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GxP/GMP and its consequences for documentation and information technology systems

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Documentation is a critical tool for ensuring GxP/GMP compliance. This is what GMP states about document control: each manufacturer shall establish and maintain procedures to control all documents that are required. In the regulated environment which must be GxP/GMP compliant, document control is the cornerstone of the quality system. It is so important that if an external audit identifies deficiencies in the document control system, the entire organization can be shut down. There are also GMP requirements for information technology. For a drug to be produced in a GxP/GMP compliant manner, some specific information technology practices must be followed. Computer systems involved in the development, manufacture, and sale of regulated product must meet certain requirements. In the regulated industries, manufactures are required to use a change control procedure. In this workshop, we will discuss the connection between GxP/GMP and document control. We will describe details of document control procedures and the role of Quality Assurance in the documentation systems. We will review GMP requirements for information technology and how computer systems including documentation management systems must meet GxP/GMP requirements. We will also review change control procedure and how it should be used in GxP/GMP environment.

Biography

Eleonora Babayants is the Founder and President of Galaxy Consulting and she 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. Her 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 has worked very closely with IT to do feasibility assessment and to capture users' requirements. She wrote technical documents and created document templates. Her experience spans multiple industries including biomedical, pharmaceutical, and medical device companies.

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