

Medical Device Manufacturer

Improve Compliance With ISO 14971

Client Situation

- Risk Management Phases and activities not consistent with ISO 14971.
- Information is repeated, traceability is difficult between SOPs.
- Risk acceptance criteria do not place enough emphasis on business risk.
- Responsibilities not clear between departments.
- Risk assessment applications, departmental outputs, and risk interpretation inconsistent.

Client Strategic Objectives

- Compliance with ISO 14971.
- Improve customer satisfaction and retention.
- Improve regulatory compliance.
- Improve product launch process.
- Reduce business risk.
- Reduce non-conformances.

Key Issues and Internal Barriers

- Resources, workload, time constraints, and lack of expertise
- Lack of risk guidance in SOPs.
- Product development process not robust enough to identify all product hazards.
- Decisions for managing risk were made at multiple levels which is inconsistent with industry standards.

Key Program Components

- Redesign SOPs consistent with ISO 14971.
- Develop departmental responsibility guidelines.
- Revise data forms to include all relevant information used by the customers for risk management.
- Develop training programs for and train:
 - Risk Management Facilitators
 - FMEA Facilitators
 - Incident Investigation Facilitators
- Revise the Risk Acceptance Criteria to align with the customers' criteria.
- Develop a system of proactive triggers for hazard identification – i.e., process mapping and FMEA.
- Review the historical risk assessment files to identify improvements.

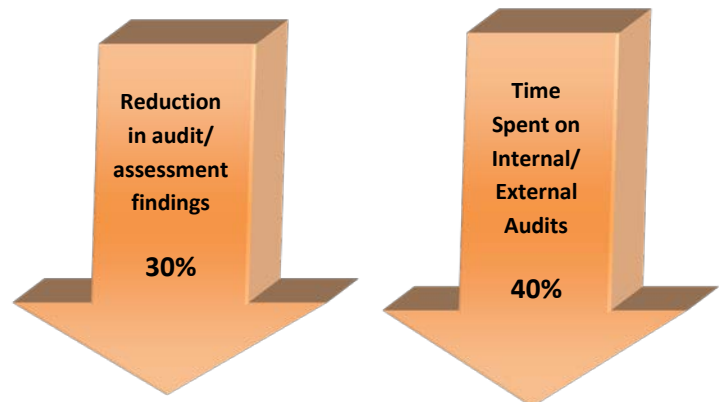
Results

- Aligned new SOPs with ISO 14971 with emphasis to manage risk at the Harm level.
- Trained and coached Risk Management Facilitators.
- Developed Value Stream map for the Product Design Process.
- Trained and coached FMEA Facilitators.
- Applied FMEA to the product development process, identifying potential risks for new product launches.
- Applied FMEA to current processes, identifying sources of problems that could result in non-compliance.
- Redesigned risk assessment files to meet the current standards with an on-going review to identify and address gaps in the Assessments.

Improvements

- Reduction in audit/assessment findings.
- Reduction in costs and time spent for internal/external audits and investigations.
- Improved reputation among stakeholders – partners, customers, and regulators.
- Increased client confidence and retention.

Projected Benefits:



Client Satisfaction

- Client has retained Malcom for additional services in improving Risk Management Maturity level: on-going follow-up, review, program implementation, and continued coaching of Facilitators.