CLINICAL TRIAL MATERIAL

At Recipharm we provide comprehensive support for customers requiring clinical trial material (CTM). Our development team use a phase appropriate approach, meaning that the level of work is adapted to the clinical phase. We always start with the end in mind, so that there is clear path from simple formulations for First-In Human studies, to later clinical stages and tech transfer, to commercial manufacture.

We understand the need for high quality and timely delivery and work with our customers throughout their development projects to ensure success. Our dedicated development facilities, cleanrooms for cGMP production of solid, liquid, and semi-solid formulations and sterile suites to produce sterile vials, allow us to cater for a range of clinical trials from Phase I to smaller Phase III trials. Large trials will be supplied from our commercial manufacturing sites.

An effective process

There are several factors that are crucial to ensuring the successful delivery of clinical trial material in a timely and cost-effective manner, as well as ensure consistent supply. At Recipharm these form the foundations of the how we approach our development projects. From the outset, we consider:

- Early phase clinical trial material vs late phase clinical trial material and balancing time and cost with ensuring success beyond the clinic
- Coordination between drug substance and drug product, including access to adequate drug substance
- Likewise reliable access to raw materials to avoid any delays
- The implications of the trial design on the CTM for example, what is the route of administration or the dosage form? What is the dosage regime, or the number of doses required? What about the comparator/placebo product, how to ensure that it will be ready in time for trials as well?

At Recipharm, our in-house drug substance team is well equipped to ensure efficient manufacture of drug substance for large and small clinical batches and even commercial scales. In addition, our raw material specialist will source necessary excipients and packaging materials. Our formulators and analytical chemists develop suitable compositions, manufacturing methods and control methods that are essential for all projects.

The Recipharm offering:

Recipharm has been supporting customers with clinical trial material for over 25 years. We have an experienced team of analytical chemists, organic chemists, formulation scientists, process engineers, manufacturing experts, quality control (QC) and quality assurance (QA) specialists who support our customers with CTM development and manufacture.

Our comprehensive service offering spans from drug development to qualified person (QP) release, including packaging and labelling. We have dedicated facilities for small scale GMP manufacture up to full commercial scale and everything in between and our experts have extensive experience in how to apply GMP at different stages of development. By utilizing our expertise, clients can overcome challenges in supplying clinical trial material for all clinical phases.

Our service offering includes:

- Development of drug substance and drug products for all clinical phases
- Development of all necessary control methods
- Stability studies
- GMP-manufacture of clinical trial material in small and large scale
- GMP-manufacture of drug substance in small and large scale
- Development and manufacture of placebos
- Packaging and labelling according to GMP requirements
- CMC support
- Quality control
- QP release

Timely planning of clinical trial material supply increases the chance of success.

If you are interested in learning more about how our development team at Recipharm can support you with your drug candidates, then please get in touch here: *https://www.recipharm.com/contact*.

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

For more information contact: info@recipharm.com

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