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According to the ISO/IEC Guide 51, the quality management system should be managed using a key aspect of the quality management system that addresses the critical areas, that is, hazard prevention and control, risk assessment, material control, organizational and procedural controls, analysis and review, assurance, and quality control. ISO/IEC Guide 51.2-2003 mentioned that the implementation of the quality management system in the organization includes risk assessment, risk analysis, risk assessment, risk management, improvement plans, risk control plan, risk analysis plans, environmental health and safety, physical and environmental health and safety, quality management, good manufacturing practice (GMP), and GMP guidelines for drugs. ISO/IEC Guide 51.2-2003 mentioned that the definition of the quality management system by ISO 9000:2000 is the process of implementing or improving a quality system which is the key to implementing the quality management system. The ISO 9000:2000 quality management system is a system which includes a set of rules, procedures, plans, and methods to ensure that quality in the products or services provided by the organization is consistent throughout the process, that customer needs and requirements are properly met, and that risks are adequately managed. According to ISO/IEC Guide 12207-2004, the overall goals of the quality management system are: “to ensure that the goals of the quality management system (QMS) are achieved within the organization. QMS is defined as a system to organize, develop, implement, and continually improve the quality of products and services, so that they meet relevant customer needs and expectations, are fit for use, conform to requirements, provide value for money, and lead to profitability and sustainability”. The overall objectives of the quality management system include: (1) *implementation of GMP and GMP guidelines* for drug products (2) *developing processes and systems* for drug products (3) *implementation of quality management system standards* for quality management systems (4) *developing and implementing quality management* for nonmedical devices and (5) *quality management to ensure quality of the products and services* that are provided by the organization. 3. Quality Management System Standard (QMSS) {#sec3} ========== ISO 9001 is a product-oriented international standard that was first published in 1986. It was developed by the International Organization for Standardization (ISO) and is primarily aimed at manufacturing organizations. The standard specifies the quality management system 82157476af

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