

## Overcoming the challenge of differing guidelines for compliance with GMP by different authorities

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Compliance to GMP is a core requirement for pharmaceutical industry. However, there are number of regulatory authorities controlling the requirement of GMP & each regulatory authority has its own GMP guideline. Hence, complying with such different guidelines is a challenge for an industry. What is GMP? How it is interpreted by the regulatory authority as well as by the inspector during inspection is also important to comply for passing the inspection. What is the approach industry should take for addressing this challenge to comply with the requirement and not going in conflict with the authority/inspector?

Following will be discussed during the presentation:

- An overview of different regulatory guidelines & their implications on your business
- Interpretation by Regulatory authorities/inspectors
- What is GMP?
- How do inspectors interpret GMP?
- Tips and techniques to address and overcome the challenge of differing interpretation of guidelines for complying with GMP

### Biography

Mithilesh Trivedi has completed his Ph. D. from UDCT (presently known as UICT), Mumbai. He is awarded Fellow of Indian Chemical Society. He has over 28 years of extensive experience in the area of Research & Development, Quality Assurance & Quality Control, and Manufacturing & Operation in Chemical; Fine Chemical; Nutraceuticals; Bulk Drugs and Formulation Industries. He also has extensive experience in product development, process optimization & control, standardizing production norms, GMP, GLP and supplier technical assurance. Mithilesh has also experience in Sterility Pyrogen including BET (LAL Test) and Toxicity Testing and he ensured compliance of various quality measures by maintenance of appropriate requisite documentation/ records. He has successfully handled number of different regulatory inspections and also audited number of sites in India and China. He is also a visiting faculty for Bachelor & Master of Pharmacy for different University & Colleges. He is member of different bodies of Bombay College of Pharmacy, Mumbai. He has attended number of National and International Conferences as participant as well as speaker. He is past President for IPA (Indian Pharmaceutical Association) Branch & presently as Committee Member. He was also Vice Chairman for Technical and R & D Committee for IDMA (Indian Drug Manufacturer's Association).

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