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4th International Summit on

GMP, GCP & Quality Control



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October 26-28, 2015 Hyderabad, India

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Day 1 October 26, 2015

09:00-10:00 Registrations

Hall-1.01 & 1.02

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10:00-10:25 **Opening Ceremony**

Keynote Forum

10:25-10:30 **Introduction**

10:30-11:00 **David Spaulding**
SeerPharma, Australia

11:00-11:30 **Shivraj Dasari**
SLS Cell Cure Technologies Private Limited, India

Networking & Refreshments Break 11:30-11:45 @ Hall-6

11:45-12:15 **Sunil Kumar Verma**
CSIR-Center for Cellular and Molecular Biology, India

Special Session

12:15-13:10 **Peter D Smith**
Parexel International, USA

Lunch Break 13:10-14:00 @ 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

14:00-14:25 **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

14:25-14:50 **Comparison of guidelines of Indian GMP with WHO GMP**
Uma Vasireddy, Kakatiya Institute of Pharmaceutical Sciences, India

14:50-15:15 **Role of "c" in cGMP**
Abha Doshi, MET Institute of Pharmacy, India

15:15-15:40 **Clinical documentation supporting core labels for generics/OTC products**
Aswin Kumar Allupati, Freyr Software Services Pvt Ltd., India

Networking & Refreshments Break 15:40-15:55

15:55-16:20 **Quality management systems**
Vaishali P Nagulwar, Government College of Pharmacy, India

16:20-16:45 **Current GMP guidelines**
Abha Doshi, MET Institute of Pharmacy, India

16:45-17:10 **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

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Day 2 October 27, 2015

Hall-1.01 & 1.02

Keynote Forum

10:00-10:30	**Per Nilsson** Profox Company, Sweden
10:30-11:00	**Rama K Pidaparti** Wipro Technologies, USA

Networking & Refreshments Break 11:00-11:15 @ Hall-6

11:15-11:45	**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

11:45-12:10	**Food safety management systems-requirements for any organisation in the food chain (ISO 22000:2005)** **R Manavalan**, Annamalai University, India
12:10-12:35	**HPLC method development and validation as per ICH guidelines** **Arunadevi S Birajdar**, K T Patil College of Pharmacy, India
12:35-13:00	**Identification of biomarker(s) from polyherbal formulation used in hyperlipidemia for qualitative and quantitative analysis** **Charmy S Kothari**, Nirma University, India

Lunch Break 13:00-13:40 @ Hall-6

13:40-14:05	**Almighty Astaxanthin: Over view on nutraceutical based approach to aim to combat cancer** **Kandra Prameela**, GITAM University, India
14:05-14:30	**Effective GMP AUDITS for APIs and Formulation Pharma Companies** **G Sundar**, PharmQA Compliance Services, India
14:30-14:55	**Pharmaceutical process validation: A tool for pharmaceutical compliance monitor** **Sheelpriya Ratnakar Walde**, Gurunanak College of Pharmacy, India
14:55-15:20	**Quality Control analytical methods- swith from HPLC to UPLC** **Y Padmavathi**, G Pullareddy College of Pharmacy, India
15:20-15:45	**Development & characterization of timolol maleate osmotic drug delivery system** **B Nagarani** , SriKurpa Institute of Pharmaceutical Sciences, India
15:45-16:10	**Effects of lean manufacturing practices to encourage continuous improvement for manufacturing excellence** **Dharmvir Uppal**, GNA University, India
16:10-16:35	**Quality control methodologies for standardization of herbal medicines: An assessment** **Raja Chakaverty**, Bengal College of Pharmaceutical Sciences & Research, India

Networking & Refreshments Break 16:35-16:50 @ Hall-6

Poster Presentations 17:00-18:00 @ Hall-6

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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

Session Chair: R Manavalan, Annamalai University, India

10:00-11:00	**Workshop on: How to prevent outbreaks in endemic countries?** **Ravi Kumar Tummalacharla,** Cleanrooms Containments, India

Networking & Refreshments Break 11:00-11:15 @ Hall-6

Young Researchers Forum

11:15-11:35	**Studies on β-CD complexation of a poorly soluble drug** **Mohidurakshan,** Sher-I-Kashmir Institute of Medical Sciences, India
11:35-11:55	**Solubility and dissolution rate enhancement of Aceclofenac by solid dispersion technique** **Khalid Bashir Mir,** The University of Kashmir, India
11:55-12:15	**Good manufacturing practice (GMP): An overview** **Firoj A Tamboli,** Bharati Vidyapeeth College of Pharmacy, India
12:15-12:35	**A validated UPLC/ESI-MS/MS bioanalytical method for the quantification of Perindopril and Amlodipine in human plasma** **Kalaiyarasi Duraisamy,** JNTU Hyderabad, India
12:35-12:55	**Adverse drug reaction reporting – A retrospective analysis** **Ibel C Fredy,** PES College of Pharmacy, India
12:55-13:15	**3G system in pharmacy practice with vigilance** **Khwaja Amtul Raouf Qazi,** MRM College of Pharmacy, India

Lunch Break 13:15-14:00 @ Hall-6

14:00-14:25	**Good Clinical Practice (GCP) and declaration of helsinki** **Pooja Roy,** Vydehi Institute of Medical Sciences and Research Centre, India
14:25-14:50	**Indian clinical trials- The unaddressed challenges of regulatory amendment** **N Srinivas,** Malla Reddy Institute of Pharmaceutical Sciences, India
14:50-15:10	**Data mining – De-Novo Quality Management tool in Food Sector** **S Thiruchenduran,** Professor Jayashankar Telangana State Agricultural University, India
15:10-15:30	**Zebrafish as a model system for drug target screening and validation** **Bhusnure O G,** Channabasweshwar Pharmacy College, India
15:30-15:50	**Estimation of Ramelteon in bulk and tablet dosage form by HPLC** **Varaprasad Adepu,** JNTU Kakinada, India
15:50-16:10	**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
16:10-16:30	**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

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August 01-02, 2016 Toronto, Canada

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