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Pharma Regulatory Summit

Ahmedabad

Date: June 13, 2018

Location: Courtyard
Ahmedabad

Ramdev Nagar Cross
Road, Satellite Road.
Ahmedabad- 380015

Time: 9.00 AM to 5.00 PM

Hyderabad

Date: June 20, 2018

Location: The Westin
Hyderabad Mindspace,
Raheja IT Park, Hitec City,
Madhapur, Hyderabad-
500081

Time: 9.00 AM to 5.00 PM

Agenda

9.00 a.m.

Welcome and introduction.

9.30 a.m.

Key note lecture: Regulatory landscape in pharmaceutical industry.

Arvind Kukrety, Deputy Drugs Controller India, Central Drugs Standard Control Organization, Ahmedabad Zone

10.00 a.m.



Key note lecture: Keeping data useful and maintaining data integrity.

Sujeet Agrawal, General Manager Corporate Quality, Zydus Group
Speaker at Ahmedabad



Jayakumar A V, Senior Vice President- Corporate Quality, Ajanta Pharma Limited
Speaker at Hyderabad

10.45 a.m.

Coffee break

11.00 a.m.

Ensuring compliance for analytical data.

Kamesh Janakiraman, Product Specialist- Lab Informatics, Agilent Technologies

Rajesh Mishra, Product Specialist- Lab Informatics, Agilent Technologies

11.30 a.m.

Regulations and risk assessment in analytical method development.

Manu Grover, Sales Development Manager – Pharma, Agilent Technologies.

Paramjeet Khandpur, Application Scientist, Agilent Technologies

12.30 noon



Key note lecture: Content Uniformity Analysis using Transmission Raman: Reducing running costs for QC labs.

Steve Wood, Global Sales Manager- Raman Instruments, Agilent Technologies
Speaker at Ahmedabad



Darren Andrews, Ph.D., Head of Pharma Business- Raman Spectroscopy, Agilent Technologies
Speaker at Hyderabad

Agenda (continued)

1.15 p.m. Networking lunch

2.15 p.m.



Key note lecture: Challenges of GTI assessments and best practice for following ICH M7 guideline.
Gopal Vaidyanathan, Ph.D. , Vice President– Analytical R & D and Development Quality Assurance,
Natco Pharma

3.00 p.m.

USP <232>/<233> and ICH Q3D: Elemental impurities analysis.
Vinay Jain, Ph.D., Application Scientist, Agilent Technologies

3.45 p.m.

Comprehensive analytical workflow for the qualitative assessment of Extractables and Leachables.
Syed Latif, Ph.D., Application Scientist, Agilent Technologies

4.30 p.m.

Panel discussion

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