Innovation for large-scale peptide production

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PolyPeptide

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PolyPeptide at a glance

Torrance (US)

Braine-l'Alleud (BE)

Malmö (SE)

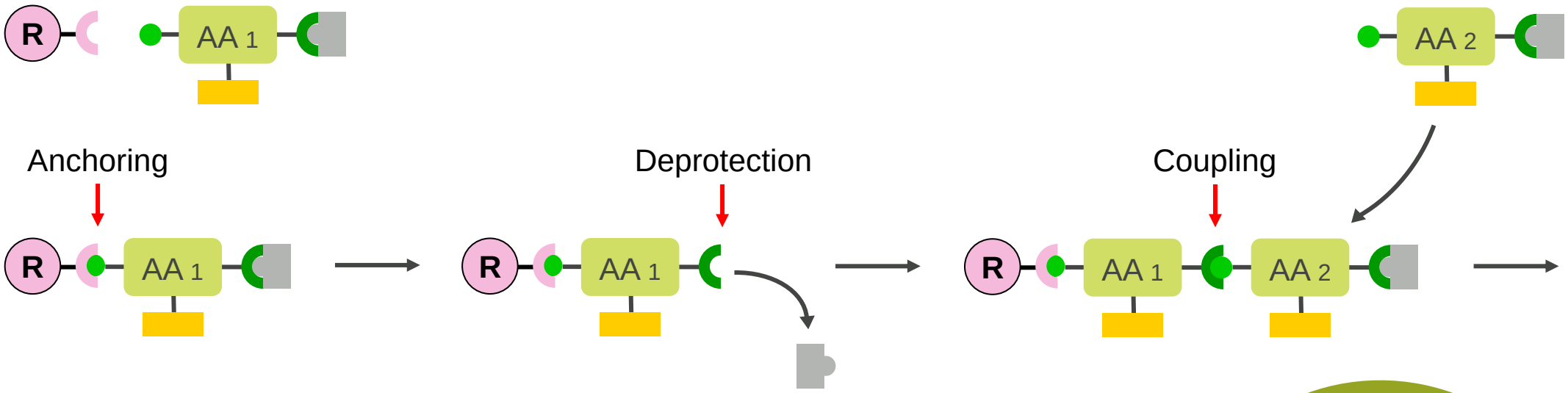
Ambernath (IN)

San Diego (US)

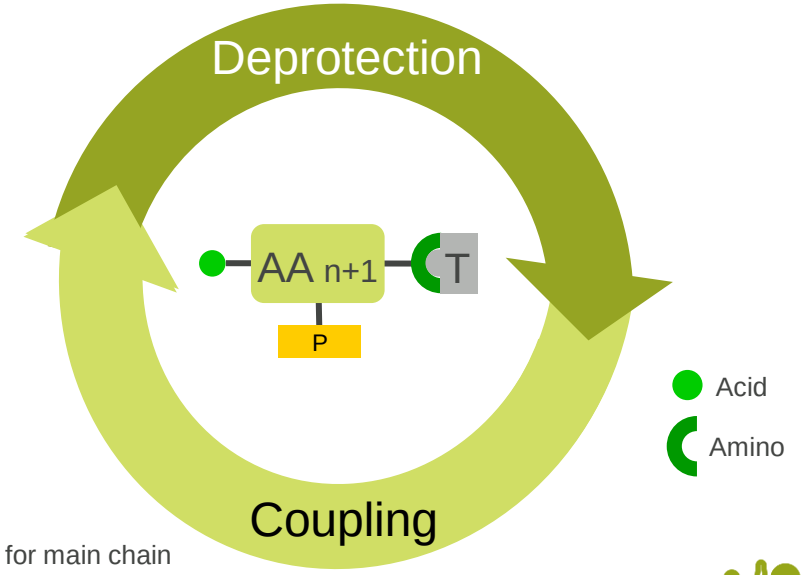
Strasbourg (FR)

- A leader in the peptide CDMO market with multisite network and over 70 years of experience
- Track record of >1,000 therapeutic peptides manufactured

