Friday August 12, 2016

### Registrations

### Opening Ceremony

**Session Chair:** Boyd L Summers, BL Summers Consulting LLC, USA

### Keynote Forum

**Title:** Planning to outsource manufacturing: Have you done your homework?  
**Mohammed R Khan,** Synergex Consulting, Canada

**Title:** Ensure quality assurance for companies and institutions  
**Boyd L Summers,** BL Summers Consulting LLC, USA

### Refreshments and Networking Break 11:00-11:20 @ Foyer

**Title:** Current FDA audit trends and most common cited drug GMP deficiencies  
**Kenneth Christie,** VTS Consultants, Inc., USA

**Title:** Importance of characterization of variation in the secondary endpoint measures prior to the trial: a key to a successful outcome of phase I trial and progression to a phase  
**Danuta Radzioch,** McGill University and Laurent Pharmaceuticals Inc., Canada

**Title:** Traceability guide for general food manufacturers  
**Nadia Narine,** Lumar Food Safety Services Ltd., Canada

### Lunch Break @ Foyer

**Title:** Stability considerations from early stage development through phase-IV of pharmaceutical drug products  
**Dharmi Trivedi,** Professional Pharmaceutical Quality and Compliance Specialist, USA

**Title:** Good clinical practices  
**Peggy J Berry,** Synergy Consulting LLC, USA

### B2B Meetings and Networking
### Keynote Forum

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality risk management</td>
<td>Rashid Mahmood</td>
<td>Surge Laboratories Private Limited, Pakistan</td>
</tr>
<tr>
<td>GMP requirements for Canadian blood &amp; blood establishments</td>
<td>Reza Shojaei</td>
<td>Canadian Plasma Resources, Canada</td>
</tr>
<tr>
<td>Bioavailability and bioequivalence concerns in pharmaceutical industry</td>
<td>Wael Ebied</td>
<td>SEDICO Pharmaceutical, Egypt</td>
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</tbody>
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#### Refreshments and Networking Break 11:00-11:20 @ Foyer

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<td>Wael Ebied</td>
<td>SEDICO Pharmaceutical, Egypt</td>
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<tr>
<td>From molecules to market</td>
<td>Luciano Calenti</td>
<td>ACIC Fine Chemicals, Canada</td>
</tr>
</tbody>
</table>

### B2B Meetings and Networking

#### Poster Presentations

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posology in children oral liquid medication studies in Liberia</td>
<td>Jacob Kolawole</td>
<td>University of Liberia, Nigeria</td>
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<tr>
<td>Buccal drug formulation – Pharmacokinetics of Verapamil and its metabolite norverapamil</td>
<td>Wiesław Sawicki</td>
<td>Medical University of Gdansk, Poland</td>
</tr>
<tr>
<td>Increase and effectiveness in the activity of audits of quality in the center of genetic engineering and biotechnology</td>
<td>Mariela Diaz Cinza</td>
<td>Havana University, Cuba</td>
</tr>
</tbody>
</table>

#### Lunch Break @ Foyer
4th International Summit on
GMP, GCP & Quality Control

October 26-28, 2015   Hyderabad, India

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conference-series.com
**Day 1  October 26, 2015**

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>09:00-10:00</td>
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<tr>
<td></td>
<td><strong>Hall-1.01 &amp; 1.02</strong></td>
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**Opening Ceremony**

