Pepceuticals Ltd
4 Feldspar Close
Warrens Park, Enderby
Leicestershire
LE19 4JS
UK

Tel: +44 (0)116 284 9301
Fax: +44 (0)116 286 2464

Website: www.pepceuticals.co.uk
Email: cgmp@pepceuticals.co.uk

cGMP – A guide to our services

PEPCEUTICALS
Peptides | Antibodies | GMP Synthesis

PEPCEUTICALS
Peptides | Antibodies | GMP Synthesis

Pepceuticals Ltd
4 Feldspar Close
Warrens Park, Enderby
Leicestershire
LE19 4JS
UK

Tel: +44 (0)116 284 9301
Fax: +44 (0)116 286 2464

Website: www.pepceuticals.co.uk
Email: cgmp@pepceuticals.co.uk

cGMP at Pepceuticals

Pepceuticals offers a versatile cGMP service to support research and in-process projects from pre-clinical toxicology studies through to early stage clinical trials. We help our customers reduce the discovery-to-market timeline by providing development to medium-scale manufacturing at one facility. We provide CMO and CMR services for the manufacture of active substances including peptides.

- Pre-GMP process development and process transfer
- Re-processing or finishing of existing materials (sterile fill)
- Preparation of reference standards
- Analytical method development and validation
- API manufacture
- Stability testing
- Process validation
- Support with regulatory documentation

Our facility which is based in Leicestershire (UK), houses over 10,000 square feet of modern laboratories which incorporates eight cGMP suites. The facility has been designed and built to meet national and international standards (EC guidance for GMP, Eudralex Vol. 4, Part I, II and Annex 1; ICH Q7A; US Federal Standard 209 E; and the ISO classification) required for API manufacture.

Designed specifically for versatility, the accwess-controlled facility operates at a minimum of Grade C (Class 10,000; M 5.5; ISO 7), encompassing Grade B laboratories incorporating a laminar flow Grade A (Class 100; M 3.5; ISO 5) cabinet. Offering a selection of large and medium sized cGMP laboratories equipped with built-in fume cupboards and walk-in fume cupboards, our state-of-the-art facility and highly trained scientists ensure that your project requirements are exceeded.

Production Capabilities

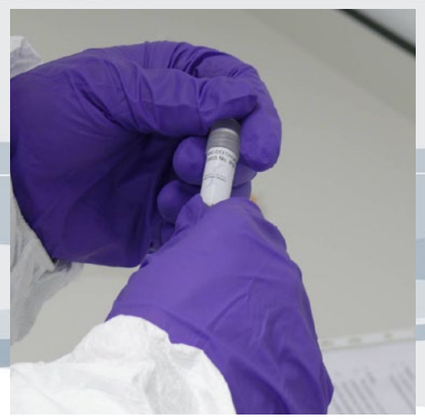
Our facility and extensive experience in cGMP enable us to offer a complete solution for your project requirements, including:

- Study management – a dedicated Study Manager will liaise with you regarding the progression of the project
- Process research and development, including process transfer – scientists working on your project will assess and improve the manufacturing process
- Analytical method development and validation – dedicated analytical scientists will optimise procedures in order to accurately identify API and related substances
- API manufacture – production scientists will manufacture the active substance to support your study, in up to multi-kg quantities
- Aseptic processing including sterile filling
- Stability testing – evaluation of active substance under a variety of environmental factors such as light, temperature and humidity.
- Cold storage
- Lyophilisation

Stability Testing

We are able to design, manage and conduct stability testing in order to support regulatory submission.

- Develop methods to test active substance stability
- Analytical testing of active substance
- Observe effects of environmental factors: Light, temperature and humidity
- Statistical analysis of results
- Evaluate storage solutions for active substance Pre-GMP process development



Active Substance Manufacture

Our team of experienced scientists will work to provide the most economic, environmentally benign and scaleable synthetic route to the active substance.

- Yield optimisation
- Impurity identification and tracking
- Safety assessment
- Environmental assessment of process
- Economic evaluation
- Feasibility study of alternative route(s)
- Process suitable for transfer to larger scale
- Identify and validate starting material suppliers
- Determine tolerance limits for processing parameters
- Identify storage conditions

Quality

We operate a BSI accredited ISO9001: 2008 UKAS Quality Management System (Certificate: FM 560179). Our Quality Manager oversees all aspects of Quality Assurance including the release of starting materials, documents and labels, audit of training, procedures and processes, final product release, and audits by regulatory bodies and customers.

Operating independently from production, the QC department evaluates the integrity of the active substance.

- Wealth of experience in analytical techniques
- Development and validation of analytical procedures
- Control and release of retention samples and standards
- Analysis of starting materials, including primary and secondary packaging
- Continuous monitoring of the cGMP facility and storages
- In-process and batch analysis
- Final product analysis
- Fully compliant ICH stability studies
- Equipment qualification

Critical analyses are undertaken using validated external procedures.

Sterile Fill

Our sterile fill capabilities include:

- Aseptic processing
- Terminal sterilisation by filtration
- Aseptic liquid and powder filling of vials, bottles, syringes and ampoules

All of our aseptic connections are made within a Grade A/ B environment.

Study Management

Each study has a dedicated Study Manager who is responsible for the Study Management Team. The team is committed to ensuring complete customer satisfaction. The Study Manager will act as a single point of contact for the customer, whilst the team will:

- Provide a Technical Agreement
- Project manage the research, method development and process transfer functions
- Provide a Quality Risk Assessment for the project
- Ensure all necessary qualifications and validations are completed
- Oversee all aspects of the manufacturing process
- Resolve issues that arise during the project
- Handle customer enquiries and provide progress reports
- Be responsible for product security, storage and 'chain of custody'
- Provide support for IND submission

Regulatory Documentation

For API manufacture we can supply the necessary documentation required for your project, or use existing documents as required. We are able to provide support with IND drug submission portfolios.

- SOPs for equipment usage, processes and activities
- Staff training records
- Certificate of Analysis for starting materials
- Technical agreements
- Production batch cards
- Certificate of Analysis for active substance

cGMP peptides

With the increasing focus on peptide therapeutic agents for healthcare, we aim to offer a complete solution to the pharmaceutical industry, by supplying peptides for pre-GMP research studies through to cGMP grade peptides.

With over a decade of commercial experience in peptide synthesis, and over 40 years expertise in synthetic chemistry we are the ideal partner for your cGMP peptide requirements.

Our cGMP peptide services include:

- Peptides up to 130 amino acids in length
- Milligram to kilogram scale
- Chemically modified peptides
- Solid phase synthesis; using Fmoc or Boc methodology, suitable for most peptide sequences
- Solid phase synthesis – suitable for short peptides
- Fragment condensation technologies – for long peptide structures
- Large scale purification – Preparative reverse-phase HPLC, ion exchange chromatography and size exclusion chromatography
- Lyophilisation
- Peptide analysis

Validation

Project validation is assessed using Quality Risk Assessment strategies in order to determine critical stages in the process and analysis. Equipment used within a critical stage is qualified before validations are undertaken. The scope and level of process validation will depend upon the number of batches of materials to be manufactured.