



Risk Management Services



Defensible Solutions for Compliance with ISO 14971:2019 and the Quality System Regulation

- Recent changes in the international standards governing the risk management have made the process much more prescriptive, requiring a change in the approach to risk management.
- Companies are forced to develop new methods for planning, implementing and reporting on risk management activities.
- Risk planning needs to take into account information from the following sources:
 - Risk Acceptability
 - Production
 - Post Production
- Residual risk must be assessed for each risk as well as the product overall.
- The benefit of the product is to be weighed against the product risk.

CCS can help you with practical and defensible compliance solutions for Risk Management.

- Procedures for Risk Management
- Library of risk management templates Including:
 - Risk Management Plan
 - Hazard Analysis (e.g. FMEA, FTA, HACCP...)
 - Benefit-Risk Analysis
 - Risk Management Report
- Checklist for General Safety and performance Requirements (GSPR)
- 14971 Risk Management Checklist
- Example Benefit-Risk Analysis Report in compliance with ISO 14971:2019, includes TR 24971:2020 recommendations

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