Remarkable.

Protecting personnel and the patient

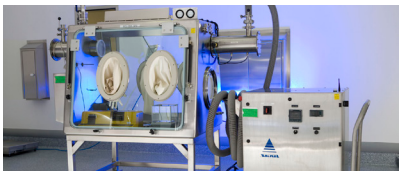
This is the word that describes the extraordinary impact on our fellow human beings' health that can be achieved when we combine the technical minds of our experts to design multi-product drug manufacturing facilities with highly potent active pharmaceutical ingredients from concept through validation.

Hormones, cyto-toxics, steroids, monoclonal antibodies, ADCs, general biohazard compounds, sensitizing compounds like β-Lactams facilities have considerable challenges and risks associated with their production, especially for multi-product facilities.

The services IPS offers to create these types of facilities, along with our ability to mitigate risk and prevent cross-contamination, can be compared to no other, as we have all of the expertise collaborating under one roof.

Integrated Solutions for Highly Potent Active Pharmaceutical Ingredients (HPAPIs) Facilities:

Profile the products and materials, define the risks and requirements, mitigate the risks through a robust design and construct, test, verify and qualify the facility.



Pharmaceutical Processing

Trends in High Tox Manufacturing

Pharmaceutical Processing Magazine, published in the August 2014 Issue
Written by: Mark Butler, Vince Cebular, Sam Halaby, George Petroka, and Thomas Woody

EH&S and Toxicology

- Profiling the products to be manufactured and define the risks
- Creating a safe working environment for the operators by establishing the OELs
- Protecting the patient through product specific toxicological evaluation and setting ADEs

Regulatory

- Understanding the current and proposed global regulations to prevent cross-contamination in production
- Defining all required for a facility based on governing regulatory agencies including dedicated equipment, dedicated suite, dedicated facility etc.
- Assessing the Risk and developing risk mitigation strategies

Cleaning Validation

- Evaluating the ADEs to assess cleaning capabilities and the potential need for dedicated equipment
- Defining the cleaning strategies to facilitate the appropriate process design

Process Equipment (Primary Containment)

- Selecting the appropriate process technology for containment
- Equipment containment technology

Facility Engineering

- Mitigating risk of operator exposure and cross-contamination via a risk-based approach
- Airlocks, gowning philosophy; Identification of level of risks
- Design to meet relevant regulatory requirements
- Optimized facility design consistent with the level of containment and manufacturing flows

Construction

- Procurement of proper process equipment and containment devices
- Clean Construction in a regulatory compliant environment

Testing, Vertification & Validation

- Proof of proper containment by site testing
- Verification of effectiveness of isolators or other containment devices
- Validation of facility and process