Project Management in a cGMP Environment

Description: This webinar will provide valuable guidance to regulated companies in development and implementation of Project Management Planning and Techniques for new product development, regulatory compliance audit responses, proof of “progress against plan”, and other activities requiring a planned documented rationale.

Three of the most common tools will be discussed. One very simple approach using common Excel- or Word -type PC applications programs that can be used immediately. Regular use of a few simple but powerful tools will virtually eliminate “fire fighting” in a new project. Regular use can contribute greatly to reduction of scheduling uncertainty, incomplete projects when time is running out, increased product liability, assist in company-wide cost reduction efforts, with less chance of recalls, and an improved bottom line.

Why you should attend: The FDA expects companies to manage projects formally - to include regulatory requirements, design and/or change control, with consideration of all applicable standards. The EU MDD and their notified bodies are no different. How can this be done from a project's inception? How can a Project Leader or Project Manager ensure critical elements are not omitted until late in the project when disaster looms? How to minimize scope creep? How to conclude a project “on time” and “within budget”? How to gain management support for the Milestones, Tasks, and Timelines? Use the Plan as a powerful tool with FDA auditors. Use variations on these tools for any project, from the smallest to major company projects. Growing high-profile field problems indicate that much project management is poor or non-existent. Buy up-front time for proper project planning. These techniques are not rocket-science, but require the implementation of formal methods with documented and defensible rationale. Use these tools to bring predictability to your company's product development process. Use them to defend your remediation efforts with the FDA. Use them to prove “progress against plan”.

Contents:
- Why formal Project Management
- The three most common tools
- How to compile
- Gantt, CPM, PERT
- Simple construction techniques
- Work breakdown Structure, Milestones, Tasks
- Effectiveness - Determining and Monitoring
- The "New Product Example"
- The "Remediation Example"

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