Implementing a Modern Pharmaceutical Quality System

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IQ Symposium 2014 – “Pre-competitive Collaboration for Innovation”

WG Members

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- Additional resources from members companies

Background

- In 2008, the International Conference on Harmonization published the ICH tripartite guideline titled, Pharmaceutical Quality System Q10. The guideline describes a model for an effective pharmaceutical quality system.
- As quoted in the document, “ICH Q10 describes one comprehensive model for an effective pharmaceutical quality system that is based on International Standards Organization (ISO) quality concepts, includes applicable Good Manufacturing Practice (GMP) regulations, and complements ICH Q8 “Pharmaceutical Development” and ICH Q9 “Quality Risk Management”.

Problem Statement

- But the question becomes: How does a business culture implement these principles effectively and efficiently
- Starting in 2013 the GMP QA LG within IQ developed and conducted a survey to see how IQ member companies implemented these concepts and to understand where trouble points may lie.
- How could the QA groups within IQ provide support for the areas where there are struggles?

Voice of the Customer

- A total of 30 surveys were sent out to the IQ member companies covering:
  - Background Information
  - Pharmaceutical Quality System
  - Management Responsibilities
  - Continual Improvement of Process Performance and Product Quality
  - Continual Improvement of the Pharmaceutical Quality System
- Overall response rate was 73%. This is an excellent response and considering the diversity of the member companies within IQ should represents a nice cross section of our industry

What did we learn

- Areas of strength
  - Knowledge Management: Most have implemented some type of KM process
  - Management Responsibilities: Most companies reported a strong management commitment to a “Quality Culture”
  - Continual Improvement of Process Performance and Product Quality: The tools for improvement of product quality as part of compliance obligations are clearly in place. Some gaps still exist.
  - Continuous Improvement of the Pharmaceutical Quality System: Overall a strong review process of the PQS exist

What did we learn

- Areas needing more support
  - Quality Risk Management:
    - More concern in this area. Member companies consider application of QRM principles highly important
    - However more guidance/support needed on how to apply the principles especially in the R&D environment.
  - Change Management
    - Most companies do have a formal system to manage change within their companies
    - Overall this is another area where we believe the IQ Consortium could develop standard recommendations and guidelines to help companies establish effective change management strategies for development organizations.

Next Steps for Precompetitive Collaborations

- How to address the gaps: ***Take advantage of the best practices for Change Management and Quality Risk Management across member companies***

  - Two working groups have been formed to provide additional guidance on Change management and Quality Risk Management focusing on development

  - Kick off meetings established that other outside organizations (ie PDA, ISPE etc) are not adequately meeting these needs.

  - Possible outputs from the WG will be guidance documents and webinars