SUCCESSFUL DRUG DEVELOPMENT IN THE EARLY CLINICAL PHASE

Moving from drug discovery into the early clinical development can be both challenging and time consuming without access to the necessary expertise. To perform a phase 1 study successfully, having drug substances and drug products (of the right quality is crucial. In addition, the right knowledge and resources must also be in place, to ensure the fastest route to clinic.

Typically, drug substance is required for all safety studies, as well as the development and manufacturing of clinical trial material.

With this in mind, the manufacturing process must be scaled up in the first instance to ensure enough drug substance is available to fulfil these requirements. The further through this scale-up process you are the more crucial the product quality is.

For the drug product, often the clinical trial material differs to what is used in later trials and ultimately taken to market. More often than not, the simpler the product is, the better, however the design of the drug product is key as it will inevitably impact the clinical study results.

Once the formula, manufacturing, methods, and controls are all developed to the correct standard, then the clinical trial material can be manufactured, packaged, labelled, and released for clinical trial. Delays are common throughout the process, but careful consideration of the above activities can mitigate avoidable delays.

Crucially, it is essential to satisfy the following to ensure a successful trial: Bioavailability:

- Stability
- Quality
- Correct dosage
- Analytical methods selected for characterisation

Recipharm

At Recipharm, we are experienced in supporting early clinical development. Our expert team can comprehensively support:

Drug substance

- Method development
- Scale up
- Manufacture for clinical trial

Drug product

- Formulation development
- GMP manufacture
- Packaging and labelling
- QA release

Analytical chemical development

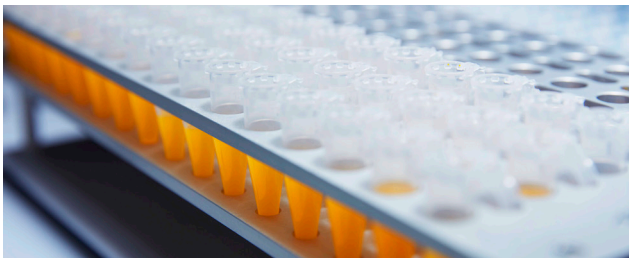
Stability studies

CMC documentation

Project management

What are the benefits of choosing Recipharm?

- Our expertise in working across a broad range of services to support early clinical development
- The coordination of services to achieve a fast and efficient development
- Cost-savings and time management through understanding the development of drug products and how to simplify the early stages
- Support through the progression stages, all the way through to the later stages and commercial manufacturing once the early clinical trials are successfully completed
- Experience of handling an array of dosage forms from development and manufacturing



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.

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