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 [ ] products are free of contaminations. Under the Code of Federal Regulations (eCFR), therefore, Biogen must record in writing and follow procedures for preventing [ ]. Contamination control [ ] 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 [ ]
  - EMA Annex II

• Waste [ ] 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 [ ]

• Although many parts of a manufacturing [ ] are closed (e.g. bioreactor, chromatography column, filtration [ ]), 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.

Aufgabe Lückentext:

Folgende Wörter bitte in den Lückentext einfüllen.
Jedes Wort kommt einmal vor.
Bitte Gross- und Kleinbuchstaben beachten.

contaminations, handling, inspection, pharmaceutical, procedures, process, systems, unit,