<table>
<thead>
<tr>
<th>Session Introduction</th>
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<tbody>
<tr>
<td><strong>Keynote Forum</strong></td>
</tr>
<tr>
<td><strong>David Spaulding</strong></td>
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<tr>
<td>SeerPharma, Australia</td>
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<tr>
<td><strong>Shivraj Dasari</strong></td>
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<td>SLS Cell Cure Technologies Private Limited, India</td>
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<table>
<thead>
<tr>
<th>Networking &amp; Refreshments Break @ Hall-6</th>
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<tbody>
<tr>
<td><strong>Special Session</strong></td>
</tr>
<tr>
<td><strong>Sunil Kumar Verma</strong></td>
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<tr>
<td>CSIR-Center for Cellular and Molecular Biology, India</td>
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<tr>
<td><strong>Peter D Smith</strong></td>
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<tr>
<td>Parexel International, USA</td>
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<table>
<thead>
<tr>
<th>Lunch Break @ Hall-6</th>
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<tbody>
<tr>
<td><strong>Track 1: Good Manufacturing Practices: The Gap within</strong></td>
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<tr>
<td><strong>Track 2: Current Regulations and Quality Standards</strong></td>
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<tr>
<td><strong>Track 3: Current GMP Guidelines (cGMP)</strong></td>
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<tr>
<td><strong>Track 4: The Role of “c” in cGMP</strong></td>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Title:</strong> Entropy in Good Manufacturing Practices driven innovative quality tool for pharmaceutical industry: New paradigm approach for manufacturing excellence and quality standards</td>
</tr>
<tr>
<td><strong>Pradeep K Jha</strong>, IIT Kharagpur, India</td>
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<tr>
<td><strong>Title:</strong> Comparison of guidelines of Indian GMP with WHO GMP</td>
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<tr>
<td><strong>Uma Vasireddy</strong>, Kakatiya Institute of Pharmaceutical Sciences, India</td>
</tr>
<tr>
<td><strong>Title:</strong> Role of “c” in cGMP</td>
</tr>
<tr>
<td><strong>Abha Doshi</strong>, MET Institute of Pharmacy, India</td>
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<tr>
<td><strong>Title:</strong> Clinical documentation supporting core labels for generics/OTC products</td>
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<tr>
<td><strong>Aswin Kumar Allupati</strong>, Freyr Software Services Pvt Ltd., India</td>
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<table>
<thead>
<tr>
<th>Networking &amp; Refreshments Break</th>
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<tbody>
<tr>
<td><strong>Panel Discussion</strong></td>
</tr>
<tr>
<td><strong>Title:</strong> Quality management systems</td>
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<tr>
<td><strong>Vaishali P Nagulwar</strong>, Government College of Pharmacy, India</td>
</tr>
<tr>
<td><strong>Title:</strong> Current GMP guidelines</td>
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<tr>
<td><strong>Abha Doshi</strong>, MET Institute of Pharmacy, India</td>
</tr>
<tr>
<td><strong>Title:</strong> Comparison of regulatory requirements for marketing authorization of biologics in United States and European Union</td>
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<tr>
<td><strong>Shashi Kumar Yadav</strong>, Sri Indu Institute of Pharmacy, India</td>
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</tbody>
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**Silver Sponsor**

![SeenPharma](seenpharma.png)
Day 2          October 27, 2015
Hall-1.01 & 1.02

Keynote Forum

Per Nilsson
Profox Company, Sweden

Rama K Pidaparti
Wipro Technologies, USA

Networking & Refreshments Break @ Hall-6

Tanmoy Chakraborty
Manipal University, India

Track 6 & 7: Quality Control & Quality Assurance
Track 8: Validation
Track 9 & 11: Contract & Sterile/Aseptic Manufacturing and Formulation Development
Track 12: GMP in Food Industry, Microbiology and Biotechnology

Session Chair: Rama K Pidaparti, Wipro Technologies, USA
Session Chair: Per Nilsson, Profox Company, Sweden

Session Introduction

Title: Food safety management systems-requirements for any organisation in the food chain (ISO 22000:2005)
R Manavalan, Annamalai University, India

Title: HPLC method development and validation as per ICH guidelines
Arunadevi S Birajdar, K T Patil College of Pharmacy, India

Title: Identification of biomarker(s) from polyherbal formulation used in hyperlipidemia for qualitative and quantitative analysis
Charmy S Kothari, Nirma University, India

Lunch Break @ Hall-6

Title: Almighty Astaxanthin: Over view on nutraceutical based approach to aim to combat cancer
Kandra Prameela, GITAM University, India

Title: Effective GMP AUDITS for APIs and Formulation Pharma Companies
G Sundar, PharmQA Compliance Services, India

Title: Pharmaceutical process validation: A tool for pharmaceutical compliance monitor
Sheelpriya Ratnakar Walde, Gurunanak College of Pharmacy, India

Title: Quality Control analytical methods- swith from HPLC to UPLC
Y Padmavathi, G Pullareddy College of Pharmacy, India

Title: Development & characterization of timolol maleate osmotic drug delivery system
B Nagarani, SriKurpa Institute of Pharmaceutical Sciences, India

Title: Effects of lean manufacturing practices to encourage continuous improvement for manufacturing excellence
Dharmvir Uppal, GNA University, India

Title: Quality control methodologies for standardization of herbal medicines: An assessment
Raja Chakaverty, Bengal College of Pharmaceutical Sciences & Research, India

Networking & Refreshments Break @ Hall-6

Poster Presentations @ Hall-6

Poster Judge: Peter D Smith, Parexel International, USA
Poster Judge: R Manavalan, Annamalai University, India

Day 3          October 28, 2015
Hall-1.01 & 1.02

Track 5: Good Clinical Practices & Good Laboratory Practices
Track 10: Storage, Distribution, Transportation
Session Chair: R Manavalan, Annamalai University, India

Workshop on: How to prevent outbreaks in endemic countries?
Ravi Kumar Tummalacharla, Cleanrooms Containments, India

Network & Refreshments Break 5 @ Hall-6

Young Researchers Forum

Title: Studies on β-CD complexation of a poorly soluble drug
Mohidurakshan, Sher-I-Kashmir Institute of Medical Sciences, India

