Quality Systems

Advisory Committee for Blood Safety and Availability
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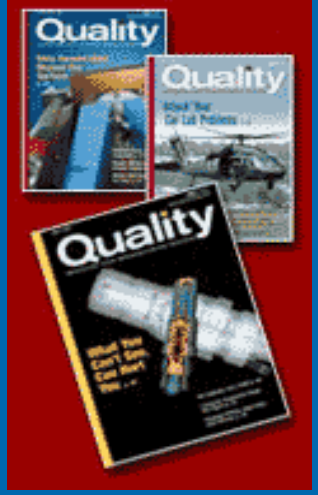

Quality Systems: Industry Perspective

- Time is money ⇨ Reduce Time
- Failure is Time ⇨ Reduce Failure
- Quality Builds Success ⇨ Invest in Quality

Quality Systems: FDA Regulatory Perspective

- “A quality system addresses the public and private sectors' mutual goal of providing a high-quality drug product to patients and prescribers. A well-built quality system should prevent or reduce the number of recalls, returned or salvaged products, and defective products entering the marketplace.”

Quality Systems

- Ultimate goal is consistent between FDA and regulated industry

Draft Guidance

Guidance for Industry:

Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations

September 2004

http://www.fda.gov/cber/gdlns/qualsystem.htm

Quality System Principles

- Robust quality systems are designed to:
  - Prevent product quality defects before they occur
  - Detect product quality defects before distribution
  - Correct manufacturing systems to prevent recurrence
  - Take appropriate action if defective products are distributed

Most important -
be proactive rather than reactive

Prevention

- Robust donor screening and testing
- Process control
  - Validation of manufacturing processes, assays and facility systems
  - Qualification of equipment to ensure consistency of manufacturing;
  - Design controls
- Personnel
  - Adequately trained and educated
  - Engaged & empowered to detect problems and bring to management's attention
- Procedures are established and are followed
- Record keeping
- Management
  - actively involved
  - provides needed resources to ensure compliance

Detection

- Procedures for sampling, testing, and acceptance of incoming materials
- In-process controls of the manufacturing process
- Monitoring of environmental conditions (as appropriate)
- Regular review and trending of all relevant data to detect negative trends
- Performance of audits – internal and external

Relevant Data?

- Deviations/failures/non-conformances
- In-process and final product data
- Environmental data
- Product complaints
- Adverse event reports
- Reportable deviations
- Product recalls
- Audit and inspectional results
- Personnel proficiency testing results

Correction

- Investigate deviations in manufacture prior to distribution of product
- Investigate all product complaints; including review of manufacturing records;
- Investigate all fatalities and unexpected AERs
- Implement corrective actions, as appropriate, to prevent recurrence
- Assess the effectiveness of your corrective action

Reporting

- Report deviations in manufacture and unexpected or unforeseen events that are discovered after the product is distributed
  - Again, thoroughly investigate the deviation, including how it was missed, and carefully consider impact on marketed product – recall?

Reporting

- Report blood recipient or donor fatalities
- Report Adverse Events/Reactions required by the regulations
- Report deviations and unexpected or unforeseen events required by the regulations
- Notify agency if recalling product

Labeling

- Regulations require that labeling provides information to the end user to ensure proper administration:
  - Adequate directions for use
  - Circular of information
- Recent addition of the bar code label requirements to the regulations

Other Activities

- Proprietary name reviews – review of newly proposed trade names/trademarks for biological drug products to identify potential for “mix-ups” (e.g. similar name/same dosage form/clinical setting may result in medication errors) and advise of findings/recommendations.

Final thought

- “Quality means doing it right when no one is looking.” Henry Ford