ISPE
Connecting a World of Pharmaceutical Knowledge

India Affiliate

ISPE INDIA ANNUAL CONFERENCE

FRIDAY 11TH & SATURDAY 12TH, JANUARY 2013

HYATT REGENCY, MUMBAI

QUALITY BY DESIGN

AND

SUPPLY CHAIN SECURITY & INTEGRITY

Hotel Hyatt Regency at Andheri (East) in Mumbai

Who will benefit

Executives, Managerial level personnel & people heading various functions like R&D, Process Development, Manufacturing, Regulatory, Quality Control, Quality Assurance, Engineering Maintenance, Qualification & Validation, Supply Chain and Distribution

"Quality by Design" AND "Supply Chain Security & Integrity"

Safe and effective medicines delivered safe and secured

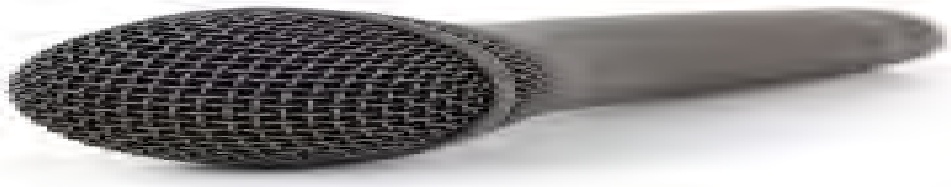
World over, the Pharmaceutical industry is going through tremendous changes. There are ever increasing pressures to ensure that products are effective and they reach the patients without any compromising on quality and safety. Regulators across the globe are expecting the industry to design the right product that retains its quality and safety throughout its life cycle.

Quality by Design

ICH brought out the base documents on Quality by Design namely Q8 and Q11 few years ago; however industry has been rather slow on their full adoption. One of the major reasons for this slow adoption is lack of understanding and interpretational issues experienced by the industry. Regulators now expect the industry to adopt the principles of Q8 and Q11 in their operations to bring out robustly designed medicines. The two day conference is aimed at educating participants of Quality by Design principles easily through knowledge sharing by a few experienced and carefully chosen speakers.

Supply Chain Security & Integrity

Delivering the medicines in a safe and secured manner across the globe is one of the top priorities for the pharmaceutical industry. Several unfortunate incidents in the recent past made buyers and regulators equally worried about the mode of supply chains adopted by the suppliers. Stringent statutes have come up in several nations to ensure supply chain security and integrity. You will be able to hear and interact with experienced speakers in the field speaking about the important aspects of pharmaceutical Supply Chain Security and Integrity.



S P E A K E R S

Charlotte Enghave Fruergaard, Ph.D.

Employed as Director, Nordic Competences at NNE Pharmaplan

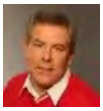
Previously she was manager of sales and marketing and before that responsible for conceptual designs of new pharmaceutical facilities. Enghave Fruergaard has over 18 years of experience with pharmaceutical projects. She has a broad experience within pharmaceutical manufacturing of sterile products and is a leading expert within isolator and barrier technology and associated sterilisation techniques. Fruergaard holds an M. Sc. in mechanical engineering and a PhD in measuring technique. She has international experience from an EU founded project where she was stationed at Physicalische Technische Bundesanstalt in Germany. During this project, she also gained the PhD degree within metrology.

Chris Watts

He is a Partner within the Consulting Group in NNE Pharmaplan and heads the company's Quality and Regulatory group in North America. He holds a Doctorate in Pharmaceutical Science from the University of Tennessee, and a Baccalaureate in Biomedical Engineering from Boston University. He recently joined NNE Pharmaplan from the FDA, where he was part of the team developing policies and systems for the Agency's science and risk-based approach to CGMP inspection and CMC application review, including the recent ICH Quality guidelines and the FDA guidance on Process Validation. Prior to the FDA, Chris was responsible for the development and manufacture of NCE and biotech products at Dura Pharmaceuticals and Shire Laboratories. He has been engaged in several quality and regulatory projects, from developing strategies for product and process development, to risk-based strategies and systems for quality management.

Malcolm Holmes

Is a Chartered Chemist, a Member of the Royal Society of Chemistry and is listed on the UK Qualified Persons Register. He is an active member of ISPE and was a co-author of the ISPE RiskMaPP. Since retirement after 41 years with GlaxoSmithKline, Malcolm maintains an active interest in the pharmaceutical industry and its regulation. He provides ad hoc consultancy and training within the industry and professional bodies and is a part time lecturer to the Faculty of Pharmacy at Brighton University (UK) for post graduate QP students. He has had extensive exposure to the global aspects of the business and the changing global regulatory climate. Whilst with GSK he was an active member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Manufacturing and GMP Committee, leading the EFPIA Topic Teams for Mutual Recognition Agreements / Regulatory Inspections /ICH Q9 (Quality Risk Management) for which he received a USFDA "Levering Collaboration Award2011".