Title: Solubility and dissolution rate enhancement of Aceclofenac by solid dispersion technique
Khalid Bashir Mir, The University of Kashmir, India

Title: Good manufacturing practice (GMP): An overview
Firoj A Tamboli, Bharati Vidyapeeth College of Pharmacy, India

Title: A validated UPLC/ESI-MS/MS bioanalytical method for the quantification of Perindopril and Amlodipine in human plasma
Kalaiyarasi Duraisamy, JNTU Hyderabad, India

Title: Adverse drug reaction reporting – A retrospective analysis
Ibel C Fredy, PES College of Pharmacy, India

Title: 3G system in pharmacy practice with vigilance
Khwaja Amtul Raouf Qazi, MRM College of Pharmacy, India

Lunch Break @ Hall-6

Title: Good Clinical Practice (GCP) and declaration of helsinki
Pooja Roy, Vydehi Institute of Medical Sciences and Research Centre, India

Title: Indian clinical trials- The unaddressed challenges of regulatory amendment
N Srinivas, Malla Reddy Institute of Pharmaceutical Sciences, India

Title: Data mining – De-Novo Quality Management tool in Food Sector
S Thiruchenduran, Professor Jayashankar Telangana State Agricultural University, India

Title: Zebrafish as a model system for drug target screening and validation
Bhusnure O G, Channabasweshwar Pharmacy College, India

Title: Estimation of Ramelteon in bulk and tablet dosage form by HPLC
Varaprasad Adepu, JNTU Kakinada, India

Title: QbD approach for the development and optimization of HPLC method for the simultaneous estimation of four component cream formulation: Application to permeability study
Prachi Bhamre, The Maharaja Sayajirao University of Baroda, India

Title: HPLC fingerprinting for quality control of herbal drugs
Nutan Kaushik, The Energy and Resources Institute (TERI), India

Award Ceremony

Bookmark your dates

5th International Summit on
GMP, GCP & Quality Control

August 01-02, 2016   Toronto, Canada

Website: gmp-gcp-quality-control.pharmaceuticalconferences.com
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Scientific Program

3rd International Summit on
GMP, GCP & Quality Control

September 25-26, 2014   Valencia Convention Centre, Spain

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## Day 1  
**September 25, 2014**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>08:00-09:00</td>
<td>Registrations</td>
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### Committee Room 5  
**Opening Ceremony**

### Keynote Forum
**Introduction**

**Victor Sanchez**  
Pharma-Bio Serv S.L., Spain

**Sundar Chellamani**  
SysComm Project Management Limited, Ireland

**Maria Pellin Amoros**  
Laboratoires Quinton International S.L., Spain

### Session 1: Good Manufacturing Practices: The Gap within

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

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

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

**Title:** Greening the pharmaceutical industry to afford Good Laboratory Practice  
**Salwa Elmeligie,** Cairo University, Egypt

### Lunch Break @ Multi Purpose Hall 2

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

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

**Title:** Role of Good Laboratory Practice in Good Clinical Practice  
**Salwa Elmeligie,** Cairo University, Egypt

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

Title: Effective CAPA program, A valuable tool in quality improvement  
Dharmi Trivedi, University of Phoenix, USA

Coffee Break @ Auditorium 3 Foyer

Title: Evaluation of bacterial contamination of clean room clothing  
Noelle H O Driscoll, Robert Gordon University, Scotland

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

Title: How to improve quality and consistency of legacy products applying QbD/Six Sigma methodology  
Alicia Tebar, Telstar, Spain

Title: Maintain the effectiveness of a QMS by using Lean Six Sigma approach  
Peter Jehander, AF Technology AB, Sweden

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

David L Chesney  
Parexel International, USA

Wael Ebied  
SEDICO Pharmaceuticals-Merck & Co., Egypt

Aziz Chraibi  
Pharma Bio Expert Inc., Canada

Coffee Break @ Auditorium 3 Foyer

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

Title: Managing equipment validation using ASTM approach for optimum cost and aggressive schedule  
Sundar Chellamani, SysComm Project Management Limited, Ireland

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 @ Multi Purpose Hall 2
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

Title: GMP system implementation and certification to manufacture seawater ampoules as a dietary supplement under ISO 5 air quality

Maria Pellin Amoros, Laboratorios Quinton International S.L., Spain

Title: DHF, DMR and DHR - The three Ds of Medical devices

Rama K Pidaparti, Wipro Technologies, USA

Title: Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)

Mootaz El Halawani, Pharmaceutical Quality Expert, Egypt

Coffee Break @ Auditorium 3 Foyer

Title: Challenges of cGMP implementation at different CMO’s - role of quality agreements

