conferenceseries.com

Tentative Program

6th International Conference and Exhibition on

GMP, GCP & Quality Control

September 25-26, 2017 Chicago, USA

Theme: "Manufacturing and Quality Guidelines: Its Importance Creates its Need!"



For Available Speaker Slots

gmpsummit@pharmaceuticalconferences.org

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

Conference Secretariat

2360 Corporate Circle, Suite 400 Henderson, NV 89074-7722, USA

Tel: +1-702-508-5200, Fax: +1-650-618-1417, Ph: +1-650-268-9744, Toll free: +1-800-216-6499

Email: gmpsummit@pharmaceuticalconferences.org

http://gmp-gcp-quality-control.pharmaceuticalconferences.com

Tentative Program

6th International Conference and Exhibition on

GMP, GCP & Quality Control

September 25-26, 2017 at Chicago, USA

Program at a Glance

Day 1

Morning Sessions	Reception/Registration	08.00-09.00	
		Time	General Session
		09.00-09.15	Inaugural Address
	Least of 3 Keynote/Plenary Talks	09.15-09.45	Keynote/Plenary Talk 1
		09.45-10.15	Keynote/Plenary Talk 2
		10.15-10.45	Keynote/Plenary Talk 3
	Panel Discussions/Group Photo		
	Coffee/Tea Break 10.45-11.00 (Networking)		
Evening Sessions	11.00-12.40	5 Speakers (20 Mins Each)	
	Lunch Break 12.40-13.30		
	13.30-15.30	6 Speakers (20 Mins Each)	
	Coffee/Tea Break 15.30-15.45 (Networking)		
	15.45-17.25	5 Speakers (20 Mins Each)	

19 Speakers for Day 1

Day 2

		Time	Session 1	Session 2
Morning Sessions	09.00-10.40		5 Speakers (20 Mins Each)	5 Speakers (20 Mins Each)
	Coffee/Tea Break 10.40-10.55 (Networking)			
	10.55-12.35		5 Speakers (20 Mins Each)	5 Speakers (20 Mins Each)
	Lunch Break 12.35-13.25			
Evening Sessions	13.25-15.05		5 Speakers (20 Mins Each)	5 Speakers (20 Mins Each)
	Poster Sessions			
	Coffee/Tea Break 15.05-15.20 (Networking)			
	15.20-17.00		5 Speakers (20 Mins Each)	5 Speakers (20 Mins Each)
	Closing Cermony			
	NOTE: Program Shedule is subject to change with final allotment of the speaker slots			

30 Speakers on Day 2

gmpsummit@pharmaceuticalconferences.org

Note: Workshops and Symposia slots are available. To book slot for Workshop and Symposium send us the proposal

Call for Abstract: http://gmp-gcp-quality-control.pharmaceuticalconferences.com/call-for-abstracts.php

Registration: http://gmp-gcp-quality-control.pharmaceuticalconferences.com/registration.php

Abstract Submission: http://gmp-gcp-quality-control.pharmaceuticalconferences.com/abstract-submission.p

e-Poster: http://gmp-gcp-quality-control.pharmaceuticalconferences.com/eposter-presentation.php

Glimpses of GMP Summit Series Conferences





















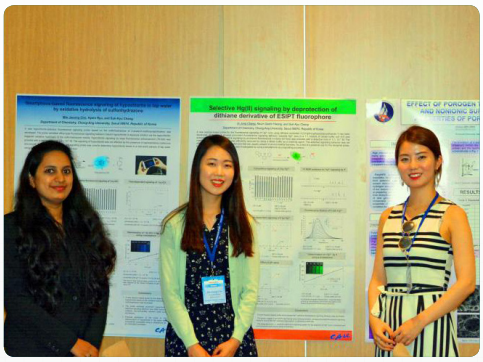




Glimpses of GMP Summit Series Conferences













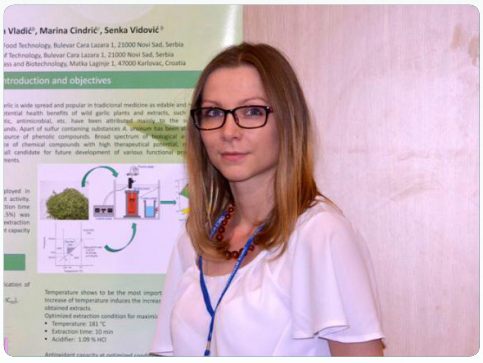












Major Scientific Sessions

- Good Manufacturing Practices: The Gap within
- Current Regulations and Quality Standards
- Current GMP Guidelines (cGMP)
- 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
- Entrepreneurs Investment Meet
- Excipient Qualification and Supply Chain Controls

