EHSSENTIALS 2018

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Good Manufacturing Practices (GMP)

A Regulatory Overview and The Role of EHS in Pharmaceutical Manufacturing Compliance

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cGMPs: We All Depend on Them

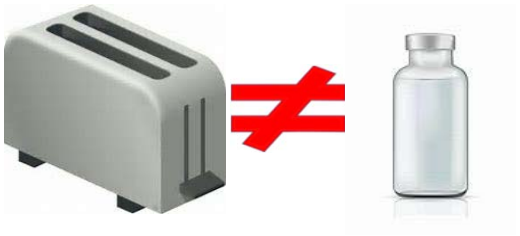
- “current Good Manufacturing Practices”
- All of us are patients.
- As patients, we all employ trust.
- Is that enough?

Trust Is Not Enough

- How do we know that what we are taking is safe; effective?
- Because it's in a sealed box?
- Because a pharmacist gave it to us?
- Because our Doctor prescribed it?

Toasters vs. Drugs

- A Toaster manufacturer can test 100% of their product.
- Pharmaceuticals cannot be tested 100% for Quality…There'd be nothing left.
- Quality must be "built in"



GMPs Origins

- Winthrop Chemical Company of New York 1940 incident involving a sulfathiazole tablet contaminated with phenobarbital
- Hundreds of deaths and injuries resulted. FDA's investigation revealed numerous control deficiencies in the plant and serious irregularities in the firm's attempt to recall the tainted tablets.

Tulsa, Oklahoma 1937

- Poisoned cough syrup
- Sweetened by diethylene glycol
- More than one hundred dead nationwide, and most of them children

Who's to Blame?

- Company President: "We have been supplying a legitimate professional demand and not once could have foreseen the unlooked-for results. I do not feel that there was any responsibility on our part."
- 1938: U.S. Food, Drug and Cosmetics Act signed
- Code of Federal Regulations (CFR)

What are the CFRs and GMPs?

- A set of expectations and behaviors that seek to ensure drugs are safe, effective, and pure.
- Working “under GMP” requires that some practices and behaviors are in place.
- Non-compliance has consequences.

Organized into Quality Systems

- Management Responsibility
- Documentation/Records
- Training/Qualified staff
- Change Control
- Materials Acquisition
- Testing
- Storage
- Manufacturing
- In-Process Testing
- Validation:
  - Process
  - Equipment
  - Testing
- Disposition
- Outgoing Shipments/Control

The Reach of GMPs

Global Impact:
Many Countries have adopted GMP

cGMP: Foundation for Quality

- Because we cannot test all product, cGMPs help us ensure we are doing the right thing to ensure quality in the product.
- However, GMPs are requirements, not instructions.
- Industry has to interpret and enact.

Multiple Approaches

- Documentation/Records
- Training/Qualified staff
- Change Control
- Materials Acquisition
- Storage
- In-Process Testing
- Validation:
  - Process
  - Equipment
  - Testing
- Outgoing Shipments/Control

Is there only one correct approach?

GMPs: Who Is Involved?

- All systems and processes that support the manufacturing, testing, storage and delivery of pharmaceuticals.
- EHS in supporting a safe workplace and practices.

Product Adulteration

- Non-compliance to cGMPs will “adulterate” the product.
- No product = compromised treatment.
- Compromised treatment = reduced quality of life or life expectancy.

EHS : Critical Partner

- Without EHS, the compliance to cGMPs would be impossible.
- Staff need :
  - Safe environment
  - Safe equipment
  - Safe materials
  - Safe practices
  - Safe disposal
  - Monitoring

EHS Assurance

- Unsafe working conditions can cause product adulteration
- How?
  - Shortcuts
  - Changes
  - Contamination

Compliance is Critical

- Inspections by authorities are designed to verify compliance.
- Failure to comply with GMP requirements can lead to:
  - Warning Letter
  - Seizure
  - Injunction
  - Criminal Prosecution

Reliance and Partnership

- EHS and GMP regulations work together
- EHS ensures safe premises, etc. for GMP production.
- EHS input into facility design and flow is critical.

EHS Up Front

- EHS should be consulted during the design and building stages of a pharma facility.
- Early EHS involvement prevents future issues.

EHS Compliance

- As in GMPs, failure to comply with EHS requirements can shut down a manufacturing operation.

EHS Presence

- EHS staff need to be expected to have a presence on the manufacturing floor, just as Quality does.

Constantly Evolving

- Both GMP and EHS regulations are constantly evolving.
- The partnership between Quality/Production and EHS must be strong and long lasting.
- Patients' lives are at stake.