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EVENTS LIST

Governance and Change Control according to GxP and GMP Requirements (com) A

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Organizer : NYMT

Venue :

Location : TBASan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 94102

Governance and Change Control according to GxP and GMP Requirements

GxP/GMP regulations are required to be used in regulated industries such as food and beverages, pharmaceutical, medical devices, and cosmetics.

Documentation is a critical tool for ensuring GxP/GMP compliance. In order to maintain documentation in GxP/GMP compliant manner, information governance should be developed and implemented.

Change control within quality management systems (QMS) and information technology (IT) systems is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. In the regulated industries, manufactures are required to use a change control procedure.

Data security is the high priority in any organization but especially in a regulated industry. E-Discovery preparedness makes it imperative for organizations to develop an enterprise wide strategy to manage the volume of electronic information. The discovery process affects many individuals in an organization, not just lawyers and others involved in discovery, but also IT professionals and records managers who have to be prepared to produce electronic content for discovery and litigation.

Crisis preparedness is the high priority in any organization but especially in a regulated industry.

With all systems in place, change management and user adoption become necessary.

In this seminar, you will learn the framework of GxP/GMP regulations, information governance procedures as well change control procedure and how to implement them.

You will also learn how to implement data security, e-discovery and crisis preparedness as well as change management and user adoption strategies.

Learning Objectives:

- Do you know how to properly manage and govern your documentation so that your organization is GxP/GMP compliant?
- Learn how to manage and govern documents as well as IT systems in compliance with GxP/GMP requirements and be able to pass quality audit.
- Is your organization ready for e-discovery and do you have crisis preparedness in place? Do you have change management and user adoption strategy?
- Learn how to secure your date, prepare for e-discovery and crisis, and how to develop and implement change management and user adoption strategy.

Areas Covered:

- GxP/GMP, its Role, and its Consequences for the Regulated Industries
- What is Information Governance?
- Information Governance Procedures
- Information Governance Implementation
- Information Governance in Document Management Systems
- Social Media Management and Information Governance
- GxP/GMP and Change Control Procedure
- Change Control Procedure Steps
- Change Control Procedure for Document Control
- IT Change Control Procedure Steps
- Data Security Implementation
- What is E-Discovery?
- E-Discovery Preparedness
- What is Crisis Management?
- Crisis Management Preparedness
- Change Management Strategy
- User Adoption Strategy

Who will Benefit:

- Quality Assurance
- Documentation Managers
- Records Managers
- Document Control
- Compliance
- Medical Affairs
- IT/Software
- Manufacturing
- Clinical
- Lab

AGENDA

DAY 01(9:00 AM - 4:30 PM)

- 9:00 AM - 9:30 AM: Registration, Meet & Greet.
- 9:30 AM – 11:00 AM: Session 1: GxP/GMP Framework (90 Mins)
    - Seminar objectives review, expectations and scope.
    - GxP/GMP, its Role, and its Consequences for the Regulated Industries
- 11:00 AM - 12:30 PM: Session 2: Information Governance (90 Mins)
    - What is Information Governance?
    - Information Governance Procedures
    - Information Governance Implementation
    - Information Governance in Document Management Systems
    - Social Media Management and Information Governance
- 12:30 PM - 1:30 PM Lunch
- 1:30 PM - 3:00 PM: Session 3: Change Control Procedure (90 Mins)
    - GxP/GMP and Change Control Procedure
    - Change Control Procedure Steps
    - Change Control Procedure for Document Control
- 3:00 PM - 4:30 PM: Session 4: Change Control Procedure for Information Technology (IT) Systems (90 Mins)
    - IT Change Control Procedure Steps

DAY 02(9:00 AM - 4:30 PM)

- 9:00 AM - 9:30 AM: Registration, Meet & Greet.
- 9:30 AM - 11:00 AM: Session 1: Data Security (90 Mins)

    - Data Security Implementation
- 11:00 AM - 12:30 PM: Session 2: E-Discovery (90 Mins)
    - What is E-Discovery?
    - E-Discovery Preparedness
- 12:30 PM - 1:30 PM Lunch
- 1:30 PM - 3:00 PM: Session 3: Crisis Management (90 Mins)
    - What is Crisis Management?
    - Crisis Management Preparedness
- 3:00 PM - 4:30 PM: Session 4: Change Management and User Adoption (90 Mins)
    - Change Management Strategy
    - User Adoption Strategy

SPEAKER

Eleonora Babayants,
Founder and President, Galaxy Consulting

Eleonora Babayants - Founder and President Galaxy Consulting, is a documentation management professional and hands-on consultant with over 25 years of experience in documentation and records management, document control, regulatory compliance, internal and external auditing, electronic document management systems, information governance, and change management.

Eleonora's past work includes development and implementation regulatory compliance processes and procedures, leading implementation and administration of document control systems in full compliance with regulatory requirements, enabling enterprise search, improving systems information architecture, creating and implementing users training programs.

She led electronic document management systems selection and deployment, administered and supported these systems, web information portals, knowledgebase applications, recommended and implemented re-structuring of the content and the information architecture of these systems. She worked very closely with IT to do feasibility assessment and to capture users' requirements. She wrote technical documents and created documents templates.

Eleonora's experience spans multiple industries including biomedical, pharmaceutical, medical devices, food and beverages companies.

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