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



Young Researchers Forum

- Present your research through oral presentations
- Learn about career development and the latest research tools and technologies in your field
- This forum will give pertinent and timely information to those who conduct research and those who use and benefit from research
- Develop a foundation for collaboration among young researchers
- The forum will provide an opportunity for collegial interaction with other young investigators and established senior investigators across the globe
- Interact and share ideas with both peers and mentors

General Queries

gmpsummit@pharmaceuticalconferences.org

Conference Venue

Chicago, USA

Contact us
America: Conference Series LLC
GMP Summit 2017
2360 Corporate Circle., Suite 400 Henderson,
NV 89074-7722, USA
Phone: +1-888-843-8169, Fax: +1-650-618-1417,
Toll free: +1-800-216-6499
Email: gmpsummit@pharmaceuticalconferences.org

Contact us
UK: Conference Series LLC
GMP Summit 2017
Heathrow Stockley Park Lakeside House
1 Furzeground Way, Heathrow
UB11 1BD, UK
Tel: +1-800-216-6499
Email: gmpsummit@conferenceseries.net

Contact us
Asia-Pacific: Conference Series LLC
GMP Summit 2017
Divyasree Building, Raidurg
6th Floor, North Block
Hyderabad 500032, INDIA
Tel: 040-33432309
Email: gmpsummit@pharmaceuticalconferences.org