Rivka Zaibel, Advanced Regulatory Services Ltd. (ADRES), Israel

Title: CMO’s challenges and strategies in sterile manufacturing

Jixing Wang, Dalton Pharma Services, Canada

Title: Production of biosimilars in developing countries: Challenges and opportunities: SEDICO case Study

Wael Ebied, SEDICO Pharmaceuticals - Merck & Co., Egypt

Title: The relevance of training in supply chain management of pharmaceutical products

Ibelema Emeh, Setax Training & Consultancy Limited, United Kingdom

Closing Ceremony

Bookmark your dates

4th International Summit on
GMP, GCP & Quality Control

October 26-28, 2017 - Hyderabad, India

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http://gmp-gcp-quality-control.pharmaceuticalconferences.com
Proposals are invited for organizing Symposia/Workshops at Conference Series Conferences or Conference Series 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.
Day 1  November 12, 2013

09:00-10:00  Registrations

Berlin

Opening Ceremony

Keynote Forum

Introduction
Gerard Pearce
SQA Services, Inc., USA
Ashraf Youssef
AY Pharma Safety Consulting, USA

Patricia Henley
London School of Hygiene & Tropical Medicine, UK
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

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

Title: Case study: Quality assurance and quality control partnering to drive compliance, science, and innovation
Jason Ruckert, Advanced Testing Laboratory, USA

Title: Quality assurance on a budget from a non-commercial perspective
Lucy H H Parker, St George’s Healthcare NHS Trust, UK

Lunch Break @ Athens

Title: Automation in validated environments
Abitha Sundararajan, Med Manage Systems, USA

Title: Quality accreditation for medical research at Universities?
Brigitte von Rechenberg, University of Zurich, Switzerland

Title: Risk assessment
M.S. Lourdes Sanchez, Sintenovo SA de CV, Mexico

Title: Modern quality systems & Risk management approaches
Naveen Kumar Venkatesham, Laurus Labs Private Limited, India

Title: 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 @ Foyer

http://gmp-gcp-quality-control.pharmaceuticalconferences.com
Title: Data integrity issues
Mohammad Iqbal Hossain, Novartis Ltd., Bangladesh

Title: Challenges in benefit-risk evaluations during co-development among partnerships and alliances
Ashraf Youssef, AYPharma Safety Consulting, LLC, USA

Title: Is your company in a state of control?
Brian Hill, Brian Hill & Associates, USA

Title: 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

Title: Mitigating the environmental impact of cleaning processes in GMP regulated facilities
Elizabeth Rivera, STERIS Corporation, USA

Cocktails Sponsored by Journal of Developing Drugs @ Athens

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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

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

Coffee Break @ Foyer

Title: A risk based scientific approach to analytical method development and validation activities for regulated laboratories
Shib Mookherjea, ValQual International, USA
Title: 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
Title: Leaderships role in change management
Myriam Ochart, Lean Compliance Partners, USA

Lunch Break @ Athens

Workshops

Zippy Lean Workshop (Production Line Simulation) by
Myriam Ochart, Lean Compliance Partners, USA & Jennifer Leny, American Society for Quality, USA

Highlights of Process Analytical Technology (PAT) & FDA Directives Workshop
Shib Mookherjea, ValQual International, USA

Coffee Break @ Foyer

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

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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

Title: Performing microbial risk analysis on a standard compounding pharmacy aseptic fill process
Anthony Grilli, Focus Scientific Solutions, USA

Title: The effect of L-arginine on mice placenta
Mohanad AbdulSattar Ali Al-Bayati, University of Baghdad, Iraq

Title: Cleaning challenges in the dietary supplement industry
Elizabeth Rivera, STERIS Corporation, USA

Coffee Break @ Foyer

Title: Myrica rubra fruit drink sub-chronic toxicity and hepatoprotective effect in rats
Mohamed AlAjmi, King Saud University, Saudi Arabia

Title: The informed consent form process: A basic contemporary standpoint for medical research professionals
Peter Odeh, SNBL Clinical Pharmacology Center, USA

Title: DHF, DMR and DHR-The three Ds of medical devices
Rama K. Pidaparti, Wipro Technologies, USA

Title: Immunosuppressive effects of mesenchymal stem cells versus corticosteroid in experimental model of arthritis
Marwa Elhussiny Younus, Cairo University, Egypt

Title: Comparative pharmacokinetics and compliance issues to optimize art- The Indian scenario
Princy Louis Palatty, Father Muller Medical College, India

Title: A new cGMP bioassay involving electrophysiological recordings of CFTR currents
Antonio Lacerda, ChanTest Corporation, USA

Lunch Break @ Athens

Bookmark your dates

3rd International Summit on
GMP, GCP & Quality Control

September 25-26, 2014  Valencia, Spain