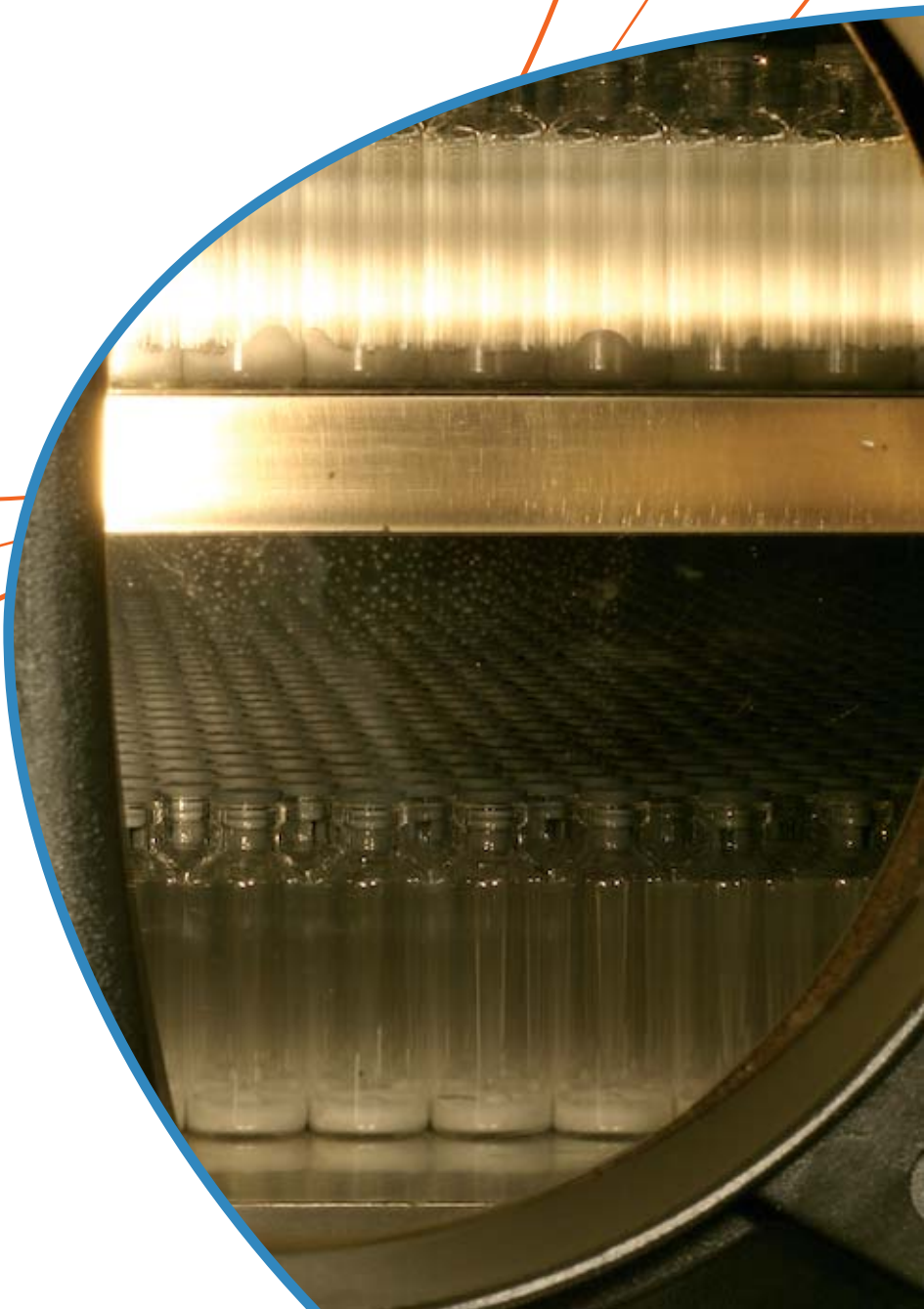


# FREEZE-DRYING FACILITY



GlaxoSmithKline

## Overview

The Parma Freeze-Drying Facility is a state-of-the-art plant for the commercial sterile manufacture of **freeze-dried** and **liquid** products. The manufacturing process extends from formulation to sterilising filtration, filling, freeze drying (if applicable) and crimping. An inspection stage comprising leak testing and semiautomatic cosmetic testing phases completes these bulk manufacturing operations.

The facility was approved in 2002 and currently supplies over 90 markets worldwide - including the USA, Japan and EU - with 8 different APIs, mainly in the Oncology and Anaesthesia therapeutic areas.

The facility is a multi-product plant capable of handling vials in 10 different vial sizes (from 0.5ml to 30ml) with a production capacity of 30 million vials per year.

## Equipment

- *Compounding* in fixed or mobile stainless steel vessels (30-1000L)
- *Filling* from 0.5 ml to 30 ml at 300 pcs/min with integrated In-Process Control fill weight testing
- *Freeze drying*: Automated loading/unloading system feeding 5 freeze dryers equipped with liquid nitrogen technology. Each Lyo has a maximum capacity ranging from 45,000 vials (25 ml) to 165,000 vials (3 ml) per batch
- Automation managed by an advanced Supervisory Control And Data Acquisition System (SCADA)

## Supporting Technologies

- Dispensing under isolator technology
- Automated Cleaning In Place/Sterilisation In Place (CIP/SIP) from preparation vessel to "point of fill"
- Filling operations use closed Restricted Access Barrier technology
- Automatic particle control in all classified areas
- Disposable aseptic in-line filtration available
- Autoclaving for sterilisation cycles
- Automated CIP/SIP, Integrity Test and Leak Test at Freeze Dryers
- 100% Automated Integrity Test for freeze dried products
- In-line Near Infra-Red spectroscopy product discrimination at crimping phase