Gordon J Farquharson

He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm. B.Sc.(Hons), C.Eng., Gordon is Chartered Consulting with Engineer more than 30 years experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is also an executive consultant for Pharm Out Pty Ltd, a consulting business based in Australia, working in the Asian and ASEAN region. In recent years he has focused on technologies such as isolators, barrier technology, mini-environments, critical utility systems and bio-containment applications.He has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing. Standards and regulatory compliance issues in the Pharma/Life Science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation & application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements.

Jean-Michel Plankeele

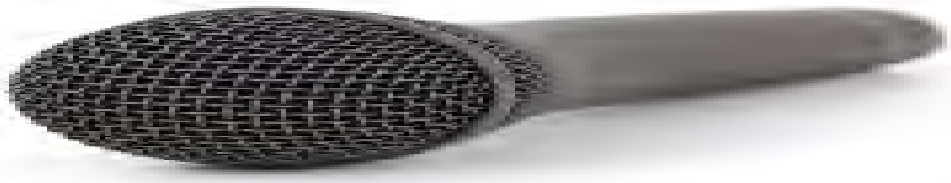
He is the UPLC Product Manager at Waters, European Head Quarters (EHQ), based in Saint-Quentin-Yvelines, France. After joining Waters in 1986, he started as a sales account manager and after three years took the position of Application Laboratory Manager in France. In 1999, he joined the marketing team at Waters EHQ as Industrial Application Specialist (GPC, HT-GPC, chemical analysis). Since 2004, he is in charge of the UPLC scientific support (method transfer, method development, 2D UPLC) for Europe and India. Prior to joining Waters, Jean-Michel Plankeele was graduated from the University of Paris with a Ph. D. thesis.

Dr. V. G. Somani

He is the 'Deputy Drugs Controller (I) ' (in Central Government of India) at CDSCO , HQ, New Delhi and additional charge at West Zone Mumbai. Worked as fecilitator in WHO organized GMP-Vaccine. He has presented seven papers in National & International Conference on Sustained Drug Delivery System specially Microcapsule. He has rose from the position of Drugs Inspector in 1998 to Dy. Drugs Controller, he has completed M. Pharm, Ph.D (in Pharmaceutical Sciences) from Nagpur University, India.

Deepshikha Jakate

She is currently General the Product Quality Manager at Johnson & Johnson Limited, Mulund. Deepshikha has a post graduate Degree in Microbiology. In her current role at Johnson & Johnson, Deepshikha has end-to-end accountability for the quality strategy and quality aspects from Early Development through commercialization for an assigned group of products. She represents Global Quality on the CMC and New Product integration team (NPT).She has held positions of responsibility in Quality Organization in her previous employment and has over 20 years of experience in Pharmaceutical industry.



M K Vasanth Kumar

He is the Founder Director of Logtech Logistics & Systems Pvt Ltd, a 4PL (Fourth Party Logistics) Company specializing in end to end Supply Chain Integration. Prior to starting Logtech in September, 2011, Vasanth was with GlaxoSmithKline Pharmaceuticals in Mumbai heading Supply Chain & front-ending various IT projects for the commercial organization. Vasanth joined SmithKline Beecham at Bangalore, India in 1993 as Manager Systems and has progressed rapidly to head the IT division as VP IT in 1999. He had played a key role in implementing ERP system, well ahead of time and setting up a countrywide VSAT network in 1998-99 thereby offsetting India's poor communication infrastructure with satellite technology. Post merger with Glaxo in 2000, Vasanth moved to Mumbai and was leading IT & Supply Chain in GSK. In addition to this, he had worked for 12 years in various organisations in the pharmaceutical, banking and mining industries prior to joining SmithKline Beecham. He is a Postgraduate in Statistics specialising in Operations Research and and a Diploma Holder in Computer Science. He also had done MDP courses in various management institutes like IIM, Ahmedabad, INSEAD Singapore etc.

