emcm
European Medical Contract Manufacturing
A Leader Biomedical Group Company

Supporting Opportunities

ANNEX 1 compliant cleanrooms

Inside EMCM GMP Annex 1 Compliant Cleanrooms

EMCM's New GMP Annex 1 cleanroom complex fully complies with EU GMP Annex 1 standards.

In the new cleanroom complex equipment is installed that is suitable for the automatic filling of parenteral drugs, from aqueous solutions to highly viscous gels into vials and syringes. Also the option to perform lyophilisation is available.

Lighthouse Facility Monitoring System controls humidity, temperature, and air pressure cascades, for each cleanroom level. Operators have access to real-time environmental status, displayed on a screen at the entrance of the complex.

Operators gain access to the cleanroom complex with a personal key fob, connected to the access management system.

Once in the cleanroom, operators enter a gowning cubical to change into basic cleanroom clothing, to be able to enter the ISO class 8 section. Their own clothing is stored in a locker which is personalised for each individual operator.

Dressed in basic cleanroom clothing in the ISO class 8 section, operators can enter the ISO class 7 manufacturing area through a separate gowning area.

To enter the heart of the manufacturing area where aseptic production takes place, operators enter another personnel airlock where they change from ISO class 7 clothing into sterile, ISO class 6 gowns. The ISO class 6 cleanroom has a separate “airlock in” and “airlock out” for incoming materials, finished goods, and personnel in accordance with the new Annex 1 regulations.

The ISO class 6 area is fitted with a filling line under a Laminar Air Flow unit to generate an ISO class 5 environment for aseptic filling of vials and syringes.

This filling line is an open Restricted Access Barrier System (RABS), suitable for filling both aqueous solutions and high viscous gels under vacuum. This technique allows for filling high viscous gels without air bubbles in the barrel.

The equipment can fill vials of various sizes for subsequent aseptical closure. Environmental monitoring in the ISO class 5 area is integrated in the Lighthouse Facility Monitoring System, providing detailed inline particle count during aseptic filling.

In addition, a lyophiliser may be installed if required for production process. How can we support your organization?
Contact us at projectmanagement@emcm.com

Introducing our NEW ANNEX 1 compliant cleanrooms

The new EMCM cleanroom complex complies with the new Annex 1. In these new cleanrooms, equipment has been installed for the automatic filling of parenteral drugs, from aqueous solutions to highly viscous gels into vials and syringes.

IN-HOUSE TECHNOLOGY, QUALITY, THE EMCM ADVANTAGE

EMCM is GMP licensed for the manufacturing of Pharmaceuticals. Subject to several national, European, and international inspections, we can manufacture products for global markets.

EMCM is an ISO 13485:2016 certified company that understands the importance of implementing and maintaining the highest stands in business and manufacturing practices.

Equipped with a range of (semi-) automatic mixing and filling units , our core expertise lies in customised batch production with formulation techniques, (aseptic) processing and filling highly viscous products.

- Ampoule Filling
- Syringe Filling
- Vial Filling
- Pouch Filling
- Lyophilisation
- Powder Mixing and Filling

European Medical Contract Manufacturing (EMCM) is a centre of excellence in developing and manufacturing (sterile) medicinal products. Within our 2000 m2 of GMP accredited facilities, we have a variety of cleanrooms ranging from class D up to class A (100.000 up to class 100).

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