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From a training perspective: What does the FDA look for during an inspection?

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Target Audience: Anyone involved in training within the pharmaceutical industry.

Session Description: The purpose of this session is to uncover and present the key factors the regulatory agencies looks for during an inspection or audit of a pharmaceutical manufacturing facility.

Attendee Learning Objectives: At the end of this session, participants will be able to:

1. State the training related reasons drug manufacturing facilities fail FDA inspections/audits.
2. Identify key training areas the FDA looks at during an inspection/audit.

Design Rationale and Format: This is to be a facilitated group discussion with workshop attendees sharing their own regulatory nspection/audit experiences. In this way, we will have a shared experience is ensured, gathering inspectio/audit information from all session attendees.

Benefits: Participants will leave with checklist that can be used for preparing for a regulatory Inspection/audit.

Biography

David Gallup is a frequent speaker at both regional and national GMPTEA and PDA conferences. Dr. Gallup has 25+ years experience as an instructional designer. His experience includes: conducting training audits and designing, developing and implementing compliance training plans and programs. Projects include working with pharmaceutical manufacturers cited by federal or international regulatory agencies to audit training, develop compliance training plans, and support the implementation of compliance training strategies.

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