



Connecting a World of
Pharmaceutical Knowledge

**India
Affiliate**

*Presents One Day Seminar
On
“Pharmaceutical Water & Steam Systems”*

Thursday, July 5, 2012 at Scitech Centre, Jogeshwari, Mumbai

Saturday, July 7, 2012 at Mandovi Hotel, Panji, Goa

Monday, July 9, 2012 at Katriya Hotel & Towers, Somajiguda, Hyderabad

About the Seminar

Water and Steam systems represent one of the most critical utilities in the Pharmaceutical and Bio-tech industry. These systems are the key to manufacture of drug substances and drug products, cleaning of the equipment and manufacturing facilities for production operations. The new ISPE Baseline Guide for Water and Steam Systems has added new chapters. There are changes in monographs in Pharmacopoeias on different compendial waters including regional and local regulatory issues. "Rouge" has been buzz word with the regulatory bodies and other GMP auditors.

The above aspects in mind, ISPE India Affiliate is organizing seminars in cities of Mumbai, Goa and Hyderabad on 5th, 7th and 9th July 2012 on Pharmaceutical Water and Steam Systems with an in-depth Study.

Our resource person is Dr. Nissan Cohen, one of the principal contributing authors to The Baseline Guide for Water and Steam, USP on Water Monographs, numerous Good Practice Guides, and an authority on quality aspects of pharmaceutical water. Dr. Cohen will be addressing the audience at all the three locations and will deliberate on the activities which should take place during development of water system for pharmaceutical manufacturing operations. He will be supplying overviews of the new Baseline Guide for Water and Steam, Good Practice Guides for Ozone and Process Gases, with specific presentations on modules of Rouge, Microbials, Hot Water sanitization versus ozone, PAT, and instrumentation.

The presentations will also cover observations from a survey of Pharmaceutical Companies manufacturing WFI by means other than Distillation, Pharmacopeia differentiation, and industry applications.

By participating in this seminar one will learn about the applicable regulatory requirements are, what constitutes continued verification, how to maintain the validated state, statistical trending of microbiological aspects and review of critical data to verify proper control of water properties.

It will be therefore a valuable opportunity to listen to and meet with Dr. Nissan Cohen and have an in-depth peep into critical aspects of water for pharmaceutical use.

Speaker - Nissan Cohen

A worldwide expert in Total Organic Carbon (TOC) and in high purity, ultrapure, reclaim and recycle water systems, with profound expertise in instrumentation, automation, and organic contamination oxidation systems using ozone, UV, ion exchange and catalysts. Accomplished writer of over 30 technical articles published in Ultrapure Water, A2C2, Pharmaceutical Technology, Pharmaceutical Engineering, Semiconductor International, The Journal of the Institute of Environmental Sciences and Technology. Twice nominated for Pharmaceutical Engineering's "article of the year". Contributing author and Chapter Leader of "Baseline Guide for Water and Steam" and "Water and Steam Commissioning and Qualification Good Practice Guide" ISPE/FDA publications, member of ISPE (International Society for Pharmaceutical Engineering), Technical Editor of the Journal of the Institute of Environmental and Science Technology (IEST), Technical Reviewer of Pharmaceutical Engineering, Chairman of the Water and Steam Forum of ISPE, Founder/Chair of the Discussion Forums of ISPE, Former member of the Technical Advisory Board of A2C2 magazine. Jeopardy! Contestant aired broadcast April 14, 2006. Education: University of Wisconsin and Rupp Institute degree in Agriculture. Bilingual in English and Hebrew. Working knowledge of 5 additional languages. Member of International Standards Committees: ASTM E-55, IEST (WG 14644 Contamination Control), ASTM D-19.03, ISPE (International Society for Pharmaceutical Engineering) Steering Committee member for Communities of Practice Standards: Critical Utilities

Former Chairman of ISPE Committees: Membership Services, Publications, Pharmaceutical Engineering and Website. Former Steering Committee member of COPs: HVAC and PAT

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.



SEMINARS

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| Mumbai | July 5 | <input type="checkbox"/> |
| Goa | July 7 | <input type="checkbox"/> |
| Hyderabad | July 9 | <input type="checkbox"/> |

5th, 7th, & 9th July, 2012

| Time | Topic |
|---------------|--|
| 08.30 - 09.00 | Registration |
| 09.00 - 10.00 | Overview: Baseline Guide for Water and Steam Systems - In depth, overview of the new chapters, changes, harmonization with Pharmacopeias, and regional regulatory issues |
| 10.00 - 10.45 | Rouge Monitoring, definition, explanation, and mitigation |
| 10.45 - 11.00 | Break |
| 11.00 - 11.30 | Microbial Overview |
| 11.30 - 12.15 | Overview of The Good Practice Guide for Ozone |
| 12.15 - 12.45 | Comparison of Ozone and Hot water Sanitization |
| 12.45 - 13.00 | Discussions |
| 13.00 - 14.00 | Lunch |
| 14.00 - 14.45 | Survey of Pharmaceutical Companies manufacturing WFI by means other than Distillation, Pharmacopeia differentiation, industry applications |
| 14.45 - 15.30 | Pure steam generation/use : Regulatory and non-regulatory myths and truths |
| 15.30 - 16.00 | Tea / Coffee Break |
| 16.00 - 16.30 | Recent Regulatory Observations/citations/ 483s in pharmaceutical operations (formulation and APIs) |
| 16.30 - 17.30 | Questions and Discussions |



For details, please contact Affiliate Manager, ISPE INDIA

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REGISTRATION FORM



SEMINARS

| | | |
|-----------|--------|--------------------------|
| Mumbai | July 5 | <input type="checkbox"/> |
| Goa | July 7 | <input type="checkbox"/> |
| Hyderabad | July 9 | <input type="checkbox"/> |

“Pharmaceutical Water & Steam Systems”

Fees: Member: INR 3,000/- Non-Member: INR 4,000/- With Membership: INR 7000/-

Name: _____

Designation: _____

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

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.