

# Sterile Manufacturing

With a fully integrated network of U.S. FDA-approved sites across Europe, Patheon can satisfy your sterile product needs from 1 to 10,000 units. Our breadth of capabilities — often within a single site — extends through all phases of development — clinical development to process scale-up and commercial manufacturing and supply.

Patheon's sterile manufacturing operations combine small and large scale manufacturing for multiple dosage formats, including:

- Sterile vial
- Lyophile
- Prefilled syringe
- Sterile dropper
- Sterile nasal spray
- Sterile ampoule

Patheon's large set of capabilities, which includes processing and packaging solutions, are supported by robust analytical and cold chain storage capabilities. What's more, we also have extensive experience with high potency compounds and biopharmaceuticals.

At Patheon, our capabilities are backed with commitment: We hold ourselves to the highest standards of quality and guarantee on-time delivery.



## Sterile Manufacturing Sites

- Ferentino, Italy – full phase development services and commercial manufacturing
- Monza, Italy – late phase clinical and commercial manufacturing
- Swindon, UK – late phase clinical and commercial manufacturing



For more information, email us at  
**doingbusiness@patheon.com**

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## Commercial Manufacturing

### State-of-the-Art Capabilities

Our manufacturing areas were constructed using specialized building materials and incorporate robust environmental control systems. “Clean in place” (CIP) and “steam in place” (SIP) functions ensure consistent sterilization of the chambers and the processing equipment.

**Ferentino, Italy** This site houses four state-of-the-art cGMP Lyophilization units ranging in shelf space from 75 ft<sup>2</sup> (7 m<sup>2</sup>) to 452 ft<sup>2</sup> (42 m<sup>2</sup>), with a total lyophilization production capacity of 990 ft<sup>2</sup> (92 m<sup>2</sup>). The facility is also designed for the aseptic filling of small volume parenterals (SVP) and offers a dedicated sterile suite for large volume parenterals (LVP) filled in glass bottles.

**Monza, Italy** This site features three separate sterile areas housing six lyophilization units ranging in size from 312 ft<sup>2</sup> (29 m<sup>2</sup>) to 398 ft<sup>2</sup> (37 m<sup>2</sup>) and offering a total of 2131 ft<sup>2</sup> (198 m<sup>2</sup>). These state-of-the-art lyophilization systems are ideal for the commercial manufacture of biopharmaceuticals and small molecules. The facility is also designed for the aseptic filling of small volume parenterals (SVP).

Monza Commercial Operations is a center of excellence, offering extensive technology transfer and commercial manufacturing experience in sterile lyophilized and liquid products, supplying all the major international markets, including the U.S., EU and Japan.

**Swindon, U.K.** Our commercial operations provide sterile manufacturing capabilities for emulsions, suspensions, creams, ointments, and sterile liquids in a wide variety of packaging formats including vials and pre-filled syringes, as well as glass and plastic ophthalmic drops.

In addition, Swindon Operations houses a fully segregated facility dedicated to the manufacture of sterile powdered cephalosporins. The facility also hosts a recently constructed state-of-the-art lyophilized cephalosporin facility that meets international regulatory standards.

### Exceptional Quality

Patheon’s sterile manufacturing facilities meet the highest quality standards of Europe and abroad. In addition to holding European regulatory approval, these three facilities have had numerous successful inspections by the U.S. FDA.

**For more information on our Sterile Manufacturing services, contact your Patheon representative or email us at [doingbusiness@patheon.com](mailto:doingbusiness@patheon.com)**

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