Solid phase peptide synthesis (SPPS) is a repetitive process

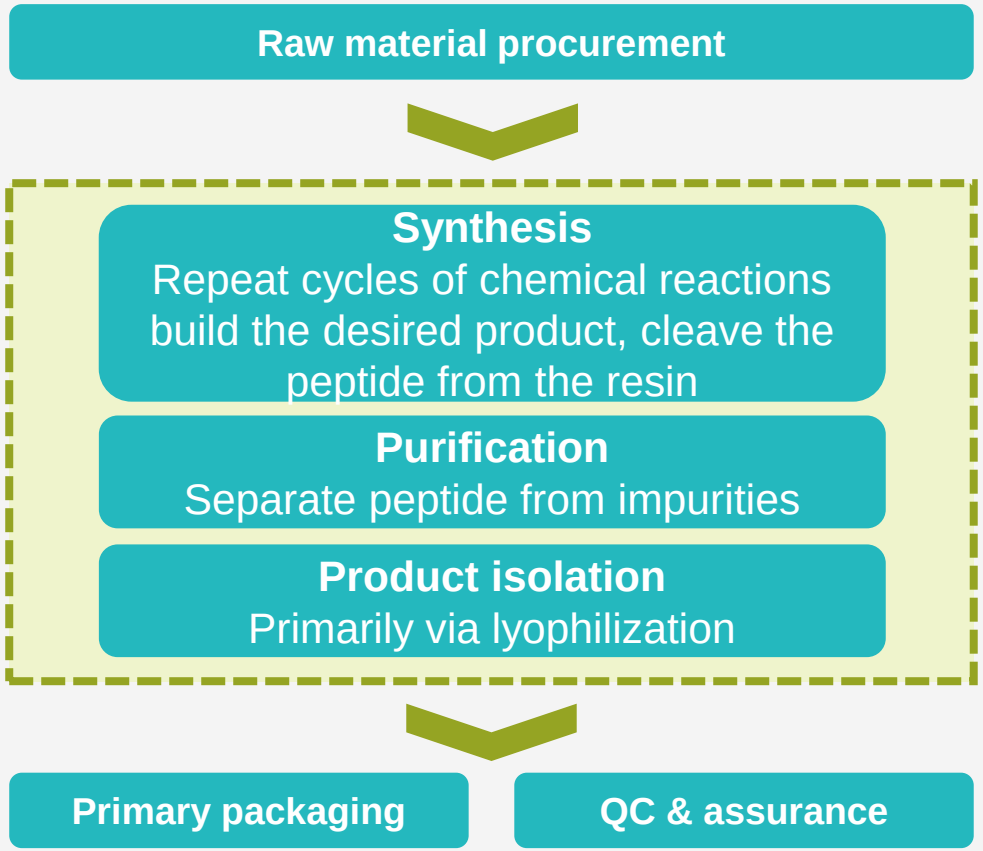


- A resin (R) as solid support is used to anchor a first protected amino acid (AA) and to build a peptide chain
- Additional AAs are linked by chemical bonding until the desired molecular structure is reached
- With every AA to be added, the cycle of “deprotection” and “coupling” is repeated



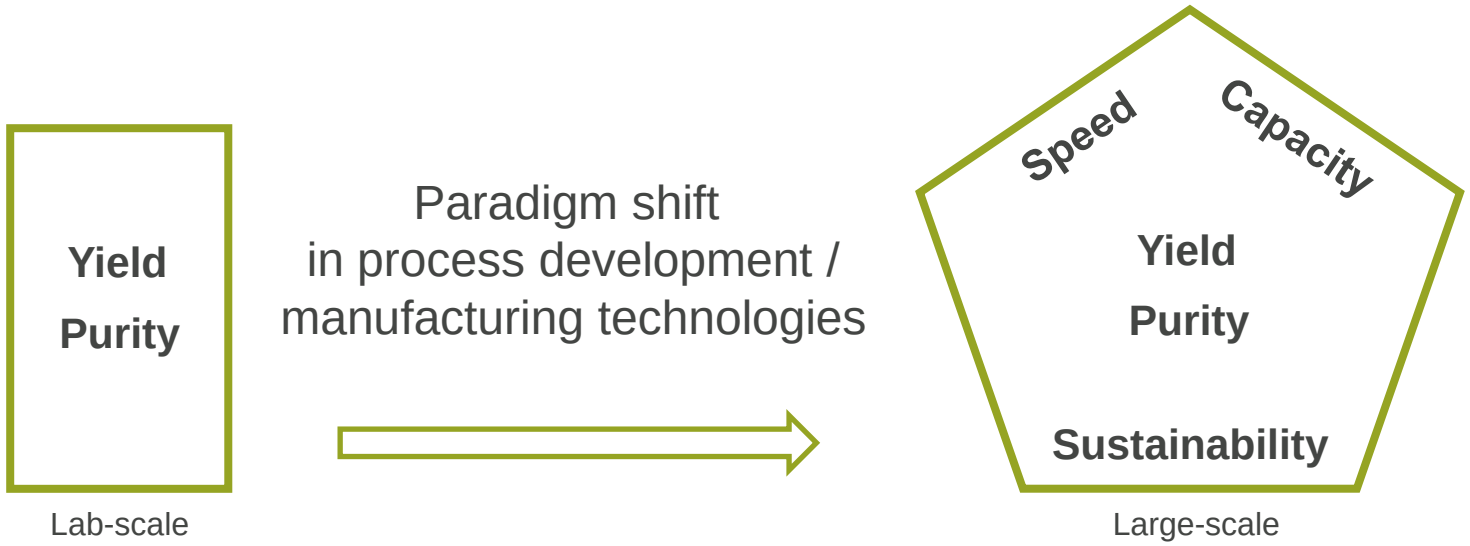
R – Resin
AA – Amino acid
T – Temporary protecting group for main chain
P – Permanent protecting group for lateral chain

