cGMP – Current Good Manufacturing Processes

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Learning Outcomes:

- At the end of the module, the participant must be able to:
- 1. Understand cGMP and it’s importance in the manufacturing industry. (example: Blood Banks – manufacturing blood components)
- 2. Identify the 5 main components of good manufacturing practices
- 3. Gain knowledge on how to handle cGMP violations
- 4. Compare six sigma and kaizen processes

Current Good Manufacturing Processes - cGMP

- Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of :
- 1. food and beverages
- 2. cosmetics
- 3. pharmaceutical products
- 4. dietary supplements
- 5. medical devices

What is cGMP

- cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA and other regulating agencies.
- cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.
- Adherence to the cGMP regulations assures the safety, purity, potency, identity and quality, (**SPPIQ**) of blood components by requiring that laboratories adequately control manufacturing operations.

Main Purpose of GMP

- Main purpose of GMP is to prevent harm from occurring to the user.
- That the end product is free from contamination
- that it is consistent in its manufacture
- that its manufacture has been well documented
- that personnel are well trained
- that the product has been checked for quality

Quality Management Systems in cGMP

- QMS must be in place for component laboratories in order to:
  - obtain appropriate quality materials / blood donors
  - establish robust operating procedures
  - detect and investigate blood product quality deviations
  - maintain reliable testing laboratories

System of Controls

- Component laboratories must have formal system of controls.
- If these controls are adequately put into practice
- Helps to prevent instances of :
  - contamination
  - mix-ups
  - deviations
  - failures
  - errors
- This assures that drug / blood products meet their quality standards.

Difference Between GMP and cGMP

- cGMP is used to refer to the 'Current Good Manufacturing Practices. The “c” in GMP just means current.
- The “current” in front of that just acknowledges that what is co*nsidered 'good changes' over time*.

5 P's of GMP

- The 5 main components of good manufacturing practices:
- 5 P's of GMP
  - 1. people
  - 2. premises
  - 3. processes
  - 4. products
  - 5. procedures (or paperwork).
- And if all five are done well, there is a sixth ------P-profit!

- *It is important to note that cGMPs are minimum requirements. Many pharmaceutical manufacturers and component laboratories are already implementing comprehensive, modern quality systems and risk management approaches that exceed these minimum standards.*

Importance of cGMPs

- A patient usually cannot detect (through smell, touch, or sight) that a blood component is safe or if it will work.
- Testing alone is not adequate to ensure quality.
- Therefore, it is important that blood components are manufactured under conditions and practices required by the cGMP regulations to assure that quality is built into the design and manufacturing process at every step.

cGMP Requirements

- Examples of how cGMP requirements help to assure the safety and efficacy of a blood component.
  - Facilities that are in good condition
  - Equipment that is properly maintained and calibrated
  - Employees who are qualified and fully trained
  - Processes that are reliable and reproducible

cGMP violations

- What can we do to protect the public when there are cGMP violations?
- If the failure to meet cGMPs results in the distribution of a drug / blood that does not offer the benefit as labeled
- For example, it has too little active ingredient, the company may subsequently recall that product.
- This protects the public from further harm by removing these drugs / blood from the market.
- If a company refuses to recall a drug, FDA can warn the public and can seize the drug.

Concept of Six Sigma

- Six Sigma is a disciplined, statistical-based, data-driven approach and continuous improvement methodology for eliminating defects in a product, process, or service.
- Six Sigma can also be thought of as a measure of process performance.
- With Six Sigma being the goal, based on the defects per million.

The 6 Sigma Principles

- Recognize
- Define
- Measure
- Analyze
- Improve
- Control
- Standardize
- Integrate

6 Sigma tools

- Six Sigma tools are - problem-solving tools used to support Six Sigma
- **DMAIC**
- D = define
- M = measure
- A = analyze
- I = improve
- C = control process is a data-driven quality strategy used to improve processes.

Types of Six Sigma

- **Six Sigma Roles**
- Master Black Belt: Trains and coaches Black Belts and Green Belts.
- Black Belt: Leads problem-solving projects.
- Green Belt: Assists with data collection and analysis for Black Belt projects.
- Yellow Belt: Participates as a project team member
- White Belt: Knowledge in DMAIC

Kaizen Lean Process

- Kaizen (Continuous Improvement) is a strategy where employees at all levels of a company work together proactively to achieve regular, incremental improvements to the manufacturing process.

Kaizen

- Kaizen is a Japanese term meaning "change for the better" or "continuous improvement."
- It is a Japanese business philosophy regarding the processes that continuously improve operations and involve all employees.
- Kaizen sees improvement in productivity as a gradual and methodical process.

5 founding elements of Kaizen

- teamwork
- personal discipline
- improved morale
- quality circles
- suggestions for improvement

Kaizen and Six Sigma

- Kaizen tries to improve the business as a whole by creating a standard way of working, increasing efficiency and eliminating business waste.
- Six Sigma is more focused on quality output (the final product).
- Lean is all about eliminating waste to increase process speed and quality through the reduction of process waste.