Basic Principles of Safety – Design Criteria

Your Objectives:

At the end of this lesson, you should be able to explain why it is important to have design criteria in place.

Design criteria is understood to mean those explicit goals which a project has set to have to achieve for it to have a successful, desired outcome. Those are then subdivided into primary and secondary criteria.

Primary criteria are those which constitute success whereby, if unsuccessful, a project will not have met its goals. **Secondary criteria** are those features which are highly desirable, but not essential.

Preliminary considerations

• Concentrations of reactants and products

• Productivity (volumetric, specific)

• Yield / conversion of product later in process

• Quality

- Purity
- Sequence
- Glycosylation
- Activity (*in vitro*, *in vivo*)

Design criteria for pharmaceutical product (e.g. antibodies)

Order of importance

1. Quality

2. Concentrations of reactants and products

3. Productivity

4. Yield / Conversion

Design criteria for bulk products (low added-value product, e.g. ethanol)

Order of importance

1. Concentrations of reactants and products
2. Productivity
3. Yield / Conversion
4. Quality

That part of the pharmaceutical quality assurance ensures that products are consistently produced and controlled in conformity with quality standards and are appropriated for their intended use as required by the product specification.