Q9(R1) Quality Risk Management

Guidance for Industry

May 2023
ICH-Quality

This guideline provides principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality. These aspects include development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substances, drug (medicinal) products, biological and biotechnological products (including the use of raw materials, solvents, excipients, packaging and labeling materials in drug (medicinal) products, biological and biotechnological products).

The purpose of this document is to offer a systematic approach to quality risk management that leads to better, more informed, and timely decisions. It serves as a foundation or resource document that is independent of, yet supports, other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the pharmaceutical industry and regulatory environment. It specifically provides guidance on the principles and some of the tools of quality risk management that can enable more effective and consistent risk- based decisions, both by regulators and industry, regarding the quality of drug substances and drug (medicinal) products across the product lifecycle. It is not intended to create any new expectations beyond the current regulatory requirements.

An understanding of formality in quality risk management may lead to resources being used more efficiently, where lower risk issues are dealt with via less formal means, freeing up resources for managing higher risk issues.

To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

TQS can assist you with your medical device quality management system. See our transition workbook and the 13485 internal auditor training products.

TRANSITIONING – 21 CFR 820 TO ISO 13485:2016

Do you need to get certified to ISO 13485:2016? Do you need to transition from 21 CFR 820 to ISO 13485:2016? The TQS 50-page Transition workbook will provide you with everything you need. The workbook is a crosswalk of the two standards, it provides you with the similarities, the differences and world class recommendations on how to comply with both standards. The transition is designed to save you time and money.

ISO 13485 Overview & Internal Auditing

What You Will Learn:

This one-day course will provide you with a detailed overview of the ISO 13485 requirements. It is also designed to prepare you to conduct internal audits to the ISO 13485 Standard.

Overview: - Following the overview of each requirement, examples of how to comply with the requirement are provided. These examples include the records that an auditor will look for during a registration or internal audit. Following each section are audit scenarios where you are asked to determine if the organization complies with the ISO 13485 requirements. Each scenarios section is followed by the answers. This will enable you to practice what you have learned.

Internal Auditing: - Once you have completed the requirements section, you will learn the basics of auditing including the right questions to ask during an interview, proper interviewing techniques and the tools of auditing. This section includes the auditor and lead auditor responsibilities and how to participate as an audit team member.

Once you have completed the course, you will be provided with an Internal Auditor training certificate