

Workshop for Vaccines & Biologics Right First Time– Quality in Manufacturing

23-24 March 2017 | NOVOTEL , PUNE



This interactive workshop intends to provide practical insight into Right First Time for vaccines and biologic manufacturing. The topics for deliberations are chosen across the domains of scale up, manufacturing, data review, quality risk management and quality operations. The cold chain distribution is critical in supply of vaccines & biologics and hence finds a reference point in the workshop.

LEARNING OBJECTIVE

- Understand regulatory expectations for Vaccines & Biologics
- Provide clarity on good documentation practice, review practices and cases of data integrity in Biologics & Vaccines
- Managing post approval changes based on the draft ICH Q12 in Vaccines & Biologics manufacturing.
- Practical approaches for Quality Risk Management in Vaccine and biologic manufacturing
- Learning approaches for deviation management & Investigation in manufacturing line
- Challenges of cold chain distribution

TARGET AUDIENCE

This course is for teams from Regulatory Affairs, Scale up/Technology Transfer, Manufacturing, Quality Control, Quality Assurance operations, who will benefit from the experience that speakers will share.

SPEAKERS FOR THE WORKSHOP

1. Dr. Akshay Goel

Sr. VP- Technical Development; Biological E. Ltd, India

2. Dr. Dhananjay B. Patankar

Vice President - Pharmaceutical & Biopharmaceutical Development, Syngene International Ltd, India

3. Dr. Gopi Vudathala

Executive Director & Head - Quality Advocacy, GSK Vaccines

4. Dr. Himanshu Gadgil

Chief Scientific Officer & Operational Head- Enzene Biosciences, India

5. Dr. Rajesh Kumar Singh

Dy. General Manager– Regulatory Affairs, Genova Biopharmaceuticals Ltd, India

6. Ravi B Menon

Additional Director - Production, Serum Institute Of India Pvt Ltd, India

7. Dr. Reinhard Glueck

Chief Scientific Officer, Zydus Cadila, India

8. Capt. Ricky Bithar

CEO - Absolute Cold, India

9. Swapnil Ballal

Sr. Director Quality Assurance Product Operations - Dr Reddy's Laboratory, India

CONTACT INFORMATION

For further details please contact
Biny Joseph
+ 91-9886-076-191
pdaindiachapter@gmail.com

