# Aspen API. **Peptides**

## Our peptide development and manufacturing capabilities

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Aspen API has over 100 years of experience in development, up-scaling and commercially manufacturing of complex high potency APIs, amongst which also peptides. We work from a deeply rooted and pro-active quality culture and we offer our customers a true partnership by consistently delivering high product quality on schedule. Aspen provides you extensive support at all stages of the project: from proof of concept forward through registration and commercialization.

## Building on +60 years of peptide experience

With more than 60 years of peptide experience, we have built a strong reputation by producing cGMP peptides with batch to batch reproducibility combined with high yields and high purity profiles. Aspen API is an active member of APIC and directly involved in discussions within EMA, US FDA, EDQM and ICH.

## Our peptide capabilities

Stainless steel and glass-lined reactors ranging from 100 to 1500 liters

Liquid Phase Peptide Synthesis (LPPS)

Solid Phase Peptide Synthesis (SPPS)

Green Continuous LPPS™

Preparative HPLC columns up to 45 cm

100 liter tray lyophilization

## Our green answer to peptide synthesis

Green Continuous LPPS™ combines the advantages of the classical solution-phase synthesis with the solidphase approach and is characterized by the fact that intermediates are not isolated. This enables a highly efficient synthesis method that is easy to scale up and yield products of reproducible high purity.

## Your CDMO or CMO peptide API project in excellent hands

Whether your project is for a New Chemical Entity (NCE), or a process for (re-)designing your peptide API, we will be your partner from the development phase to the commercial implementation. At Aspen API we understand what you need, advise you on green and efficient alternatives and provide the ultimate solution. Aspen API adds expertise, innovation, compliance, registration and partnership to your project. You will be working with a high-quality partner who offers skills and well-equipped pilot laboratories, pilot plants and cGMP facilities to enable development, efficient technology transfer and scale up of your peptide API.

| Key Product Development Parameters | | Determined by | Green Continuous LPPS™ | LPPS | SPPS |
|---|---|---|---|---|---|
| **Time-to-market** | Route development | Amenable to a generic protocol | ✓ | - | ✓ |
| | Scale-up & validation | Homogeneous synthesis | ✓ | ✓/- | ✓ |
| **Manufacturing effciency** | Cycle times | No isolations/High throughput | ✓ | - | ✓ |
| | Materials | Reagent excess minimized | ✓ | ✓ | - |
| | | Minimal side-chain protection | ✓/- | ✓ | - |
| | | No solid support | ✓ | ✓ | - |
| **Product quality assurance** | High purity | No insertion sequences | ✓ | - | ✓ |
| | | No deletion sequences | ✓ | ✓ | - |
| | | No side-chain reactions | ✓ | - | ✓ |
| | Reproducible | Reproducible isolations | n.a. | - | n.a. |
| | | Reproducible supports | n.a. | n.a. | n.a. |
| **Enviromental demands** | Organic waste streams | No Solvent changes | ✓ | - | ✓ |
| | | No organic washings | ✓ | ✓ | - |