Supplier Management for Medical Device Manufacturers (Washington, DC - May 26th & 27th, 2016)

Description: Supplier selection and management is one of the critical issues for medical device manufacturers. Suppliers provide materials and services to the device manufacturer, which means that they can be critical to performance and delivery of your device. Neither the FDA nor your notified body regulates your suppliers (with a few exceptions). They expect you to have an effective process to ensure your suppliers perform in the regulatory environment.

How well do you understand the requirements for supplier management?

Could you pass a regulatory audit or inspection without any issues?

This course delivers the tools, templates, and methods to help participants implement an effective and efficient supplier management program.

This two-day hands-on course provides a clear understanding of the underlying principles of supplier management. The course uses exercises to solidify understanding. In addition, the course uses FDA Warning Letters to illustrate the points and help you learn from others. As part of the practical implementation, the course includes receiving acceptance activities, outsourced processes, process validation at the suppliers' location, supplier auditing techniques, and supplier issues in management review.

The course uses the Global Harmonization Task Force (GHTF) framework, but expands it to cover other issues and techniques important in effective implementation.


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