

GMP Peptides from Biosynth

At Biosynth we combine smart peptide science and flexible GMP manufacturing capabilities. We offer GMP compliant synthesis for peptide NCEs and commercial peptides. From early R&D to GMP peptides supply, Biosynth's team of experts is passionate about devising a customized synthesis plan to meet your needs.



At our facility in the Netherlands, we provide synthesis of drug substances suitable for use in clinical trials (according to EudraLex). We also participate in the optimization and scale up of the synthetic protocol for the NCEs. Our other GMP peptide site, in the UK, can produce peptides at multi-kilogram scale for clinical trials or commercial supply.

- Strong track-record and flexible GMP manufacturing capabilities.
- Short timelines for different phases of production.
- Best practice template for process, analytical methods and documentation.
- Synthesis protocols that are fully optimized by experts in peptide chemistry.
- Range of QC analyses under GMP as well as stability testing
- Upscaling service.

Scientific and Operational Excellence

Our efficient set-up, combined with our flexible team and organization, enables us to reliably deliver GMP peptides on short timelines. Biosynth can support all phases of the product life cycle from discovery to commercialisation. We also have the ability to simultaneously run projects in different phases up to multikilogram scale.

We have an additional service to deliver a CMC report to support IMPD/IND filing. We are experienced in stability testing according to the Q1A principles of the ICH guidelines.

GMP Specialities:

- Diagnostic peptides.
- Antimicrobial peptides.
- Lipidated peptides.
- Peptide theranostics.
- From mg-scale up to multi kilogram-scale (2 sites).
- Step-wise multiple disulfide bond formation.
- Peptide (fluorescent) labeling.
- Incorporation of non-natural building blocks.
- Radiopharmaceuticals & synthesized precursors for radiolabeled peptides.



Therapeutics Areas

Oncology Neurology **Dermatology Antimicrobials** Virology

Applications

Theranostics Immunotherapy Diagnostics Vaccines Therapeutic Peptides

Modifications

CLIPS™ Technology (Multi) Cyclic Peptides **Lipidated Peptides Post-Translational Modifications**

Partnership at Every Stage

With a diversified offer from peptide discovery and R&D up to GMP production, Biosynth's team is passionate about peptides and experts in developing custom synthesis plans that meet your needs.

Ultimately, we grow with you over the various stages of the process up to clinical trials and commercialization. Our versatility starts with a different range of equipment that produce GMP products from milligrams (routinely 100 mg) up to multikilograms scale from our UK and Netherland facilities.

Key Benefits of Working with Biosynth

With our strong track-record and flexible GMP conforming manufacturing capabilities, we enable you to start your clinical trial with confidence.



- Multiple GMP sites located across the globe with ISO 9001:2015 certification to suit your regulatory requirements.
- Short timelines across GMP production phases due to flexible in-house peptide expertise.
- Expert-optimized synthetic protocols, focus on yield improvement and cost reduction.
- A range of different analyses under GMP (e.g. identity and purity, peptide content, residual solvents (e.g. ACN/TFA), H20, bioburden), sequencing.

For more information about our GMP peptide production visit:

www.biosynth.com/peptides/gmp-peptides

