Product Cycle Improvements/ Medical Devices

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Product Cycle Improvements

- Quality Management System
  - Provides a framework to meet various regulations and standards.
    - Quality System Regulation
    - ISO 9001
    - ISO 13485

QUALITY MANAGEMENT SYSTEM

- Determines the regulatory culture and mindset of the organization.
- Sometimes it is a paperwork exercise rather than a management tool.
- Allows for flexibility within an organization.
- Should cover all aspects of the Quality System Regulation.

Management Culture

- The Quality Management System must be developed throughout the entire organization.
- It must be a part of the day-to-day operating philosophy.
- Each employee must buy-in and contribute to the system for it to be successful.
- Feedback must be encouraged at all levels of product life cycle and production.

INTEGRATED FEEDBACK

- A proper managed system integrates many programs:
  - Risk Management Program
  - Risk Communication
  - Design Controls
  - Production and Process Controls
  - Monitoring
  - Verification and Validation
  - Corrective and Preventive Actions

INTEGRATED FEEDBACK

- Facilities
- Supplier Controls/Vendor Audits
- Cleaning and Sanitation
- Training
- Personal Hygiene
- Hazardous Materials Handling
- Consumer Complaint Handling
- Distribution
- Traceability and Recall

CONTINUOUS UPWARD SPIRAL

- Each cycle of production and review should result in an improved product and process.
- Each of the integrated elements must provide continuous feedback to the Quality Management System.

CONTINUOUS UPWARD SPIRAL

- Research and Development
- Design stages (Premarket)
- Production
- Distribution
- Use (Postmarket)
- Customer feedback
- Audits

HOW IT SHOULD WORK

- Report of a failure:
  - Appropriate Risk Management Tool Evaluation for prevention?
  - Root Cause Analysis
  - Product or component failure?
  - Was the failure expected?
  - Shelf-life for the component?
  - Increase in failure rate?
  - Could the manufacturing process cause the failure?

HOW IT SHOULD WORK

- Is a design change needed?
- Component or raw materials specification?
- Purchasing controls/vendor audits?
- Monitoring?
- Are proper controls in place?

OPPORTUNUITY

- Each failure is an opportunity for improvement!
- Use each product cycle to enhance your operation!
- Negative findings and feedback is positive for your continuous upward spiral!
- The minimum is not good enough!
- GO BEYOND COMPLIANCE!

Summary

- The Quality Management System must prescribe to the product and process level to be successful.
- Organizational programs must integrate.
- Culture must change within the organization.

Thank you

- Questions

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