CHDR
Centre for Human Drug Research

The Pharmacy at Leiden University Medical Centre

The LUMC Pharmacy: a full-service partner in early-stage clinical research

The Pharmacy at Leiden University Medical Centre (LUMC) prepares and delivers the pharmaceutical products used by CHDR, including investigational medicinal products (IMPs). This Good Manufacturing Practice (GMP)-licenced pharmacy offers tailor-made solutions to help answer our sponsors' questions.

Highlights

- Because the LUMC pharmacy is located adjacent to CHDR, IMPs are prepared and delivered to our researchers quickly and efficiently, even after hours, thereby facilitating overnight trials.
- The Pharmacy is fully GMP-licensed for importing, manufacturing, compounding, and dispensing study drugs.
- The Pharmacy also repackages, labels, randomises, and codes the compounds used in our randomised clinical trials.
- LUMC's pharmacists work closely with CHDR and the sponsor throughout the design and execution of the clinical study, ensuring that the timeline is feasible and helping address issues as needed.

A long-standing relationship

CHDR and LUMC have a long history. CHDR's first facility was actually located at the former LUMC pharmacy in what was then called Leiden University Hospital. Over the past 25 years, as CHDR grew, both the LUMC Pharmacy and the Analytical Laboratories at LUMC have grown with us, playing a central role in our studies. At the same time, the LUMC Pharmacy has also grown – particularly the GMP facilities – in order to keep up with the increase in translational research at the LUMC.

CHDR and LUMC have a long-standing master service agreement, which covers the business and legal aspects, as well as our clinical and analytical activities. In addition to this general, overarching agreement, with each new study a specific contract is signed by all key parties, including the Pharmacy, the sponsor, and CHDR.

A state-of-the-art GMP-certified facility

At the LUMC Pharmacy, more than 100 pharmacists and support staff produce, package, and deliver the thousands of pharmaceutical products used at the LUMC and CHDR. Because the Pharmacy is actually two GMP-certified facilities – a GMP warehouse and a series of fully-equipped laboratories for analysing medicinal compounds – they can deliver products that meet, or even exceed, the highest quality standards when preparing and packaging IMPs formulated to meet the sponsor's specific needs.

The Pharmacy contains eight class D clean rooms, and their sterile facility includes eight class C clean rooms and one class B clean room. In addition, their reconstitution facility contains three additional class D clean rooms.

Maintaining close contact with the sponsor

Meeting the high standards of a GMP facility is time-consuming. That's why LUMC pharmacists work closely with both the researchers and the sponsors, anticipating potential pitfalls and developing solutions, thereby ensuring that quality remains high. This highly collaborative approach also allows the Pharmacy to make any necessary changes in the formulation and/or dose during the study, helping ensure that the study stays on schedule and meets both the rigorous demands of cutting-edge research and GMP standards.

Why choose CHDR?

The Centre for Human Drug Research specialises in early-phase clinical drug research. CHDR's overall mission is to improve the drug development process by collecting as much information as possible regarding the candidate drug in the early phases of development. This information helps sponsors make informed decisions regarding the course of clinical development for their product.

Research at CHDR covers a wide range of fields, including the central nervous system (CNS) and pain, the cardiovascular system, haemostasis, immunology, and dermatology. In addition, CHDR is at the forefront in developing novel biomarkers and methods for measuring drug-related effects in all of these research areas.

Pharmacology matters

Whether studying a new cognitive-enhancing drug, a next-generation painkiller, or a new monoclonal antibody designed to treat rheumatoid arthritis, the goal is to determine how the compound's effects correlate with both the dose and blood concentration at any given moment. In addition, understanding which biological systems are activated is an essential first step towards quantifying this relationship. At CHDR, our focus on pharmacology is reflected clearly in what we call question-based drug development.

Question-based drug development

CHDR actively uses question-based drug development - or QBD - as a more rational approach to drug development compared to conventional approaches. QBD can be best described as a series of questions that are addressed throughout the process. These questions often seem simple enough, but failing to answer even one question - or even addressing the questions in the wrong order - can have dire consequences. Thus, using this approach can potentially save companies millions of dollars by helping predict a catastrophic issue early in the development process, before the more expensive latter stages (for example, large-scale clinical trials or the marketing phase).

From a general perspective, the most important questions are:

1. Does the biologically active compound and/or active metabolite(s) reach the intended site of action?
2. Does the compound cause its intended pharmacological and/or functional effect(s)?
3. Does the compound cause any unintended pharmacological and/or functional effect(s)?
4. Does the compound have a beneficial effect on the disease and/or clinical pathophysiology?
5. What is the compound's therapeutic window?
6. How does any variability with respect to the drug response in the target population affect the product's development?

Contact

To learn about CHDR's full range of services, contact us today.

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