



INTEGRATED QUALITY RISK MANAGEMENT

From operational tool to decision-making support

PTM Consulting is a leading company for its risk management approach methodology as a fundamental theoretical base for every activity . The INTEGRATED QUALITY RISK MANAGEMENT approach, developed by Ptm, transformed the concept of QRM from a simple operational tool to a strategic tool to support decision-making processes. Starting from practical applications, Quality Risk Management (QRM) has gradually taken on an increasingly integrated character within companies to identify product and / or process risks; PTM R&D department is creating new

organizational and strategic tools suitable to expand QRM concepts also in other business areas. This evolution of the QRM was highlighted by the inclusion of the ICH Q9 as a constituent part of the GMPs. This step started a real evolution reflecting the increasing importance that Quality Risk Management (QRM) achieved over the years within pharmaceutical companies as a systematic process to evaluate, control and communicate the risks associated with quality of the product.



iqrm



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ICH Q9

INTEGRATED QUALITY RISK MANAGEMENT

A decision-making tool supporting project management

PTM provide its clients the support for using Risk Management as a strategic tool to benefit decision-making processes, gaining an exhaustive and complete perception of risk and evaluation scientific and business aspects. The PTM approach to Risk Management is HOLISTIC: a risk management strategy is formulated for every aspect

quality, development, production, including all the different levels of the company. With systemic methodologies PTM helps companies define and share key risk management information throughout the entire product life cycle from research and development to production.



INITIATE QUALITY RISK MANAGEMENT PROCESS



RISK ASSESSMENT

- Risk Identification
- Risk Analysis
- Risk Evaluation



RISK CONTROL

- Risk Reduction
- Risk Acceptance



OUTPUT / RESULT OF THE QUALITY RISK MANAGEMENT PROCESS



RISK REVIEW

Review Event





INTEGRATED QUALITY RISK MANAGEMENT

IQRM system advantages

Combining a formalized risk management process with an existing Quality Management System (QMS) to form an Integrated QRM is an important strategy to:

- ✔ Improve quality by tracking and resolving issues upon early identification;
- ✔ Booster business goals by reducing investment in the two separate systems: QMS and a risk management process;
- ✔ Reduce costs associated with non-quality related products by mapping out a way to handle issues before they arise and thus have a better likelihood of avoiding the risk altogether;
- ✔ Share information about product knowledge and decision making processes, therefore accelerating product development, manufacturing and time to market;
- ✔ Ensure compliance with regulatory bodies and demonstrate an ability to deal with and mitigate potential risks;
- ✔ Deliver a high quality product to the patient.

IQRM

MAIN CORE SERVICES

- Risk Analysis, Risk Review, Risk Management Guidelines and SOP
- System Compliance Strategy & Remediation According to Data Integrity
- RM for Change and CAPA Deviations
- RM for Cleaning / Utilities and Cross Contamination