Quality Assurance

The management of clinical trials at the pharmacy is described in the Standard Operating Procedures. Pharmacists' CVs are regularly updated. The pharmacy has the quality assurance documents to show staff qualifications, and conformity of the equipment. The pharmacy has a Swissmedic's manufacturing authorisation (GMP) and is certified according to the system of quality management ISO 9001 and RQPH (Quality reference system for Hospital Pharmacy).

Staff

Head of Pharmacy Clinical Trial Unit

- Dr Marianne Gazengel-Marchand
- Dr Fabiana Tirone

Head of Pharmacy

- Pr. Pascal Bonnabry

Head of Pharmacy Production Unit

- Dr Lucie Bouchoud

The personnel in charge of clinical trials is composed of:

- Two pharmacists who supervise all activities, GCP certificated;
- Two technicians;
- On-call pharmacists are trained for study drug delivery and preparations, if this is needed at night or over the weekend.

Useful **Information**

Opening Hours

Open for receipts, removals and for dispensation from 8 am to 12 pm and from 1 pm to 5 pm, Monday-Friday.

Outside of these hours, a 24/7 on-call service is provided by a pharmacist.

Address for Receipts

Pharmacy HUG
Secteur essais cliniques
Avenue de la Roseraie 51
1211 Geneva, Switzerland
☎ +41 (0)22 372 34 83
☎ +41 (0)79 553 10 70
Fax: +41 (0)22 372 34 85
Essai.c.pharmarcie@hcuge.ch

The access to the pharmacy is secure and strictly reserved for pharmacy staff only.

Cette brochure a été réalisée par la Pharmacie HUG en collaboration avec la Direction de la communication.

Janvier 2020

THE PHARMACY'S **CLINICAL TRIAL UNIT**

For clinical trials sponsors and investigators

Hôpitaux Universitaires Genève

Presentation

Each new clinical trial is registered in the Microsoft Access® database. The clinical trials at the pharmacy are managed in accordance to Good Clinical Practice (GCP) requirements.

For any clinical trial a financial agreement must be established and signed by the pharmacy and the parties (investigator, sponsor, CRO) before the site initiation visit.

https://pharmacie.hug-ge.ch/infos-pratiques-et-procedures/essais-cliniques

Management of Clinical Trial Products

Receipt of Products

The products are received according to the instructions provided by the sponsor. The products are stored in a dedicated 'clinical trials' area at the pharmacy, under their storage conditions.

The pharmacist in charge of clinical trials counts the received products, checks quantities, batch numbers, kit numbers, expiration dates, and the temperature of shipping.

In case of non-conformity, products are kept in quarantine in their normal storage conditions and the sponsor is informed.

Dispensation and Stock Accountability

The dispensation modalities are defined during the site initiation visit. Dispensation is personal, on a prescription signed by the authorized prescribers (a list is provided by the Principal Investigator). Traceability of clinical trial products is conducted on HUG pharmacy specific accountability log forms.

Preparation of Products

The clinical trial unit of the pharmacy conducts preparations for trials requiring double-blind administrations, reconditioning of formulations, development of placebo, and the manufacture of specific products (serial or individualized production; non-sterile or sterile, etc.).

Storage and Temperature Monitoring

- Room-temperature storage: Products requiring storage between 15°C and 25°C are stored in a specific storage area, whose temperature is monitored 24 hours a day by the Labguard® system, which triggers an alarm if the values: < 15°C or > 25°C are exceeded.
- Cold room storage: Products requiring storage between 2°C and 8°C are stored in the cold room, whose temperature is monitored 24 hours a day via the Labguard® system, which triggers an alarm if the values: < 2°C or > 8°C are exceeded.
- Freezers: The pharmacy has -20°C and -80°C freezers that are linked to the Labguard® system. The alarm system is the same as the one in the cold room. The high temperature of -15°C and -70°C respectively sets the alarm off.

A backup procedure is in place at the pharmacy in case of temperature deviations, in order to keep the treatments in the correct storage conditions.

Management of Returns and Destructions

Return or destruction modalities are defined during the site initiation visit.

The clinical trial unit of the pharmacy manages the returns of products stored at the pharmacy and also, if required, from the care units, and complete the accountability in the study binder.

The clinical trial unit of the pharmacy manages the destruction of products. For each destruction, a destruction form is completed, signed and dated by the pharmacist in charge of clinical trials. The products are destroyed according to the institutional procedure in force at the HUG on waste incineration.

Visit of Sponsor and their Representatives

Appointments for selection, initiation, monitoring and closure visits can be taken by phone or by e-mail, with the pharmacists. A reserved room at the pharmacy allows the sponsor's representatives to consult study binders, inventory products and returns. The pharmacists are present for the initiation visit with the investigator. Monitoring, audit or closure visits take place from 9 am to 12 pm, and from 1 pm to 5 pm. Exceptions are possible if needed.

Archiving of Documents

The archiving of a clinical study documentation takes place after the closing visit is completed. Each document received or produced by the pharmacy since the initiation to the closure of the trial is kept, and archived for 15 years (from the official closure date) at the central archive of HUG, according to the specific procedure of the pharmacy.