



Process Technology Center (PTC)

Cleanroom – sterile
pharmaceutical production

Cleanroom – sterile pharmaceutical production

Pharmaceuticals must be produced in cleanrooms to ensure that they do not contain any impurities. This is particularly important if they are to be administered to the body as infusions or injections.

In the PTC's cleanroom, the entire process chain required for sterile dosage forms can be reproduced on a pilot scale. This includes key steps from formulation production, filling, freeze-drying and terminal sterilization to visual inspection of the product. This makes the PTC cleanroom particularly suitable for developing processes with scale-up/scale-down potential, filling reference samples, manufacturing drugs for preclinical studies or developing processes for sterile pharmaceutical manufacturing on a pilot scale under non-GMP conditions.

The PTC cleanroom facility is equipped with class C and D areas and is suitable for processing chemical and biological active ingredients and producing sterile solutions, emulsions and suspensions. Up to 10 litres of product solution can be filled automatically or manually into ready-to-use syringes (1 ml, long, staked needle format), vials (6R format) or other formats. Up to 3,000 units per batch can then be freeze-dried. During PTC cleanroom internships, students learn how pharmaceutical sterile production processes work and how a cleanroom is operated.

Infrastructure:

- Class C and D clean rooms (according to EU GMP Guideline)
- Formulation production in temperature-controlled glass or stainless steel containers (0.5–10 l)
- Clean room washing machine, capacity 500 l
- Steam sterilization, capacity 305 l
- Freeze dryer 2.02 m² floor space
- Automatic filling line, Peristaltic pump, nested packaging materials, up to 1000 units/hour
- Heat sterilization/depyrogenation up to 260 °C, capacity 450 l
- Safety cabinet class 2, cleanroom class A or ISO 5
- Mobile cleanroom monitoring (particles, air velocity, temperature, relative humidity)
- Climatic chambers for stability studies incl. photostability according to ICH
- Controlled storage of active ingredients and products at -80 °C, -20 °C and 2–8 °C



Prof. Dr. Oliver Germershaus
FHNW School of Life Sciences
Institute for Pharma Technology
Hofackerstrasse 30
4132 Muttenz
T: +41 61 228 55 26
oliver.germershaus@fhnw.ch



The FHNW incorporates nine faculties:

- FHNW School of Applied Psychology
- FHNW School of Architecture, Civil Engineering and Geomatics
- FHNW Academy of Art and Design
- **FHNW School of Life Sciences**
- FHNW Academy of Music
- FHNW School of Education
- FHNW School of Social Work
- FHNW School of Engineering
- FHNW School of Business

FHNW Northwestern Switzerland
School of Life Sciences
Hofackerstrasse 30
CH - 4132 Muttenz

T +41 61 228 55 77

info.lifesciences@fhnw.ch

www.fhnw.ch/lifesciences



www.fhnw.ch/lifesciences