Quality by Design - Essential Techniques for Medical Devices

Description: This webinar will help you learn the basics of design controls for medical devices. This webinar will focus on the fundamental concept that quality cannot be inspected in--it must be designed in. We'll cover the regulations and expectations for design control. We'll discuss how design control fits into your Quality Management System. Successful integration can enhance your new product development process.

Objectives of the Presentation:

- Overview and definitions
- FDA expectations, regulations
- Lessons learned and enforcement case studies
- Common mistakes and how to avoid them
- Design control process
- Design History File
- Linkages to other quality system requirements
- Best practices
- Preparing for an FDA or NB Inspection

Why Should you Attend:

Intrinsic quality, safety and effectiveness of a device are known to be established during the design phase. However, statistics show a significant percentage of all medical device recalls are due to design problems. Because of this, Design Control is considered a critical process by the FDA. Yet it is still one of the most frequent areas for 483 and Warning Letter observations. Most importantly, Design Control is critical to product quality and the ensuring safe and effective products for your customers. This webinar will cover the basics of design control for medical devices. We will discuss the requirements for design controls and how to translate them into an efficient and effective process for your company. A device recall can have disastrous impact for your customer, your reputation and your business success. This webinar can help you avoid common problems and create a design control process that is a competitive strength for your company.

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