Best Tourist Destinations in Chicago



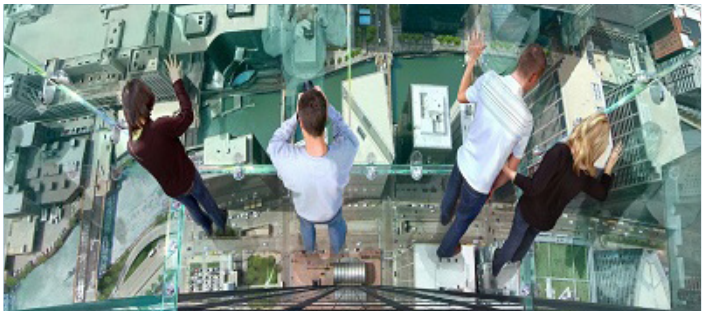
Millennium Park



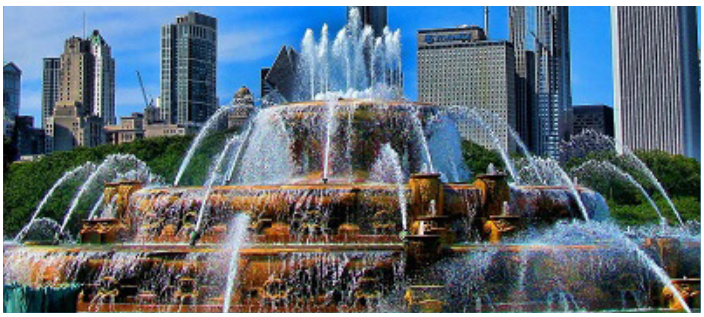
Navy Pier



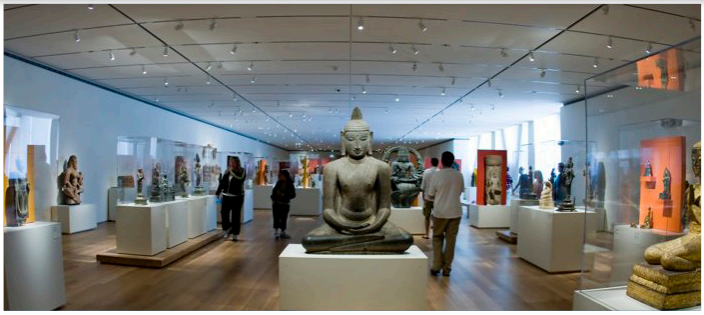
Lincoln Park Zoo



Willis Tower Sky Deck



Buckingham Fountain



Art Institute



Field Museum



Shedd Aquarium

conferenceseries.com

Scientifc Program

612th Conference

5th International Summit on

GMP, GCP & Quality Control

August 12-13, 2016
Toronto, Canada





Hosting Organizations: Conference Series LLC
2360 Corporate Circle., Suite 400 Henderson, NV 89074-7722, USA
Ph: +1-702-508-5200 Ext: 8044, Fax: +1-650-618-1417, Toll free: +1-800-216-6499

Conference Series Ltd
Heathrow Stockley Park Lakeside House, 1 Furzeground Way, Heathrow, UB11 1BD, UK, Tel: +1-800-216-6499
Email: gmpsummit@conferenceseries.net

Conference Day One | Friday August 12, 2016

MacDolald

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 1 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

Conference Day Two | Saturday August 13, 2016

MacDolald

Session Chair: **Reza Shojaei**, Canadian Plasma Resources, Canada

Keynote Forum

Ramakrishna Pidaparti, Wipro Technologies, USA

Title: Quality risk management
Rashid Mahmood, Surge Laboratories Private Limited, Pakistan

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

Title: GMP requirements for Canadian blood & blood establishments
Reza Shojaei, Canadian Plasma Resources, Canada

Title: Bioavailability and bioequivalence concerns in pharmaceutical industry
Wael Ebied, SEDICO Pharmaceutical, Egypt

Title: From molecules to market
Luciano Calenti, ACIC Fine Chemicals, Canada

B2B Meetings and Networking

Poster Presentations

Title: Posology in children oral liquid medication studies in Liberia
Jacob Kolawole, University of Liberia, Nigeria

Title: Buccal drug formulation – Pharmacokinetics of Verapamil and its metabolite norverapamil
Wiesław Sawicki, Medical University of Gdansk, Poland

Title: Increase and effectiveness in the activity of audits of quality in the center of genetic engineering and biotechnology
Mariela Díaz Cinza, Havana University, Cuba

Lunch Break @ Foyer

Scientific Program

4th International Summit on

GMP, GCP & Quality Control



Silver Sponsor

SeerPharma®
CONFIDENCE IN COMPLIANCE

Bag Insert Sponsor

the nature network®
PhytoLab

October 26-28, 2015 Hyderabad, India

Conference Series LLC
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

conferenceseries.com

Day 1 October 26, 2015

09:00-10:00 Registrations

Hall-1.01 & 1.02

Opening Ceremony

Keynote Forum

Introduction

David Spaulding
SeerPharma, Australia

Shivraj Dasari
SLS Cell Cure Technologies Private Limited, India

Networking & Refreshments Break @ Hall-6

Sunil Kumar Verma
CSIR-Center for Cellular and Molecular Biology, India

Special Session

Peter D Smith
Parexel International, USA

Lunch Break @ Hall-6

Track 1: Good Manufacturing Practices: The Gap within
Track 2: Current Regulations and Quality Standards
Track 3: Current GMP Guidelines (cGMP)
Track 4: The Role of "c" in cGMP

Session Chair: Peter D Smith, Parexel Internationl, USA
Session Chair: Sunil Kumar Verma, CSIR-Center for Cellular and Molecular Biology, India
Session Chair: Shivraj Dasari, SLS Cell Cure Technologies Private Limited, India

Session Introduction

Title: Entropy in Good Manufacturing Practices driven innovative quality tool for pharmaceutical industry: New paradigm approach for manufacturing excellence and quality standards
Pradeep K Jha, IIT Kharagpur, India

Title: Comparison of guidelines of Indian GMP with WHO GMP
Uma Vasireddy, Kakatiya Institute of Pharmaceutical Sciences, India

Title: Role of "c" in cGMP
Abha Doshi, MET Institute of Pharmacy, India

Title: Clinical documentation supporting core labels for generics/OTC products
Aswin Kumar Allupati, Freyr Software Services Pvt Ltd., India