Krishna Venkatesh

He is currently the Senior Director & Head of Process Engineering at Dr. Reddy's. He is responsible for all new product launches for Dr. Reddy's globally. He has completed his B. Pharm degree from BITS Pilani and MS in Pharmaceutics from University of Mississippi. He was a part of Barr Laboratories in NY for 12 years in various capacities. He has extensive experience in developing complex oral solid dosage forms with special emphasis on process development and optimization, utilizing engineering principles in scale up. Krishna then worked for Teva Pharmaceuticals USA, where he was responsible for technical aspects of all new product launches from North America and all site transfers into North America. He then relocated to India in 2010 where he joined Dr. Reddy's labs. Krishna has worked closely with the OGD and CDER in CRADA and PAT related aspects. He has also delivered lectures to the FDA inspectorate. He has extensive experience in guiding teams in the areas of application of QbD tools such as DoE, PAT, MVA and engineering principle based scale up.

Shyam Sundar Chellamani

He is Technical Director at SysComm Project ManagementLtd, Ireland and currently C&Q consultant at MSD project in Hangzhou,China. He is highly capable Technical Engineer and Project Manager. He studied M.E. in Thermal Engineering and B.E. in Mechanical Engg. from Bharadidasan University, India. He has more than 24 years' experience out of which 12 years as a Process Mechanical Engineer primarily in the field of C&Q and has worked in India, Singapore, Ireland and China in various Biotech/ Pharma and/Medical devices sector such as MSD, Schering Plough (MSD), Wyeth (Pfizer), Pfizer, KCI He is a Class II Certified Steam Engineer, accredited by the Ministry of Manpower, Singapore.

Sanjit Singh Lamba

He is the Managing Director of Eisai India, President of Global Brand Demand Chain Unit and Head of Global Procurement Strategy. He is an astute business executive with cross functional experience in diverse functions and equipped with over 23 years of proficiency in the field of pharmaceutical technology, Sanjit was instrumental insetting up Eisai's state-of-art Integrated Manufacturing and Research Complex in India which won the Facility of the Year award for 2012 by ISPE. Sanjit is named in the list of one of the "100 of the Most Inspiring people" in the life science industry by PharmaVOICE magazine,USA in August 2012. He has served as Director-Global Pharma Manufacturing of Ranbaxy and also as Vice President - Operations of Lupin with overall responsibility of innovation, implementation, commissioning and production of new sterile and non-sterile APIs and dosage forms. He has proved his headship and fighting spirit by receiving the approval of facilities from USFDA and MHRA for the first time in India for Sterile Cephalosprins during his tenure at Lupin Ltd. He has also worked with multinational pharmaceutical companies including Pfizer, Merck Sharp and Dohme in various disciplines including Projects, Commissioning/Qualification, Drug Regulatory Affairs, Quality Assurance and Supply Chain Management, etc.

Harpal Singh

He is currently the Director Business-Development at ACG-Inspection. He holds a Bachelors Degree in Electronics and Communications Engineering (E&CE) from Gulbarga University (1996). He started his career with one of the leading Instrumentation companies in India, in the field of Environment Monitoring instrumentation wherein he promoted state-of-the- art technologies available worldwide for water pollution, air pollution and solid waste management solutions. During last three years of association with ACG Group, Harpal has focused heavily on new product development and value based inspection solutions for Indian and global market to fulfill the group companies inspection needs. He is driven to take ACG-Inspection's Value proposition in inspection systems for packaging lines and Track and Trace implementation solution to global levels and make ACG-Inspection a very highly profitable and respected company in the inspection and serialization business.

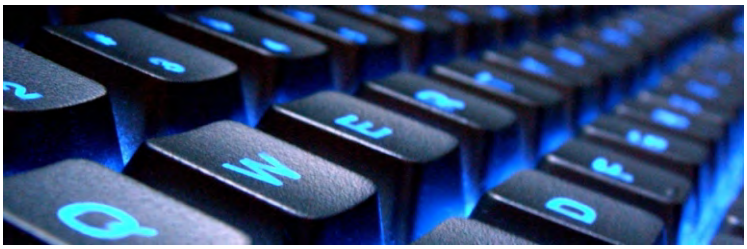
Himanshu Kothari

He is a Consultant and Professor for Business Excellence at JBIMS, NMIMS, SP Jain. He specializes in achieving high returns from business excellence focused management practises by attaining 6 Highs, 6 Lows and 7 R's. He is the Founder Director of Syncore group specializes in Business excellence based on Operational excellence & Supply Chain Management Excellence. A Consultant to large Indian and MNC companies in India & Abroad like L&T, Tata, Godrej, Marico, Dr. Reddy's, Nilkamal, Cipla etc.

