

MEDICINAL PRODUCTS MANUFACTURING FACILITY

With the implementation of the Clinical Trial Directive 2001/20/EC in May 2004, it will be a requirement that all clinical trial supplies are manufactured to GMP standards. This necessitates not only GMP compliant facilities but also approved processes, practices and methods operated by suitably trained and qualified staff.

In order to fulfil these needs and to complement its pre-formulation, formulation and analytical development expertise, MedPharm is now able to offer a comprehensive pharmaceutical development service: from scale-up and technology transfer to GMP/GLP clinical supply manufacture and analysis, including Quality Control, Quality Assurance and stability testing to ICH standards.

GMP facility

MedPharm's facility operates under GMP requirements. The facilities, processes and practices are accredited by the UK regulatory body, the Medicine and Healthcare Products Regulatory Agency (MHRA), which assures acceptance by all European authorities. They are designed to provide GMP-compliant clinical trial materials that fulfil the Safety, Integrity, Strength, Purity and Quality (SISPQ) characteristics.

Equipment necessary for manufacture and filling of supplies for Phase I/II studies of most semi-solid and liquid dosage forms can be provided, including tube filling and capsules. Clinical trials materials can be packed and labelled in-house. For Phase III/IV studies, MedPharm can manage the co-ordination of the bulk manufacture and primary packing with supply to specialist clinical supply packing and distribution partners.

Analytical chemistry and ICH stability testing

MedPharm can provide a complete analytical service - physico-chemical analysis, method development, method transfer, impurity characterisation and quantification, and quality control of Active Pharmaceutical Ingredients or API (small molecules or biologicals), excipients and formulated product.

Our QC Analytical Unit has access to the state-of-the-art equipment (HPLC, IR and UV spectrometry, GC, GC-MS, DSC, MALDI-TOF) and our scientists have extensive expertise in analytical biochemistry and immuno-chemistry.

Stability storage and testing of API and clinical trial materials to ICH guidelines can also be undertaken.



The expertise of MedPharm

Manufacture of clinical trial supplies of new products requires specialist expertise. They are unlikely at early stages to have the well-defined and fully qualified manufacturing and analytical processes found in routine manufacture and production.

MedPharm can provide the expertise to smooth the passage of your product through these crucial development stages. Our scientists bring together a range of skills to solve your problems. Our R&D Centre, based in the Franklin-Wilkins Building at King's College London, is complemented by a team of scientists with many years' industrial experience in formulation, analytical method development, scale-up, technology transfer, clinical supply manufacture and distribution.

MedPharm development services

MedPharm is committed to the development of high-quality pharmaceutical products of API for dermal, mucosal, nasal, and pulmonary delivery.

MedPharm provides a fully integrated service to its clients including:

- Mathematical modelling of drug absorption,
- Analytical development,
- Pre-formulation,
- Formulation development and optimisation,
- In vitro performance and efficacy studies,
- Small scale manufacture and stability studies,
- Scale-up to Phase III/IV supplies manufacturing sites,
- Pre-clinical and clinical studies.

Further information

Please contact: Dr Andrew Muddle, C.E.O., tel. +44 (0) 160 881 9267, email: andrew.muddle@medpharm.co.uk
We will be pleased to organise a visit to audit our facilities.