PLA 3.0 SUPER USER TRAINING

CONTENT

The training concept is modular and the agenda depends in some parts on the needs of the attendees.

- Introduction to PLA 3.0
  General introduction into the capabilities of PLA 3.0 and the basic concepts
- What has changed from PLA 2.x?
  If users of PLA 2.x are present in the training, the major differences between versions will be explained.
- Basic Operations
  Day-to-day operations within the PLA system from an operator and administrator perspective
- Capabilities (Document Types)
  Analytical capabilties of the system in terms of Quantitative Response Assays, Dichotomous Assays (optional), Equivalence Margin Development for the support of the USP <1032>, Control Charting, Combination Calculation for the calculation of reportable values and Basic Bioassay Protocol. Measurement Documentation capabilities of the system.
- Advanced Operations
  Operations and capabilities beyond the day-to-day operations, e.g. Raw Data Traceability features, Audit Trail
- Workflow Support
  Template System and Basic Bioassay Protocol to support integrated runs for reportable values
- Template Generation
- Setting up complex assays
  Definition and protection of templates, efficient template generation
- Statistical Aspects
  Statistical capabilities of Quantitative Response Assays and Combination Calculations within PLA 3.0
- IT Administration
  Optional: How to setup and manage PLA 3.0. Active Directory Integration, User and Security Management.
- Validation
  Configuration Item List, 21 CFR Part 11 Compliance, Audit Trail, Installation Qualification, Operational Qualification, Performance Qualification

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