Conference Schedule

DAY 1 | Friday, January 11, 2013

8.30 am - 9.30 am	REGISTRATION	
9.30 am - 9.40 am	Welcome Address - Mr. Ajit Singh, Chairman Emeritus, ISPE India Affiliate & Chairman ACG Worlwide	
9.40 am - 10.05 am	About ISPE and India Affiliate - Mr. Gopal Nair, Chairman, ISPE India Affiliate	
10.05 am - 10.25 am	Address by Chief Guest - Dr. G. N. Singh, DCGI and Director of IPCL (TBC)	
10.25 am - 11.00 am	Address by Keynote Speaker - Dr. Charlotte Enghave Fruergaard, Director, NNE Pharmaplan Chairman - ISPE Board of Directors	
11.00 am - 11.30 am	NETWORKING BREAK	
	Track 1- Quality by Design **Track Leader - Mr. Gordon Farquharson**	**Track 2 - Supply Chain Security & Integrity** **Track Leader - Mr. Malcolm Holmes**
11.30 am - 11.40 am	Introduction to the Track Mr. Vijay Kshirsagar - Executive Vice President, Unichem Laboratories Ltd.	Introduction to the Track Mr. Kapil Bhargava - Hon. Secretary, ISPE India Affiliate
11.40 am - 12.25 noon	Introduction to QbD Mr. Gordon Farquharson - Managing Director, Critical Systems Ltd	Importance of Supply Chain Security in Pharma Industry Mr. Malcolm Holmes - Chartered Chemist & Consultant
12.25 noon - 1.10 pm	QbD - Regulatory expectations Dr. Hemant Koshia (TBC) - Commissioner, Food & Drug Administration, Gujarat	Why track and trace regulations Dr. V. G. Somani - Deputy Drugs Controller, CDSCO, West Zone - Mumbai
1.10 pm - 1.20 pm	Discussions - All	Discussions - All
1.20 pm - 2.15 pm	NETWORKING LUNCH	
2.15 pm - 3.00 pm	QbD in Pharmaceutical development Mr. Krishna Venkatesh - Senior Director, Dr. Reddy's Laboratories	Risk Assessment through Supply Chain Mr. Shaktipada Mohapatra - Vice President (Supply Chain), GlaxoSmithKline Pharmaceuticals Ltd.
3.00 pm - 3.45 pm	QbD in Pharma Manufacturing Mr. Sanjit Singh Lamba - Managing Director, Eisai India	Global Developments In the field of Supply Chain Dr. Charlotte Enghave Fruergaard - Director, NNE Pharmaplan
3.45 pm- 4.15 pm	Case study - How to handle QbD for legacy Products Leader - Mr. Gordon Farquharson	Case study - Current Supply Chain problems faced by Industry in India Leader - Mr. Malcolm Holmes
4.15 pm- 4.45 pm	NETWORKING BREAK	
4.45 pm- 5.15 pm	Feedback from case studies Any two team members	Feedback from case studies Any two team members
5.15 pm- 5.30 pm	Summing Up Mr. Vijay Kshirsagar - Unichem laboratories Ltd.	Summing Up Mr. Kapil Bhargava - ISPE India Affiliate
5.30 pm	Close of conference - Day 1	



Conference Schedule

DAY 2 | Saturday, January 12, 2013

	Track 1- Quality by Design Track Leader - Mr. Gordon Farquharson	Track 2 - Supply Chain Security & Integrity Track Leader - Mr. Malcolm Holmes
9.00 am - 9.45 am	QbD and PAT Mr. Chris Watts - Partner, Consulting Group in NNE Pharmaplan	Supply Chain Security - Regulatory Perspective Mr. Bruce Ross (TBC) - Country Director, India Office USFDA
9.45 am - 10.30 am	QbD in New Products Development Ms. Deepshikha Jakate - General Product Quality Manager, Johnson & Johnson Ltd.	Developing anti- counterfeiting measures Mr. Harpal Singh - Director Business Development, ACG Inspection Systems Pvt Ltd.
10.30 am - 11.00 am	NETWORKING BREAK	
11.00 am - 11.45 am	QbD in Analytical Method Development Dr. Jean-Michel Plankeele - UPLC Product Manager, Waters	Cold Chain Management Mr. M. K. Vasanthkumar - Founder Director, Logtech Logistics & Systems Pvt Ltd.
11.45 am - 12.30 noon	QbD in API manufacturing covering ICH Q11 Dr. Albinus D'Sa (TBC) - Deputy Director, India Office, US FDA	Business Excellence in Supply Chain Management Prof. Himanshu Kothari - Founder Director, Syncore Group
12.30 noon - 1.15 pm	QbD based Process Validation Mr. Gordon Farquharson - Managing Director, Critical Systems Ltd	Supply chain security - Global experience Mr. Malcolm Holmes - Chartered Chemist & Consultant
1.15 pm - 2.15 pm	NETWORKING LUNCH	
2.15 pm - 2.45 pm	Q&A on the sessions so far All	Q&A on the sessions so far All