Networking & Refreshments Break

Title: Quality management systems
Vaishali P Nagulwar, Government College of Pharmacy, India

Title: Current GMP guidelines
Abha Doshi, MET Institute of Pharmacy, India

Title: Comparison of regulatory requirements for marketing authorization of biologics in United States and European Union
Shashi Kumar Yadav, Sri Indu Institute of Pharmacy, India

Panel Discussion

Silver Sponsor

SeerPharma®
CONFIDENCE IN COMPLIANCE

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 Internationl, 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

Sponsor

the nature network®
PhytoLab

Session Chair: R Manavalan, Annamalai University, India

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

Networking & 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
e-mail: gmpsummit@conferenceseries.net

Contact us
America: Conference Series LLC
GMP Summit 2017
2360 Corporate Circle., Suite 400 Henderson,
NV 89074-7722, USA
Phone: +1-888-843-8169, Fax: +1-650-618-1417,
Toll free: +1-800-216-6499
Email: gmpsummit@pharmaceuticalconferences.org

Contact us
UK: Conference Series LLC
GMP Summit 2017
Heathrow Stockley Park Lakeside House
1 Furzeground Way, Heathrow
UB11 1BD, UK
Tel: +1-800-216-6499
Email: gmpsummit@conferenceseries.net

Contact us
Asia-Pacific: Conference Series LLC
GMP Summit 2017
Divyasree Building, Raidurg
6th Floor, North Block
Hyderabad 500032, INDIA
Tel: 040-33432309
Email: gmpsummit@pharmaceuticalconferences.org

Scientific Program

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 Biotecnología

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
MEDEAS clinics directory
PharmaVOICE
PharmaVision
Medical News TODAY

"Organize your Events at Conference Series LLC Conferences"

Proposals are invited for organizing Symposia/Workshops at Conference Series LLC Conferences or Conference Series LLC 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*

Conference Series LLC

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

Day 1 September 25, 2014

08:00-09:00 Registrations

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

Coffee Break @ Auditorium 3 Foyer

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

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, Laboratoires 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

B2B

Bookmark your dates



Contact us
America: Conference Series LLC
GMP Summit 2017
2360 Corporate Circle., Suite 400 Henderson,
NV 89074-7722, USA
Phone: +1-888-843-8169, Fax: +1-650-618-1417,
Toll free: +1-800-216-6499
Email: gmpsummit@pharmaceuticalconferences.org

Contact us
UK: Conference Series LLC
GMP Summit 2017
Heathrow Stockley Park Lakeside House
1 Furzeground Way, Heathrow
UB11 1BD, UK
Tel: +1-800-216-6499
Email: gmpsummit@conferenceseries.net