Peptide manufacturing is complex



- Technical considerations
  - Each peptide unique with particular impurity formation and process performance
- Regulatory considerations
  - Need to demonstrate consistent product profile with no new impurities
- Financial considerations
  - High capex requirements for facilities and equipment
  - Multiple steps, leading to long campaign duration and high opex

Dimensions of large-scale SPPS innovation



PolyPeptide areas of innovation

Sustainability → greener solutions

Speed → number of couplings per day

Capacity → «scale up» versus «scale out»

Examples

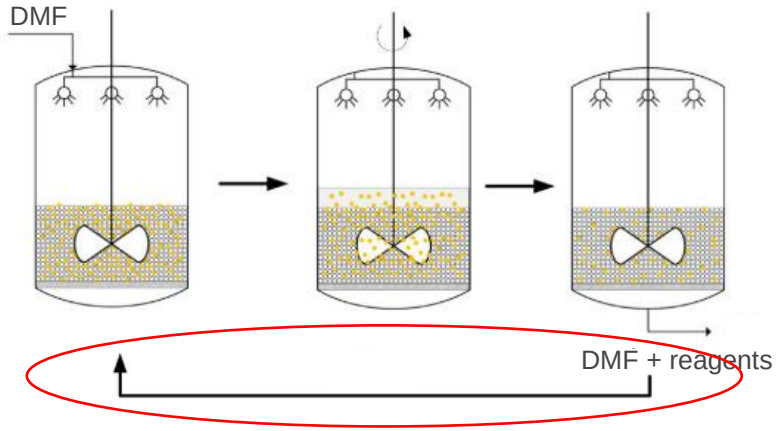
1. Proprietary flow washing by percolation
2. Infrastructure design & automation
3. Throughput and potential of modularity

Proprietary flow washing by percolation

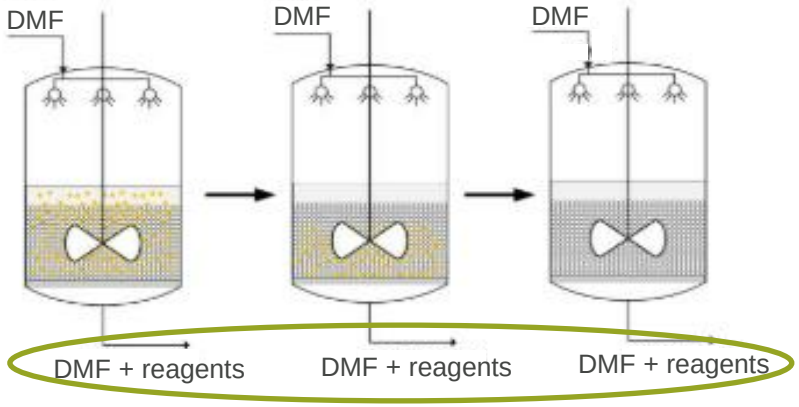
Example

1

Repetitive batch washing



Continuous flow washing



Process mass intensity (PMI)[1]	
Small molecules	168–308
Biologics	~8,300
Peptides (SPPS)	~13,000

- Intensive resin washing between each chemical step required to avoid impurities
  - Typically, washing accounts for >75% of solvent consumption in traditional SPPS
- PolyPeptide's proprietary washing concept by percolation[2]
  - Experimental solvent savings of >50%
  - Improved process productivity
- Percolation deployment of 84% in 2023[3]
  - 23.5% reduction of Group-wide solvent consumption, relative to kg manufactured products

[1] Defined as kg of input materials (water, solvents, reagents, etc.), divided by kg of API output; source: ACS GCIPR, 20 March 2024.
[2] R. Ravetti Duran, and O. Ludemann-Hombourger, Speciality Chemicals Magazine, Jan/Feb 2022. Patent granted in Sweden, further applications pending.
[3] Percolation deployment defined as kg of DMF used by solid-phase peptide synthesis (SPPS) projects with percolation implemented, relative to the overall DMF consumption of all SPPS projects.

