



RCA Case Study

Product
Development

Risk Management in
Product Development and
Manufacturing

Background

A global manufacturer of pharmaceutical and medical devices needed to better integrate risk management throughout the product life cycle. FDA had noted issues with risk management among a list of 483 observations. Additionally, standardization of the product development process (PDP) across multiple businesses and global locations was needed.

Challenge

Regulatory Compliance Associates, Inc. (RCA) was requested to write new PDP procedures that would apply to both drug and device developments. These procedures needed to be comprehensive, yet flexible to be usable for design changes, line extensions, and OEM manufacturing.

Approach

RCA provided subject matter experts in Product Development and Quality System Regulations and wrote a portfolio of over ten new procedures and thirty templates. Training was provided to client locations in the US and Europe.

Result

The new PDP process was implemented and risk management was integrated in the following ways:

- Risk Management Planning is a part of Design & Development Planning
- Risk Analysis is an input to Verification and Validation test planning
- Risk Analysis via Process FMEA is required for OEM business
- Risk Reports and Risk Benefit Analysis are inputs to Final Design Review
- Risk Analysis and Reports reviewed periodically based on internally generated data and data received from customers (i.e. complaints)

References

1. Code of Federal Regulations (CFR) – Title 21, Parts 820.30 – Design Controls
2. FDA Guidance, “Design Control for Medical Device Manufacturers” 3-11-97
3. FDA Guidance, “Q9 Quality Risk Management” June - 2006
4. ISO 14971 (2007) - Application of Risk Management to Medical Devices

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