PathWise

cGMP Annual Training

Many companies conduct cGMP (Current Good Manufacturing Practice) training on an annual basis. This White Paper discusses:

- What is cGMP?
- Why is cGMP training important?
- Why conduct cGMP training annually?

What is cGMP?

cGMP stands for Current Good Manufacturing Practice. cGMPs make up the USA FDA's Regulations for Regulatory Compliance. cGMPs are listed in the Code of Federal Regulations (CFR), such as:

- 21 CFR 820 – Medical Devices Quality System Regulation
- 21 CFR 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- 21 CFR 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing, Or Holding of Drugs; General

The Food and Drug Administration (FDA), Medical Devices: Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation; October 7, 1996 (Volume 61, Number 195), effective June 1, 1997, provides the following discussion on CGMP:

"Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food,
drugs, biologics, and devices) are known as CGMP's.

CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), which was among the authorities added to the act by the Medical Device Amendments of 1976 (Pub. L. 94-295)."

Within the October 7, 1996 Final Rule, the FDA revises CGMP requirements for medical devices and incorporates them into a quality system regulation. This allowed for the inclusion of preproduction design control to the CGMP regulation. This is summarized within the Final Rule as follows:

"The Food and Drug Administration (FDA) is revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation. The quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. This action is necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. This regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements."

To the extent possible, the CGMP regulation was intended to be consistent with the requirements for quality systems contained in applicable international standards, primarily, ISO 9001 and ISO 13485.

One thing to note, is that the October 7, 1996 Final Rule removes the provision making the CGMP regulation applicable to component manufacturers. The following statement is made, making CGMP applicable to finished device manufacturers only:

"FDA will continue to focus its inspections on finished device manufactures and expects that such manufacturers will properly ensure that the components they purchase are safe and effective."

This is further reflected in 21 CFR 820.1 which states:

"This part establishes basic requirements applicable to manufacturers of finished medical devices."

There are also GMP exemptions published in the Federal Register and codified in 21 CFR 862 to 892. Please reference these sections for details.

Why Is cGMP Training Important?

Personnel training requirements are identified in 21 CFR 820.25, ISO 13485 (2003, 2012 & 2016) § 6.2, and ISO 9001:2008 § 6.2 (ISO 9001:2015 § 7.2).

Within the October 7, 1996 Final Rule, there is a discussion on the requirement that the training procedure include the identification of training needs. FDA notes the following:

"…a training program to ensure personnel adequately perform their assigned responsibilities should include information about the CGMP requirements and how particular job functions relate to the overall quality system. FDA further believes that it is imperative that training cover the consequences of improper performance so that personnel will be apprised of defects that they should look for, as well as be aware of the effect their actions can have on the safety and effectiveness of the device."

Further noting that:

"In order for the full quality system to function as intended, all personnel should be properly trained."

Beyond this, the October 7, 1996 Final Rule notes that industry benefits from the CGMP regulation in three ways:

"Cost savings from fewer recalls, productivity gains from improved designs, and efficiency gains for export-oriented manufacturers who would now need to comply with only one set of quality standards."

Please reference the Final Rule for further information on Industry Benefits.

Why Conduct cGMP Training Annually?

Training frequencies can be established based upon the requirements of individual organizations. An annual cGMP training frequency allows for a standardized schedule for cGMP training for new employees and can include refresher training for existing employees.

Please note, the "c" in cGMP, stands for "current", as previously discussed. Current reflects that practices are always changing and evolving. An annual cGMP training allows for discussion of any cGMP changes (including changes that have occurred within the organization's Quality Management System) within the last year.

Annual cGMP training allows for an opportunity to discuss key principals of good manufacturing practices that all employees should be aware of. These include, but are not limited to:

1. Importance of cGMP within regulated environments;
2. Awareness of the Quality Management System and what it entails;
3. Follow approved Standard Operating Procedures (SOPs);
4. Perform tasks only when appropriate training has been completed for those tasks;
5. Follow appropriate Good Documentation Practices;
6. Conduct changes to controlled documents according to Change Control procedures; etc.

Summary

cGMPs make up the USA FDA's Regulations for Regulatory Compliance. Quality Systems for FDA regulated products are known as cGMPs. The intent of these Quality Systems (or Quality Management Systems) is to help ensure that resulting products consistently meet applicable requirements and specifications. To the extent possible, they are in alignment with requirements set forth within ISO 9001 and ISO 13485.

cGMP training is important and allows communication of cGMP requirements to employees as well as how specific job functions relate to the overall Quality Management System. To conduct cGMP training annually, allows for the communication of current practices on an annual basis and provides an opportunity for refresher training on key principals of good manufacturing practices.

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