Basic Pharma

Investigational Medicinal Products (IMPs)

Basic Pharma Manufacturing runs GMP-certified clean room facilities at the Brightlands Chemelot Campus in Geleen, the Netherlands. These facilities are supported by a well-equipped, certified laboratory. We have a profound knowledge of the CMC requirements for Drug Substance and Drug Product, as directed by the relevant guidelines and regulatory requirements.

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Introduction

Manufacturing, testing and distribution of investigational medicinal products (IMPs) is strongly regulated by the relevant authorities to assure high quality when administered to patients in clinical trials. Full transparency and traceability, from the origin of the starting materials to dosing and the ultimate destruction of the study medication, all in compliance with Good Manufacturing practices (GMP), is mandatory. Maintaining a GMP-certified status for clean rooms requires continuous investment in equipment, facilities and well-trained people.

Basic Pharma Manufacturing can offer the following services in its GMP-controlled clean rooms:

- Aseptic fill and finish of solutions for injection in vials and prefilled syringes;
- Lyophilisation of sensitive clinical trial medication;
- Autoclave sterilisation of clinical trial medication & medical devices;
- Preparation of creams and ointments for clinical studies;
- Preparation of nasal sprays for clinical studies;
- Randomisation, blinding, packing and labelling of clinical trial medication;
- Authorised for use of narcotic drug and cytotoxic compounds;
- Preparation of corresponding placebo's.

In addition to the clean room activities mentioned above, we offer the following professional services:

- Drafting and compiling IMPDs and PSFs;
- QP release of the Drug Product;
- Import of study medication from outside EU;
- Wet chemical analysis of DSs & DPs.

Aseptic fill and finish

Our certified clean rooms are adequately controlled and operate at the required conditions for aseptic fill and finish, using well-trained operators. Basic Pharma is able to produce batch sizes up to several thousand units per day for a broad range of vial sizes and syringes. In addition, we have a dedicated clean room for handling cytotoxic compounds. In recent years Basic Pharma gained expertise in producing sterile injectables of sensitive nanoparticles and liposomes containing high loads of toxic drugs. With our flexibility and expertise, we can support you in finding the right solution for your promising products.

Study medication randomisation and blinding

Randomised, blinded and placebo controlled clinical studies are often used to generate reliable clinical data. Basic Pharma can perform randomisation and blinding of study medication. We have access to a wide range of differently sized capsules for masking the trial medication, thereby making it impossible to distinguish the medication being tested from the placebo.

Preparation of placebo

Using different types of non-transparent capsules, Basic Pharma Manufacturing can swiftly produce placebo capsules filled with harmless excipients such as starch or microcrystalline cellulose. Due to their colour, shape and variable weight, these capsules cannot be distinguished from the capsules containing the active study medication. Basic Pharma is also capable of manufacturing virtually any other type of matching placebo like (coloured) solutions and creams.

Packaging and labelling of clinical trial medication

GMP requires clear protocols for all activities concerning manufacturing of medicinal products. Packaging and labelling are both activities that need to be performed with great accuracy and built-in controls in order to avoid product mix-ups. Basic Pharma Manufacturing has skilled, well-trained operators for labelling and packing your clinical trial medication.

Authorised use of narcotic drugs

Narcotic drugs are notorious for their addictive properties. Their strong biological activity also makes them very interesting for use in clinical studies. Their use, handling and destruction should be subject to even more stringent regulation than non-addictive substances. Basic Pharma Manufacturing is authorised to support you with IMP activities using these controlled medications.

Autoclave sterilisation

Basic Pharma Manufacturing has a state-of-the-art autoclave for the sterilisation of IMPs and medical devices under the required quality system. This autoclave can be used stand-alone or as an integral part of a more complex project.

Drafting and compiling IMPD and PSF

Before a Sponsor can start a clinical trial, approval from the competent authorities is required. One of the documents required for review is the Investigational Medicinal Product Dossier (IMPD). The IMPD is a document that describes the Chemistry, manufacturing and Control of the Drug Substance and Drug Product to be used in the clinical trial. It should contain detailed information on the production process, analytical testing and product stability. The document has to be prepared in a predefined format to facilitate review. The Product Specification File (PSF) is a document comprehensively described in Annex 13 of Eudralex, Volume 4. The PSF lists (and refers to) the quality documentation of the IMP, such as production records, analytical method validation reports and stability reports. This document is used by the QP for release of the IMP.

QP release of the Drug Product

One of the most critical aspects of the GMP-based quality system is the final batch release of the IMP before it can be used in a clinical trial. To ensure the IMP has the required quality, the product and the documentation (listed in the PSF) must be reviewed by an independent Qualified Person (QP). Basic Pharma Manufacturing's QPs are experienced in both commercial and non-commercial batch release.

Import of study medication (non-EU)

The import of any study medication registered outside the EU requires an import license. The quality of the imported medication will be assessed before it can be relabelled and released by a QP for a clinical trial study in the EU. Basic Pharma has the relevant import license and a Qualified Person to review and release the imported trial medication.

Certified analytical support

Adjacent to the production facilities, our certified laboratory offers a plethora of the analytical tests required for starting materials and finished products. High-level analytical support is crucial for guaranteeing the quality of IMPs. This includes full ICH-compliant stability studies on DS or DP.

For additional information please contact

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