FOCUS
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RISK MANAGEMENT

Focus Compliance and Validation Service's personnel understand implementation of risk management in the medical device and pharmaceutical industries. They have the knowledge, understanding, and experience to implement risk management tools to various aspects of your project; from planning and design to process improvement to root cause analysis and corrective and preventative actions.

PUBLICATION

Focus personnel authored a contributed chapter on risk management tools for the book, *Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing, First Edition*. This book covered risk management techniques and discussion of many risk management tools including:

- Fault tree analysis (FTA)
- Hazard operability analysis (HAZOP)
- Hazards analysis and critical control points (HACCP)
- Failure modes effects analysis (FMEA) / Failure modes effects criticality analysis (FMECA)
- Preliminary hazard analysis (PHA).

This book was published in 2012.

TRAINING

Focus CVS has presented training on risk management techniques in several venues. Focus CVS personnel prepared and presented a three day training program on Quality Risk Management for a major biopharmaceutical manufacturer and provider. Additionally, Focus CVS personnel have been involved in preparing and presenting web seminars on risk management and particularly for computer systems and software.

RELEVANT PROJECTS

Focus CVS personnel have performed FTA to assess compliance, led HAZOPs for processes and changes to processes, used the 5 why and Fishbone (Ishikawa) Diagram to assess root cause in investigating non-conformances under facility CAPA procedures, and implemented FMEA and PHA risk analysis. Typical methodology for Focus CVS computer validation projects is to conduct a risk assessment early in the process to drive the identification of hazards and mitigations in order to tailor the validation process to assure the software requirements with the most potential for harm are thoroughly evaluated to minimize the overall system risk.

REFERENCES

Focus CVS personnel are familiar with a number of relevant industry reference documents:

- *Risk management – Principles and guidelines, ISO 31000*
- *Risk Management - Risk Assessment Techniques, ISO /IEC 31010*
- *Medical devices — Application of risk management to medical devices ISO 14971*
- *Quality Risk Management Q9*