Infrastructure design & automation

Example

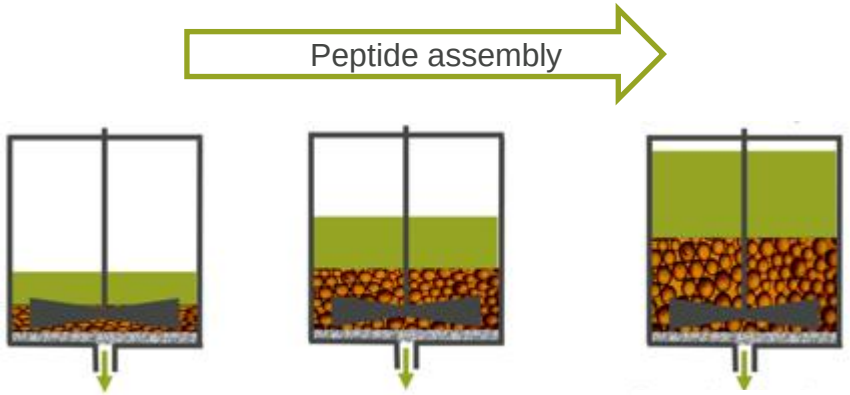
2

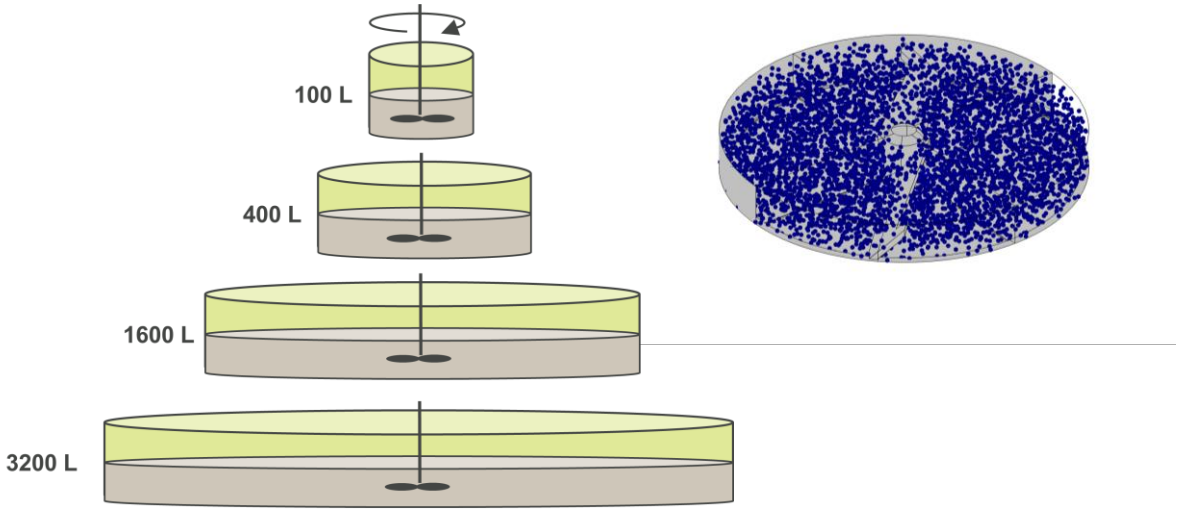
- New large-scale SPPS capacity in Braine l'Alleud, Belgium
  - Integrated design, incl. flow washing
  - Advanced automation and process control
  - Closed material flows
  - Optimized solvent consumption
- Start of production on track
- Supporting multi-year commercial agreement with annual order value of around EUR 100 million after ramp-up phase

SPPS with volumetric scale-up limitation

Example

3





- SPPS uses resin support for assembly of peptide chain
- Process performance impacted by resin height
  - Increase of draining time
  - Risk of resin to collapse

