USDM | Simplify, Unify, Optimize

Webinar Series

Guidelines for Good Laboratory Practices

Presented by
Diane Gleinser
Vice President Operations USDM

This PDF is generated automatically by Vizle.

Slides created *only for a few minutes* of your Video.

For the full PDF, please Login to Vizle.

https://vizle.offnote.co (Login via Google, top-right)

Stay connected with us:

Join us on Facebook, Discord, Quora, Telegram.

Introductions

- **Diane Gleinser**
  - Vice President Operations at USDM
  - 11 years with USDM
  - 23 years in Life Sciences
  - Background in GLP Laboratories, Manufacturing, Analytical Chemistry, Quality Control, Quality Assurance, Validation, Auditing, Project Management, Regulatory Compliance
  - Leads USDM's Laboratory Practice Group
  - Among her many accomplishments Diane has;
    - Presented on many compliance and regulatory subjects worldwide, including most recently the risk based validation methodology.
    - Led Audit teams for IT compliance, regulatory compliance, Vendor Audits
    - Expert in risk-based validation methodologies, GAMP, lab system implementations and validation, and overall Pharmaceutical and Medical Device regulatory issues
    - Worked with small, medium, and large Life Sciences firms worldwide and is a recognized leader in he field.

USDM At a Glance

- Focused exclusively on the life science domain
- Market leader in providing IT, Quality & Regulatory Compliance professional service solutions to the heavily regulated Life Science industry
- Headquartered in Ventura, CA
- Compliance partner for many best-of-breed vendors including Agilent, Sparta Systems (TrackWise), OpenText ECM, Oracle and SAP
- Proven track record – successful projects with over 130 life science clients
- Preferred Compliance Partner for small, mid-tier and large Life Science companies alike

USDM's Other Practice Areas:

- IT & Virtualization
- Quality and Auditing
- Nutraceuticals 21CFR Part 111
- Enterprise Content Management (ECM)
- Enterprise Resource Planning (ERP)
- Product Lifecycle Management (PLM)
- Enterprise Quality Management
- Manufacturing Automation and Equipment
- Laboratory Systems and Equipment
- Clinical and Drug Safety
- Business Intelligence
- Project Management
- Governance, Risk & Compliance (GRC)

Webinar Logistics

- Webinar is 30 minutes in duration.
- We invite you to enter questions in the chat area during the webinar. They will be addressed immediately following the presentation.
- Webinar recording will be available on USDM's website: **www.usdatamanagement.com**
- Discuss this webinar on LinkedIn: **http://www.linkedin.com/groups?home=&gid=2226293**
- Contact us following the webinar: **(rmeledy@usdatamanagement.com)**

Agenda

- GLP Overview
- GLP Applicability
- Basics and Key Requirements for Good Laboratory Practices
- Failure to Comply

Vizle

GLP Overview

- The GLPs are formal regulations (i.e., laws) governing the safety and efficacy of human and veterinary drugs and devices and the safety of food and color additives created by the FDA (US Food and Drug Administration) in 1978 (final rule). [21CFR Part 58]
- GLPs have a world wide impact.
- Non-US companies doing business with the US or registering their pharmacies in the US must comply with GLP regulations.
- In 1981 OECD (Organization for Economic Co-operation and Development) produced GLP principles that are international standard. [Directive 2004/10/EC]

USDM Simplify, Unify, Optimize

GLP Overview

- Until mid 1970's reports submitted by sponsors to regulatory agencies (FDA, EPA) were considered by that agency to be largely accurate.
- 1975: FDA inspected Searle Laboratories, whose facilities conducted toxicology testing:
  - Sloppy work
  - Untrained personnel
  - Poor data collection and analysis
  - Omission of test results
  - Inadequate review of data and reports
- Good Laboratory Practice developed and distributed for voluntary compliance

Vizle
USDM Simplify, Unify, Optimize

GLP Overview

- 1975 – 1978: Biometric Testing Inc. and Industrial Bio-Test
  - Falsification of test procedures and data
  - Fraudulent reporting of test results
  - Inadequate environmental control
  - Poor animal tracking rendering study data unusable
  - Dead animals unaccounted for
- 1978 GLP promoted to law (21 CFR Part 58)

Vizle
USDM Simplify, Unify, Optimize

This PDF is generated automatically by Vizle.

Slides created *only for a few minutes* of your Video.

For the full PDF, please Login to Vizle.

https://vizle.offnote.co (Login via Google, top-right)

Stay connected with us:

Join us on Facebook, Discord, Quora, Telegram.