PLENARY SESSION (ALL PARTICIPANTS)

3.00 pm - 4.00 pm	Role of Quality Risk Management in QbD and Supply Chain Security	Mr. Shyam Sunder Chellamani - Technical Director, SysComm Project Management Ltd.
4.00 pm - 4.30 pm	NETWORKING BREAK	
4.30 pm - 5.00 pm	Q & A and Open Session	
5.00 pm - 5.10 pm	Vote of thanks -	Dr. A. K. Singal, Vice Chairman, ISPEIndia Affiliate & Managing Director, NNE Pharmaplan
5.10 pm	Close of conference - Day 2	

REGISTRATION FORM

ISPE India Annual Conference
On
"Quality By Design
&
Supply Chain Security & Integrity"

CONFERENCE

Friday 11th & Saturday 12th
January, 2013
Hyatt Regency, Sahar Airport Road,
Andheri East, Mumbai - 400099

Fees: For ISPE Members: INR 11,000/- Non - Members: INR 15,000/- with 1 year ISPE membership

For ISPE Student Members: INR 5,500/-

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Cheques / DD must be made payable in Mumbai to "ISPE India Affiliate"

Completed registration form with payment must be sent to:

ISPE Connecting a World of Pharmaceutical Knowledge | India Affiliate

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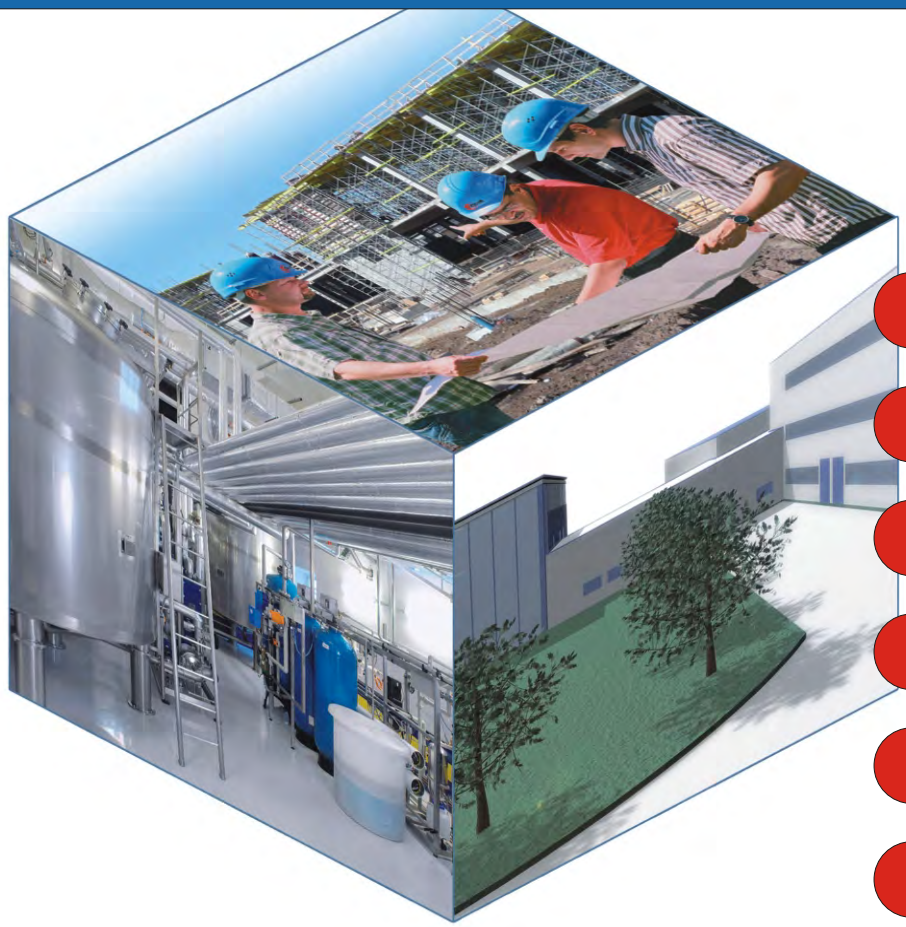

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