

# SENN



Solutions Synthesized



- › Peptide APIs
- › Peptide Fragments
- › Fmoc/Boc/Z-protected Amino Acid Building Blocks
- › Your partner from development to cGMP commercial production

## Swiss Quality for more than 50 years



Senn Chemicals, founded by Guido Senn in 1963, in Dielsdorf, Switzerland, remains independent and family owned. Beginning as a catalog business for carbohydrates and rare sugars, Senn today has evolved into a custom peptide manufacturer serving pharmaceutical and biotechnology companies worldwide.

### Specialized in Challenging Chemistries

#### Certifications

- › cGMP by Swissmedic
- › cGMP inspected by U.S. FDA
- › ISO 9001:2008 by SQS

#### Key competences

- › Extensive experience in synthesis of amino acid building blocks
- › Fmoc, Boc, Cbz protection
- › Specialized in peptide synthesis
- › Solution phase synthesis up to 2500 L
- › Fmoc solid phase technology (SPPS) incl. prep HPLC and lyophilisation
- › Functionalized and preloaded resins suitable for SPPS

#### Your partner for

- › Key intermediates and APIs
- › Pre-clinical to commercial cGMP supply
- › Amounts from grams to 100+ kg

#### Our Services

- › Route finding
- › Novel Process Development
- › Process Optimization
- › Analytical Method Development
- › Scale-up & Validation
- › cGMP Manufacturing
- › Dedicated Key Account /Project Manager for your projects

## Development Capabilities



Senn Chemicals provides outstanding synthetic expertise in the manufacturing of complex peptides. Our knowledge accelerates your success and accompanies your project, starting from the early development in preclinical through the various clinical phases to commercialization. Using advanced purification techniques such as chromatography, crystallization, precipitation and lyophilisation, we obtain highly purified products matching or exceeding your specifications. Based on your regulatory and cost requirements we manufacture under non-GMP or cGMP.

- › Non-GMP and cGMP synthesis mg - kg
  - New Chemical Entities
  - QC & Reference Compounds
  - Complex Derivatives & Intermediates
  - Development & Commercial Compounds
- › Use Tests
- › Process Optimization
- › Second Generation Processes
- › Feasibility Studies
- › Scale-Up
- › Trouble-Shooting

### Development supported by

- › Semi-preparative HPLC Chromatography System
- › Preparative MPLC Chromatography System
- › Lyophilizers
- › Semi-preparative MPLC Chromatography System
- › Preparative HPLC Chromatography System
- › State-of-the-art analytical techniques, such as HPLC, LC-MS, LC-MS/MS, Headspace GC



### Case studies: Complex long peptides

As a pioneer in amino acid building block synthesis, Senn Chemicals is proud to offer you its extensive experience and knowledge in peptide chemistry, amino acid building blocks, carbohydrates, small molecules, complex organic molecules as well as functionalized polymers. From a single derivatized amino acid up to a 30+ amino acid peptide, we are ready to exceed your expectations. Increase the likelihood of the success of your projects by choosing Senn as your reliable partner. The case studies outlined below demonstrate Senn's expertise to deliver your valuable project on time.

#### 17-mer cyclic peptide API

- › Developed linear approach and scaled up new strategy within 17 weeks
- › Clinical Phase IIa in EU

#### 31-mer cyclic peptide API

- › Developed novel synthetic strategy using fragment hybrid approach (Fmoc SPPS and solution phase) within 12 weeks, scaled up to 100 g
- › Clinical Phase I in EU

#### 18-mer bicyclic peptide

- › Developed synthetic solution phase strategy suitable for hundreds of kilograms annually without chromatography
- › Reached Clinical Phase II in EU

### cGMP Production Capabilities



In order to produce a wide variety of high quality peptide related products, Senn Chemicals has refined solid and solution phase peptide synthesis technologies, which can eliminate the need for traditional chromatographic purification techniques, thereby in many cases saving time and money. With fully automated SPPS reactors, we can support your peptide production needs from gram to multi-kilogram scale. Our scientific staff has accumulated decades of expertise in the manufacture of high yield peptide fragments and peptidomimetics using solution phase synthesis. Therefore we are able to deliver unparalleled purity and exceptional cost-efficiencies with every batch.

- › Multi-Purpose Glass-Lined Reactors  
100 - 2500 L
- › Hydrogenation Reactors  
630 - 2500 L
- › Solid Phase Reactors  
80 - 160 L
- › Low Temperature Reactors (- 80 °C)
- › Preparative HPLC Chromatography (up to 20 cm)
- › cGMP Suites
- › Lyophilisation (20 kg ice)



## Quality Unit



Senn Chemicals operates under the quality parameters and guidelines established by both the European and United States authorities. As such, cGMP compliance is routinely audited and confirmed by both Swissmedic and the U.S. Food & Drug Administration (FDA). Moreover, in the spirit of continual improvement, we routinely commission independent third party auditors to evaluate our facilities and processes. Consequently you can rely on our superior quality standards. Senn Chemicals complies with the Swiss regulations concerning environmental protection and occupational health and safety regulations.

State-of-the-art analytical technology ensures the control of all parameters related to your products. As required we collaborate with third party contract laboratories that have been qualified to meet all regulatory demands as well as your specification requirements.

- › Method Qualification and Validation
- › Physical Characterization
- › Impurity Identification
- › Stability Studies
- › Reference Standard Qualification
- › Residual Solvent Determination
- › Compendial Testing
- › Chromatographic Assays
- › Spectrometry
- › LC-MS and LC-MS/MS
- › Headspace GC
- › HPLC
- › Qualified External Service Laboratories



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