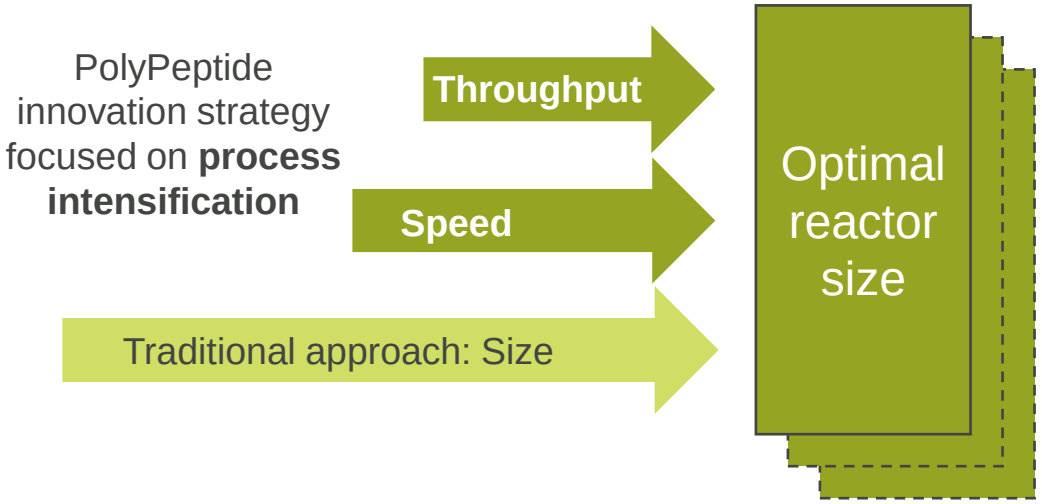
- No linear correlation reactor volume / output
  - Ideal scale-up consideration is to keep same resin height, whatever the size
  - Additional engineering considerations needed, also due to geometric constraints[1]
- Throughput and speed as inherent challenges for the design of large-scale reactors

[1] R. Bayle, J. Wheeler, R. Ravetti, P. Namy, O. Ludemann-Hombourger: Modelling of the rinsing of a fixed bed reactor for SPPS using COMSOL multiphysics, 34th European Modeling & Simulation Symposium, EMSS 2022.

Throughput and potential of modularity

Example

3



Potential of modularity

- Time to market
- Operational flexibility

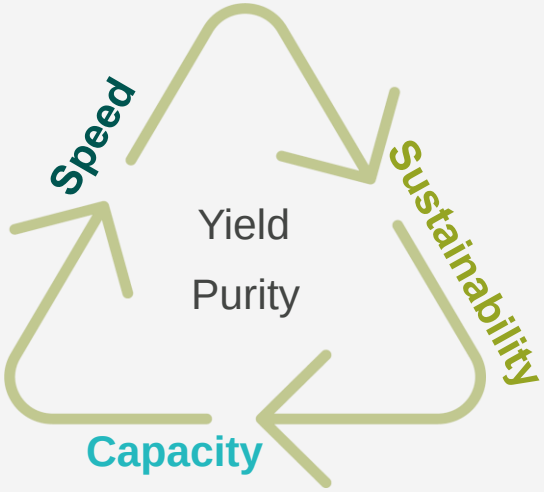
Options for capacity scale up[1]

1. Increase reactor size (volume)
   - Volumetric limitations
2. Increase speed (number of couplings / day)
   - Process considerations, including automation
   - Chemical considerations to boost kinetics
3. Enhance throughput
   - Novel proprietary SPPS resin development to boost loading capacity

[1] O. Ludemann-Hombourger, Speciality Chemicals Magazine, May 2013: The ideal peptide plant.

Conclusion

Increasing GLP-1 (and other) volumes
require innovative peptide manufacturing technologies



- Polypeptide's focus is on technology-driven SPPS capacity enhancements: bigger is not always better
- At PolyPeptide, innovative solutions are already deployed, improving productivity AND sustainability
- PolyPeptide strives for high capital returns by combining proprietary technology with the potential of modularity

Thank you

Contact and calendar

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Events 2024

06 December 2024	Kepler Cheuvreux GLP-1 day, Zurich

Events 2025

09 January 2025	Baader Helvea Swiss Equities Conference, Bad Ragaz
10 January 2025	Octavian Swiss Seminar, Davos
15 January 2025	JP Morgan Healthcare Conference, San Francisco
11 March 2025	Full year results 2024
09 April 2025	General Meeting 2025
12 August 2025	Half year results 2025

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