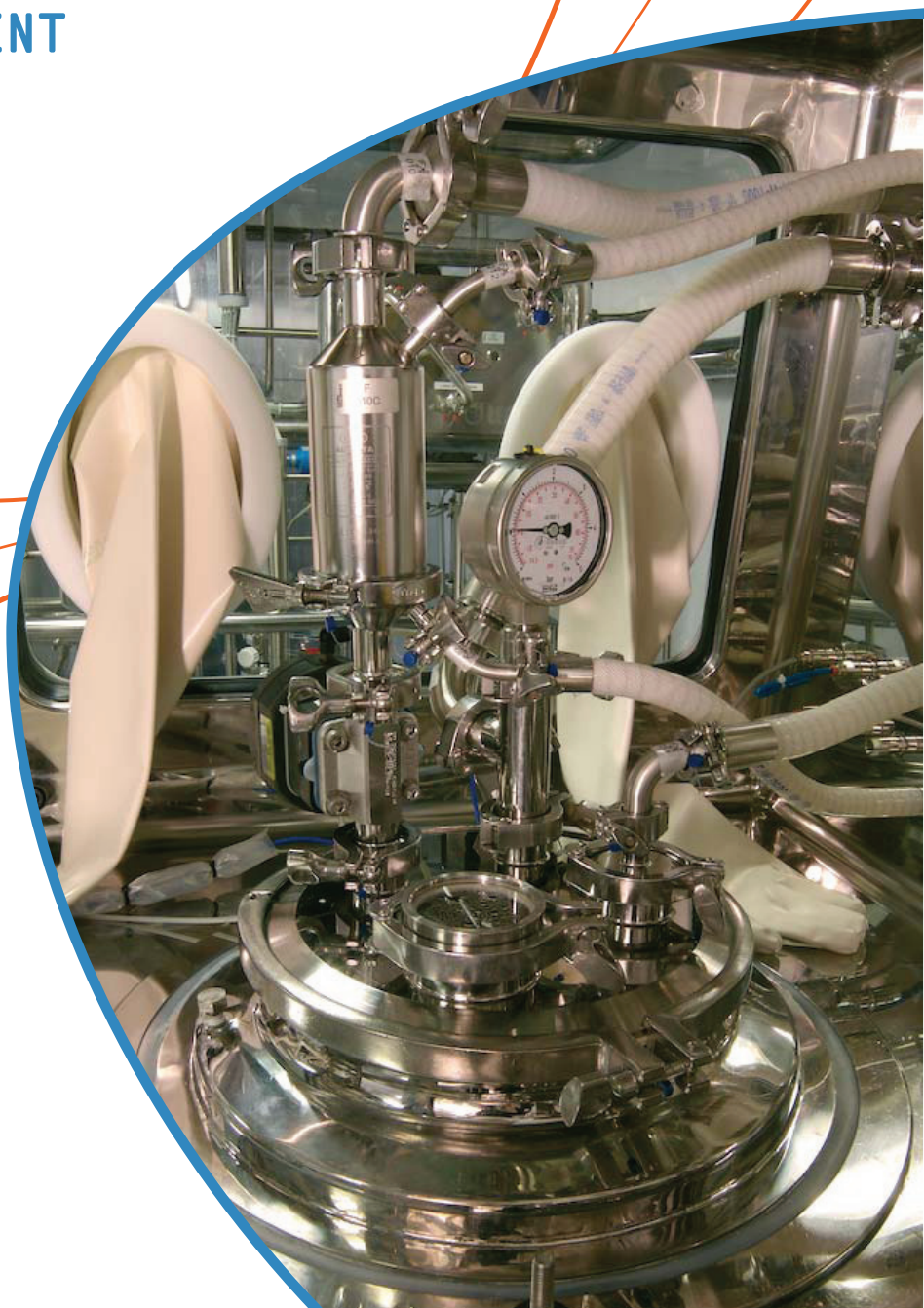
STERILE HIGH-CONTAINMENT FACILITY



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Overview

The GSK Parma site's Sterile High-Containment Facility is a state-of-the-art sterile manufacturing operation suitable for **freeze-dried** and **liquid cytotoxic** products, housed in a dedicated standalone building. The facility is also approved for the production of Clinical Batches.

The entire manufacturing process is carried out in a dedicated building that provides a total-containment environment.

Approved in 2006, this advanced multi-product plant has a capacity of 6 million liquid vials per year and currently supplies around 70 markets worldwide - including the USA, Japan and EU - mainly with products in the Oncology therapeutic area.

Equipment

- *Compounding* suite equipped with 2 separated vessels (batch size from 10L to 180L) integrated with isolator technology
- *Filling:* 0.5 ml to 10 ml at 200 pcs/min - Automated integrated fill weight IPC with closed Restricted Access Barrier technology
- *Freeze-drying:* fully-contained loading/unloading system feeding 25 sq.m FD (from 45,000 x 15 ml vials to 80,000 x 2 ml vials)
- *Crimping* phase under isolator technology
- *Final decontamination:* external vial washing integrated with crimping

Key Characteristics / Technologies

- Designed for containment
  - Dedicated HVAC system
  - Isolator technology for dispensing, freeze drying, crimping and disposal management
  - Closed Restricted Access Barrier (c-RAB) technology for filling phase
  - Additional Decontamination In Place (DIP) cycles for freeze drying
- Automated Cleaning In Place/Sterilisation In Place (CIP/SIP) for critical unit operation
- Automated Vaporised Hydrogen Peroxide (VHP) cycles for isolator sanitisation
- Automatic continuous-particle and microbiological monitoring systems in classified areas
- Manufacturing process managed by iFix advanced Supervisory Control And Data Acquisition System (SCADA)
- Liquid waste treatment through Ozone plant

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