Basic Principles of Safety – Plant Design

Your Objectives:

At the end of the lesson, you should be able to describe why a specific facility design works best for the biotech-industry

As was stated in a previous lesson, it is the duty of the manufacturer to ensure that its pharmaceutical products are free of contaminations. Under the Code of Federal Regulations (eCFR), therefore, Biogen must record in writing and follow procedures for preventing contaminations. Contamination control procedures exist on several levels.

Facility design is covered by FDA regulations:

- Basics
    - 21 CFR 211:42-58
    - 21 CFR 600.3(t)
    - 21 CFR 601.22
    - 21 CFR 600.12e

- Basics for European inspection
    - EMA Annex II

- Waste handling and flow
    - 40 CFR Part 261
    - 40 CFR Part 264
    - Safety in processing
    - 21 CFR part 600.11, subchapter F

There are two (2) types of facility design:

1. Closed systems
    - categorised as controlled not classified, if it can be proven that the risk of any section being open to surrounding areas is zero;

2. Open systems
    - Although many parts of a manufacturing process are closed (e.g. bioreactor, chromatography column, filtration unit), many parts remain open to surrounding areas (e.g. during media and buffer prep);
    - Therefore, there is a need for a carefully controlled process environment (containment), to avoid all risks of product / process contamination.

With respect to all physical phases entering and leaving the facility, we need to have a containment in place for:

1. Gases 2. Liquids 3. Solids 4. 'Humans' 5. 'Product'.

The last two are not real phases.