

PRESENTATION ABSTRACT

Presentation topic: High potency product containment - isolation technology

Speaker:

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Company:

NICOMAC

Nicomac is specialized in the design & supply of high-containment Isolator systems and granulation machinery.

Pharmaceutical Industries quest for high containment processing coupled with ease of productivity, increasing need for specialist containment suppliers capable of meeting these specific challenges. Nicomac success founded on proven ability to produce advanced tailor-made solutions able to integrated production machinery with isolation technology.

Defining the Requirement:

- Is the Requirement for a Potent API, Aseptic or Potent and Aseptic?
- Is the Product, Liquid, Powder, Slurry or Cake?
- What Are the Process Requirements?
- What Is the OEL (Operator Exposure Limit) of the Product?
- Quantification of the Hazard
- Assess the Hazard and the Risk
- Hazard - Fixed
- Risk - Dependent on Circumstances
- Consider
- Toxicity
- Evaluate the Operators' Exposure - Exposure Level
- Volatility or Dustiness
- Quantity of Material Being Transferred
- Duration of Operation

The requirement to interface isolator with process equipment is a central aspect keeping in mind ergonomic, handling and cost effective.

That's why Nicomac designed and successfully installed a complete granulation line contained in a single isolator working in negative pressure with a capacity of 5 kg of cytotoxic drug used in chemotherapy for cancer care with sleeves and gloves.