

Decontamination Solutions by PBSC

Creating a standalone system for Hikma's cleanroom environment



High-quality medicines to treat a range of conditions

Helping to shape a healthier world that enriches all communities...

Hikma Pharmaceuticals PLC is a multinational pharmaceutical company and one of the largest suppliers of generic injectable medicines.

In response to the changing needs of the people, Hikma continuously develops its range of medicines, delivering systems and manufacturing hundreds of generic medicines.

Founded in 1978 with a dedication to transforming people's lives by providing quality medicine and support for their needs every day.

Providing high-quality, affordable medicines to the people who need them.

Hikma launches their new 503B compounding business, operating in a purpose-built facility in Dayton, New Jersey, which was acquired by Hikma in 2020.

Hikma's 503B is focused on providing high-quality, ready-to-administer injectable medications that are customized to the specific needs of patients in the United States.

The launch of Hikma 503B builds on the company's expertise and position as a leading supplier of injectable medicines, with a strong reputation for quality and reliability.

PBSC is a leading manufacturer of cleanroom, high containment and material decontamination products around the world provided the expertise and solutions allowing Hikma's state-of-the-art sterile compounding and distribution facility to keep in line with the company's high standards of quality.

Products

- Decontamination Chambers



PBSC's chambers were designed bespoke to Hikma's requirements, being the longest chambers at 6m long PBSC has produced for MDS to date. Integrated into Hikma's cleanroom environment for the purpose of decontamination of material/equipment transfer.

Solutions

- 2 x MAL50 version 2 software decontamination chambers made from 304 stainless steel.
- 3 valve AHS 800 air handling systems
- 2 x Aeration units
- Integrated control panel and pneumatics
- Extract 800 extraction units
- Win CC software loaded and data networked to Hikma's site server for the purpose of complying with 21 CFR part 11.

Results

- Standalone chambers, having their own air handling system so Hikma was able to run the chambers without connection to their building HVAC system.
- The 2 x aeration units aided the breakdown of H2O2 at the end of the cycle reducing the overall cycle period resulting in a higher production rate.
- The controls, wiring and pneumatics were integrated into the chamber panels so

Hikma did not need to house any additional panels in the technical space.

- The extract 800 unit is used to extract the air from the chamber and reduce the saturation levels of H2O2 by passing air through a carbon filter.
- Hikma utilized PBSC's networking option to enable the receiving of HPV cycle reports and audit trail data straight to Hikma's server.
- The 2 x MAL bespoke chambers accommodating Hikma's high-quality standards give this facility a large chamber area for material transfer capabilities, and decontamination material using a Bioquell SeQure generator.

Both chambers are approx 25m² internal volume with cycle times of around 2 hours.

PBSC contributed to the constant commitment Hikma has towards their customers by providing decontamination solutions to help create high-quality medicines.



Emma Wolanski - Project Manger

“ We are proud to work with such an important worldwide company and help Hikma reach their goal of putting better health within reach for millions ”

www.pbsc.co.uk

Unit 3, Moor Park 25
54 Leeds Road, Mirfield, WF14 0DE, UK