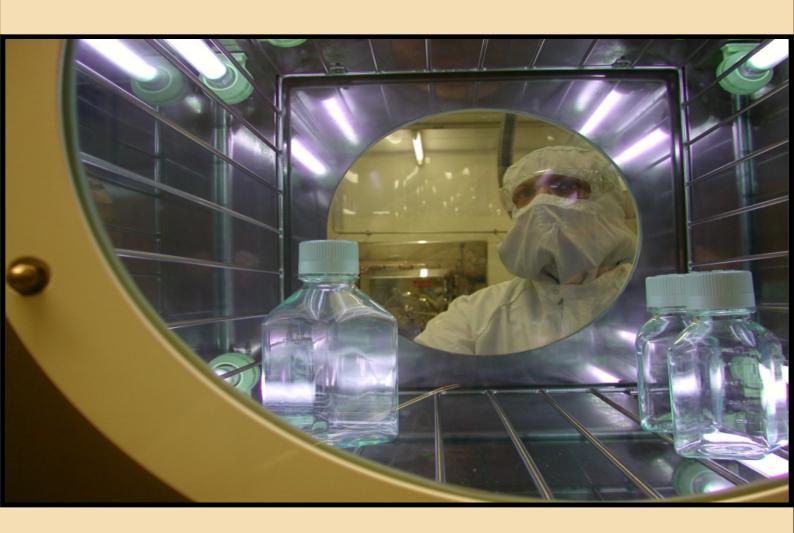


Presents Young Pharma Professionals Education Programme (YPEP)



"PERFECTING STERILE PRODUCT MANUFACTURE"

On

Saturday, 16th March, 2013 Cambay Grand, Ahmedabad

About the Conference

If sterile products are not manufactured to exacting standards and processing conditions it is not possible to maintain high sterility assurance levels. Being a high risk activity a very systematic, well planned and validated approach is required for reducing threat to patient safety during the manufacture of sterile products. Sterile Technologies are highly technology driven processes and meticulous attention is required to every minute detail during manufacture of these products.

Various steps in sterile product manufacturing process carried out in the clean rooms like filtration, blending, filling, stoppering etc. are critical to sterility assurance levels and newer technologies offer the best solutions to these critical operations. The conference will focus on current technology advancements and practices as well as current regulatory expectations. Experienced industry speakers will share their valuable experience with the participants that could generate discussions.

About ISPE

ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 25,000 pharmaceutical science and manufacturing professionals in 90 countries. ISPE aims to be the catalyst for "Connecting a World of Pharmaceutical Knowledge" by providing members with opportunities to develop technical knowledge, exchange practical experience and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE has worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; its Asia Pacific office in Singapore. Visit www.ISPE.org for additional Society news and information.

Who will benefit

Young Pharmaceutical Professionals from the field of:

- Manufacturing
- Quality Control / Quality Assurance
- Engineering Maintenance
- Research & Development
- Regulatory Affairs
- Contract Manufacturing
- Also sites manufacturing injections & sterile products on contract for Big Pharma and companies intending to contract out or manufacture sterile products in house.



CONFERENCE

Cambay Grand, Ahmedabad, Saturday,16th March 2013

AGENDA

Time	Topic	Speaker
08.30 - 09.00	Registration	ISPE desk
09.00 - 09.15	ISPE in Brief	Mr. Gopal Nair Chairman- ISPE India Affiliate & Former Technical Director, GlaxoSmithKline Pharmaceuticals Ltd, Mumbai
09.15 - 09.30	Address by Chief Guest	Dr. Hemant Koshia Commissioner, Food & Drugs Control Administration, Gujarat
09.30 - 09.40	Address by Guest of Honour	Dr. A Ramkishan Asst. Drugs Controller, CDSCO, Ahmedabad
09.40 - 10.20	What is new in Sterile Products Manufacturing	Mr. Hartmut Schaz Senior Technology Partner NNE Pharmaplan, Germany
10.20 - 11.00	Current FDA and EU requirements in aseptic manufacturing Salient features	Mr. S. G. Belapure President-Manufacturing, Cadila Healthcare Limited, Ahmedabad
11.00 - 11.20	Tea / Coffee break	
11.20 - 12.00	Sterilization Validation How critical	Ms. Premalatha Khambave Dy. General Manager - QA & RA Zydus BSV Pvt. Ltd., Ahmedabad
12.00 - 12.40	Manufacturing of high potent products	Mr. Hartmut Schaz Senior Technology Partner NNE Pharmaplan, Germany
12.40 - 13.20	Risk Assessment in Aseptic Manufacture	Mr. R. Raghunandanan Vice Chairman- ISPE India and Former Vice President, Quality, GlaxoSmithKline Pharmaceuticals Ltd, Mumbai
13.20 - 14.20	Lunch	
14.20 - 15.00	Environmental Monitoring in Aseptic Manufacture	Mr. Kapil Bhargava Secretary- ISPE India and Former Dy. Drugs Controller, CDSCO, Mumbai
15.00 - 15.40	Dealing with Sterility Failures	Ms. Trupti Bhagat Director Quality, Astral Pharmaceutical Industries Pvt. Ltd., Baroda
15.40 - 16.00	Tea / Coffee break	
16.00 - 17.00	Q & A, open session	All
17.00	Close of sessions	



For details, please contact Affiliate Manager, ISPE INDIA

1001, Dalamal House, 10th Floor, Nariman Point, Mumbai - 400 021, India. Mob.: +91-95942 00961, Tel.: +91-22-3008 9475 / 76, +91-22-3295 6800, Fax: +91-22-2204 5309

E-mail: ispeindia@gmail.com / admin@ispeindia.org, Website: www.ispe.org/india

REGISTRATION FORM

Young Pharma Professionals Education Programme (YPEP) "Perfecting Sterile Product Manufacture"

Fees: INR 3,500/-

CONFERENCE

Cambay Grand Near PERD Centre, Sola Over Bridge, Thaltej, Ahmedabad - 380 054, India.

Saturday, 16th March 2013

Name:				
Organization:				
Address for Correspondence:				
City:	Pin:	State:		
Mob Phone:	Direct Line:	Board Line:		
E Mail (at Work):	E Mail (personal):			
Payment Details: Cheque / DD No & date:				
Issuing Bank , Address & Amount :				
Cheques / DD must be made payable in Mumbai to "ISPE India Affiliate"				
Completed registration form with payment must be sent to:				





ISPE India Affiliate, 1001 Dalamal House, 10th floor, Nariman Point, Mumbai 400021

Tel: +91 22 3008 9475 / 76 Fax: +91 22 2287 2560

Terms & Conditions: After payment no refund will be given on cancellation, delegate name may be substituted with another, ISPE will not be responsible for any loss or damage, alteration or cancellation by your organization.