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Quality management and quality audit according to GxP/GMP requirements

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GxP/GMP regulations are required to be used in regulated industries such as food, pharmaceutical, medical devices, and cosmetics. GMP regulations describe required quality management system for production and testing of products in these regulated industries. The purpose of the GMP regulations is to ensure that a product is safe and meets its intended use. Quality management system ensures that a product is safe and meets its intended use. Quality management system has four main components: Quality planning, quality assurance, quality control, and quality improvement. Quality audit is the process of systematic inspection of quality management system which is carried out by an internal or external auditor or an audit team. It is an important part of organization's quality management system and is the major part of GxP/GMP regulations. In this keynote speech, the framework of GxP/GMP regulations, quality management system, and quality audit will be described.

Biography

Galaxy consulting founder and president Eleonora Babayants is an information 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.

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