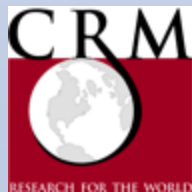




Regulatory Forum Webinar

October 21, 2009

sponsored by



CLINICAL RESEARCH MANAGEMENT, INC.

Today's Agenda

- Intro by Matt Schutte, BioOhio
- Purchasing Controls
 - Laureen Geniusz - FDA Investigator
 - Laura Green, REU Associates Inc.
- Risk Management and Corrections & Removals
 - Donna M. Haire - Director, Quality, Regulatory, Clinical & Standards Philips Healthcare - Imaging Systems
 - Holly Wright Lee - Senior Manager Quality Assurance and Regulatory Affairs, Philips Healthcare
- Concluding Remarks and Q&A



Quick Overview

- BioOhio's 5th webinar... educate and connect
- Free... thanks to our sponsor
 - Clinical Research Management, Inc. (www.clinicalrm.com)
- Participation and interaction is encouraged
 - “raise your hand” if you'd like to ask a question via phone
 - Type in a question on your webinar dashboard
- The webinar is being recorded and will be on the BioOhio web site tomorrow



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Purchasing Controls

- **Control of Suppliers and Contract Manufacturers is still a key issue with the Agency.**
 - **Manufacturer's Supplier qualification procedures are not being followed**
 - **Contract manufacturers are accepting manufacturing without clearly defined requirements**
 - **FDA is increasing scrutiny of contracts between manufacturers and suppliers**

Purchasing Controls

- **Does FDA have the authority to inspect contract manufacturers who are not required to register?**
- **What constitutes a finished device?**
- **Is risk assessment being considered during supplier qualification?**

Purchasing Controls

- **Should manufacturers provide contractors their design FMEAs?**
- **Contract Manufacturers can only make changes that are “contractually” agreed upon.**

Purchasing Controls

- **Contract manufacturers should be included on the manufacturers annual internal audit schedule.**

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Risk Management Post Market

ISO 14971

Risk Management: ISO 14971

- **ISO 14971**
 - **Excellent model for implementing Risk Management requirements into your Quality Management System (QMS)**
 - **Recognized by the FDA and other countries**

- **It enables you to:**
 - **Control the risks of your device**
 - **Address problems quickly and effectively**
 - **Make your QMS a complete approach to quality**

- **It does not:**
 - **Provide acceptable risk levels**
 - **Specify a life-cycle model**
 - **Tell you what tools you need to apply**
 - **How to design your device**

Risk Management:

Post Market Data Collection and Evaluation

“Closing the Loop on the Risk Management Process”

- **Ensure a process/procedure is in place for collecting and reviewing information gained in the “post market” phase for product safety risk in the field**
 - **Process should include:**
 - **Evaluation of data such as CAPA/adverse event reporting/customer complaints/regulatory authority notifications/new or revised standards**
 - **Evaluation of “publicly” available information about similar devices on the market**
 - **Sources of information: FDA Website, News Articles (e.g. AdvaMed SmartBrief, FDA News, The Gray Sheet etc.)**
 - **Changes in state-of-the art**
 - **Initiation of new or revised mitigations or control measures if required**
 - **Document in a Risk Management File**
 - **Transfer knowledge back into the Design Phase**
 - **Include in Management Review**
 - **Establish performance measurement criteria**

Risk Management: Risk Evaluation

- **Best Practices:**
 - **Define the policy for determining acceptable risk**
 - Key to an effective risk management system
 - Gets everyone on the same page
 - Can/must accommodate the state-of-the art
 - **Reduce both acceptable and unacceptable risks to the lowest possible level**
 - **Evaluate the overall “residual risk” acceptability of the product once all risk control measures have been implemented and verified**
 - Ensure that the risk controls used to mitigate single risks do not result in additional overall risk
 - **Risk/Benefit Analysis**
 - **If further risk mitigation is not possible or does not result in an acceptable risk, a risk/benefit analysis can be conducted to determine if the benefits outweigh the risks**
 - Senior management review and approval
 - Documented rationale

Risk Management: Health Hazard Evaluation (HHE) Harmonization

■ Best Practices:

- **HHE is used to analyze and document the risk associated with affected devices**
 - Need to determine “triggers” for when to conduct an HHE
 - Determine how this ties in with the “field action decision” when applicable
- **Standardize the HHE/Risk Evaluation Process:**
 - Terminology
 - Severity Levels
 - Probability Levels (e.g. Quantitative vs. Qualitative)
 - Similar Hazards/Hazardous Situations across Product Lines
 - Top Level Management Review and Approval
- **Leverage FDA HHE Form**
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRRegulatoryAssistance/ucm126206.htm>

Corrections and Removals

21 CFR Part 806

21 CFR Part 810

21 CFR Part 7

Corrections and Removals

Areas of Concern for the Medical Products Industry

- **Correction and Removals/Recall Teams not established – Plan in advance. Don't wait for crisis to strike.**

- **Who should be on the team?**
 - **Coordinator**
 - **Quality & Regulatory Representative**
 - **Manufacturing**
 - **Development**
 - **Field Service**
 - **Shipping**

- **Key decision makers and team members must be available.**

Corrections and Removals

Areas of Concern for the Medical Products Industry

Root cause analysis:

- **Failure to establish appropriate failure investigation procedure(s). Provide step-by step guidance to ensure that the team arrives at a complete and objective root cause analysis.**
- **Appropriate team members not involved**
- **Sufficient importance is not placed on root cause analysis – appropriate time and resources not devoted.**
- **Emphasis placed on “fixing” the immediate issue without a complete analysis of the issue. (root cause)**

Corrections and Removals

Areas of Concern for the Medical Products Industry

Health Hazard Evaluation:

- **Health Hazard Evaluation (HHE) templates are not comprehensive enough or may be non-existent. Does the template ask the right questions asked?**
- **Reference FDA template or create your own template.**
- **Completed HHEs should include all the data needed to make determination regarding risk and reportability.**

Corrections and Removals

Areas of Concern for the Medical Products Industry

General Problems:

- **Procedures are difficult to follow.**
- **Procedures are living documents.**
 - **Like your risk management plan, your corrections and removals process should be periodically reviewed and refined to ensure that it reflects the current ways of working and reflects best practices**
 - **Keep abreast of changes in FDA requirements**

Corrections and Removals

Areas of Concern for the Medical Products Industry

General Problems:

- **Senior management or decision makers are not kept in the loop. This causes delays in the implementation process.**

- **Timing, timing, timing. Delays in the Corrections and Removals process (10 day reporting deadline):**

- **Appropriate team members not involved**
 - **Development**
 - **Manufacturing**
 - **Field Service**
 - **Senior Management**

Q&A



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