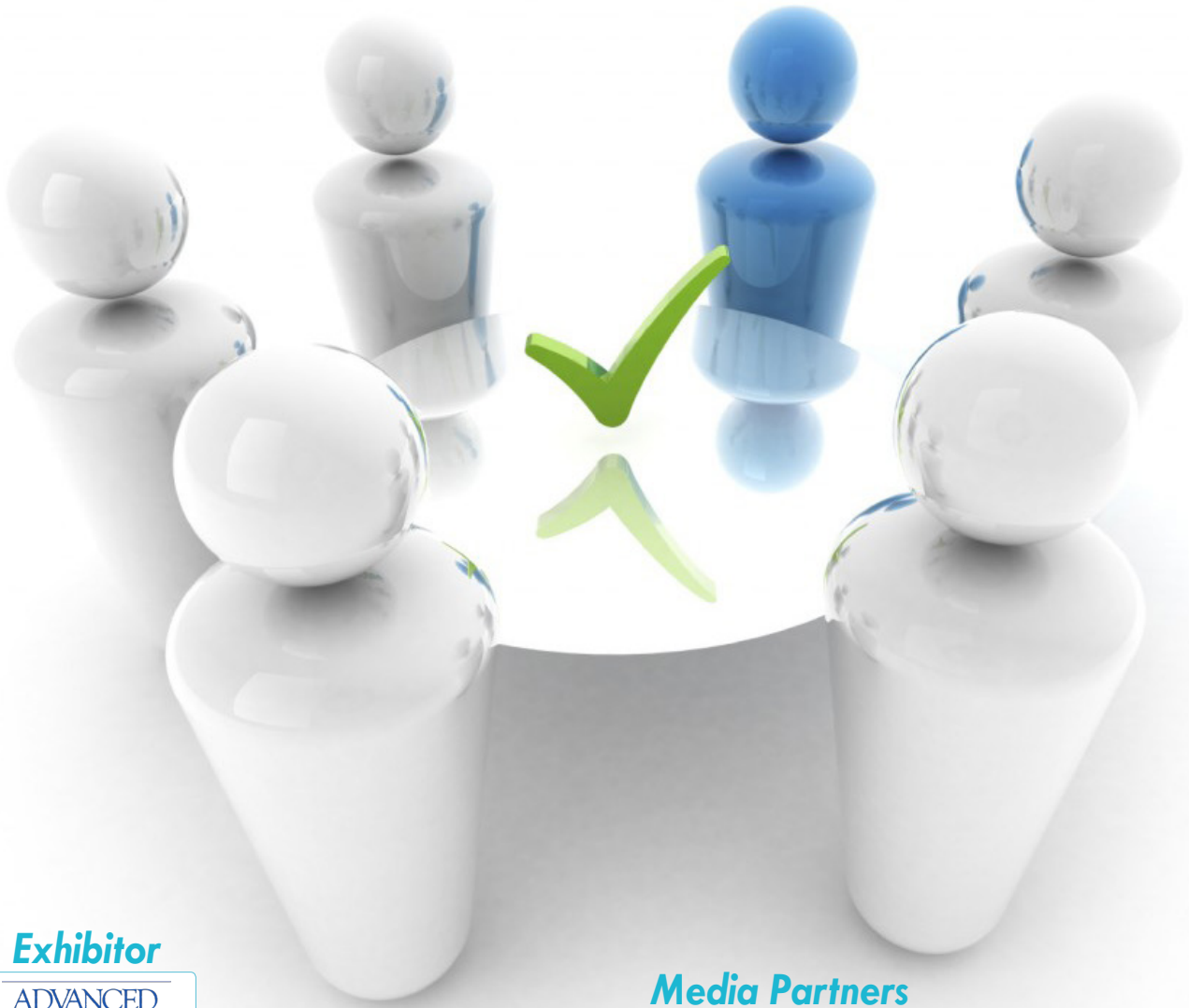
Contact us
Asia-Pacific: Conference Series LLC
GMP Summit 2017
Divyasree Building, Raidurg
6th Floor, North Block
Hyderabad 500032, INDIA
Tel: 040-33432309
Email: gmpsummit@pharmaceuticalconferences.org

Scientific Program

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

"Organize your Events at Conference Series Conferences"

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*

Conference Series LLC
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

Opening Ceremony

Keynote Forum

Introduction

Gerard Pearce
SQA Services, Inc., USA

Ashraf Youssef
AYPharma Safety Consulting, USA

Coffee Break @ Foyer

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

Session Introduction

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

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**

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

Coffee Break @ Foyer

Highlights of Process Analytical Technology (PAT) & FDA Directives Workshop

Shib Mookherjea, ValQual International, USA

Athens

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

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 Younnis, 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



Contact us
America: Conference Series LLC
GMP Summit 2017
2360 Corporate Circle., Suite 400 Henderson,
NV 89074-7722, USA
Phone: +1-888-843-8169, Fax: +1-650-618-1417,
Toll free: +1-800-216-6499
Email: gmpsummit@pharmaceuticalconferences.org

Contact us
UK: Conference Series LLC
GMP Summit 2017
Heathrow Stockley Park Lakeside House
1 Furzeground Way, Heathrow
UB11 1BD, UK
Tel: +1-800-216-6499
Email: gmpsummit@conferenceseries.net

Contact us
Asia-Pacific: Conference Series LLC
GMP Summit 2017
Divyasree Building, Raidurg
6th Floor, North Block
Hyderabad 500032, INDIA
Tel: 040-33432309
Email: gmpsummit@pharmaceuticalconferences.org

http://gmp-gcp-quality-control.pharmaceuticalconferences.com