

# Cephalosporin

Patheon is one of a select number of outsourcing companies to offer dedicated sterile cephalosporin manufacturing facilities for a range of dosage forms. With U.S. FDA-approved manufacturing capabilities for aseptically-filled powder cephalosporins, Patheon is an industry leader in cephalosporin manufacture.

In late 2006, Patheon completed the construction of a new lyophilized cephalosporin facility on the grounds of its Swindon, UK site. This state-of-the-art lyophilized cephalosporin facility compliments our sterile powdered cephalosporin manufacturing at the Swindon site.



## Powder Filling Capabilities:

- 2 Bosch AFG320 filling lines
- New IMA powder filling line
- Ready-to-fill sterile material
- Residual vacuum capability
- 15mL, 20mL, 30mL, 50mL, 70mL & 100mL conventional vial formats
- 15mL & 30mL AddVantage® vial formats
- 0.25g – 10g fill

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

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## CASE STUDY



### The Challenge

The client had a new cephalosporin product requiring lyophilization but did not have the capability to manufacture this class of products within their own network. At that time there were no commercial-scale facilities in the world available for contract manufacture of lyophilized cephalosporins. The client had to decide whether to build and run a facility within its own network, or to outsource. Due to the specialized nature of the requirements, the client was aware that any outsourcing would require shared investment.

Speed to market was a critical factor for the client. The client's estimated timeline to build a commercial manufacturing facility in its own network was 2-3 years, compared to Patheon's timeline of 12 months.

### The Solution

Patheon would design, build and validate a commercial scale manufacturing facility at its Swindon UK site within the required timeline. This would be achieved by leveraging extensive experience gained building lyophilization facilities at Patheon's Italian sites.

### The Outcome

Facility construction started in September 2005, with registration batches manufactured in October 2006. This accelerated timeline allowed the client to file its NDA at the soonest possible date.

The Patheon project team and the client worked collaboratively to prepare for the successful PAI of the facility by the FDA, who approved Swindon as the site of manufacture for the client's product in January 2008. The same spirit of cooperation continues to this day.

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

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