GMP facilities at the PSI

Hot and cold facilities for your pharmaceutical projects

Introduction

The Center for Radiopharmaceutical Sciences is one of the few research organisations in Europe that are able to produce radiopharmaceuticals not only for research purposes but also for clinical trials. The production of radiopharmaceuticals under good manufacturing practice (GMP) offers excellent opportunities for proof of principle studies at clinical levels.

The Center for Radiopharmaceutical Sciences has several manufacturing sites. The site located at the Paul Scherrer Institute in Villigen (PSI) is specialized on the production of radiopharmaceuticals for use in clinical trials phase I.

With its clean rooms for manufacture and analytical labs for chemical and microbiological quality control PSI is able to produce and test all kinds of parenteral solutions for human use.

The proximity to PSI's 72 MeV Injector Cyclotron allows the on site production of some radioisotopes.

We offer this attractive potential to external cooperation partners whose projects are oriented towards clinical trials.

Services / Applications

We can offer GMP compliant facilities that may be used by customer staff but also tailored Research & Development as well as Production Services to customers that either do not have their own specialized facilities or do need additional capacity and expertise.

Our specialists are ready to train and support you.

Expertise

in the manufacture of sterile radiopharmaceuticals for clinical trials:

- Development and Validation of methods (manufacture and analytics)
- Maintenance of facilities and documentation; training of staff to comply with current GMP requirements
- Establishing product quality documentation and submission of clinical trial notification dossiers to concerned authorities
- Method transfer

Experience

- Development of GMP-compliant process and analytics, validation and transfer to Customer
- Manufacture of cold labelled product for toxicity study
- Manufacture of hot labelled batches for animal studies (pharmacology)
- Central labelling of 90Y Zevalin®, on order of Swiss NUK Clinics for individual patients
- Study notification dossiers and dosimetry estimation

We have performed projects in collaboration with Research partners as well as Fortune 500 companies, and are ready to support smaller companies with our knowledge expertise and facilities.

Facilities

GMP production labs outside the radioprotection zone (55 m^2):
Clean rooms grade C, B and A:
Manufacture of sterile semi-finished products (e.g. kits) under aseptic conditions or terminally sterilised.

GMP production and analytical labs within the radioprotection zone (A-Lab, 95 m^2):
Clean room grad D with:

- Hot-cells: 2 clean room grade C / 2 grade A with B background
- Clean room grade A bench with grade B background
- Clean room grade C bench

Manufacture of sterile finished products under aseptic conditions

Chemical Lab equipment:

- 2 calibrated dose calibrators
- γ-ray spectroscopy
- HPLC with UV and radio detector
- TLC scanner with radio detector

Microbiological Lab:

- Laminar flow work bench (grade B)
- Incubators (57°C, 35°C, 25°C)

The building was constructed in 1984. The clean room areas completely renewed in 2003; the labs within the radioprotection zone renewed in 2008/09. A Site Master File is available on request.

Isotope Production:
Production of Cu-67, Cu-64, Zr-89 (non-GMP grade). All other isotopes are purchased from appropriate suppliers.

Capacity

Simultaneous manufacture of 2–3 products, each in dedicated hot-cells/ synthesis modules. For the development of methods and products, there is more non-GMP lab space available.

Certification / Licenses

Handling of open radioactive sources; Type A Laboratory:
Federal Office of Public Health FOPH (BAG).

Manufacture, wholesale and export of radiopharmaceuticals for clinical trials: Swissmedic.

Audited for GMP-compliance by Swissmedic and customers.

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