



Course FDA-GMP For Medical Devices Quality System Requirements -21CFR820

About GMP series

CGMP refers to the FDA's "current Good Manufacturing Practice". There are different GMPs for the various industries regulated by the FDA i.e. Medical Device, Human Food, and Pharmaceuticals. The GMP for medical devices is a set of quality system requirement very similar to the previous 1994 version of ISO 9000. The GMP for Pharmaceuticals or Human Food set regulations, which have the force of law and require that manufacturers, processors, and packagers take proactive steps to ensure that their products are safe, and effective. Failure of firms to comply with GMP regulations is a federal offence and can result in recall, seizure, fines, and jail time. You are required to implement processes and procedures that comply with the requirements listed in the applicable GMP before you can release your product, you can be audited by FDA inspectors at anytime. And, Registrar Notified Bodies such as TUV or UL will certify your organization to this standard. To achieve compliance, you need to train employees who will drive the implementation internally, and/or use a consulting firm that can assist in the training and implementation. Providing training on the basis of the GMP for key players (in all areas of the organization that can have an impact on product safety and efficacy) in your organization so that they can understand what it entails, is a good starting point.

Online FDA-GMP class for Medical Devices

- Can be taken from home or at work through the Internet.
- Have "save and exit" features so that you can do it at your own pace
- After registration, there are no time limits, and you have complete flexibility in taking the course around your schedule.
- Use examples and quizzes that give very good exposures on industry related implementation issues.
- Provide the text of FDA's GMP for medical devices (in dark blue) and uses quizzes to give guidance in implementation of quality systems. The Code of Federal Regulations Title 21, Volume 8 Revised as of April 1, 2003, can be obtained from the U.S. Government Printing Office via GPO Access [CITE: 21CFR820]. .
- Use a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.