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How to develop fermentation API at CCSB

Update:09/25/2025

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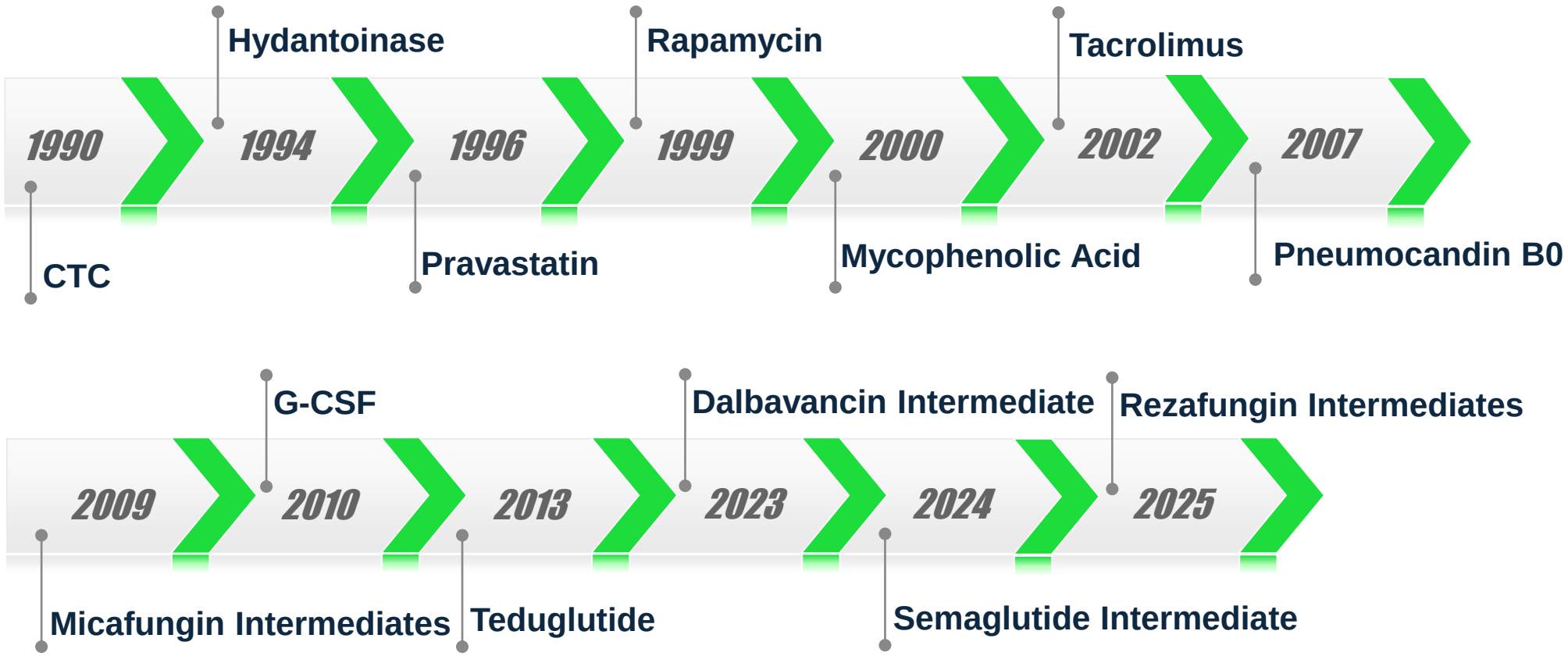
More Than 30 Years Experience in Developing Fermentation Products



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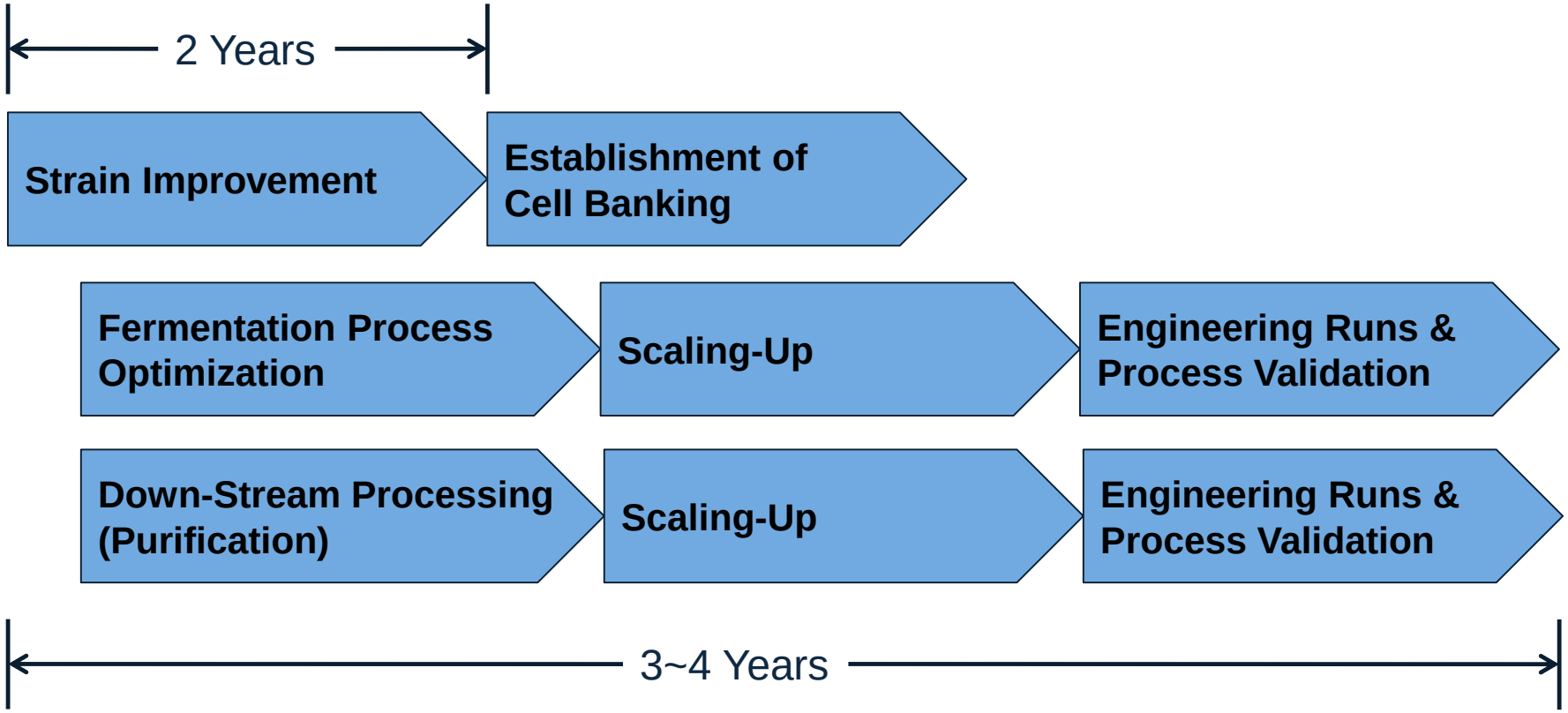
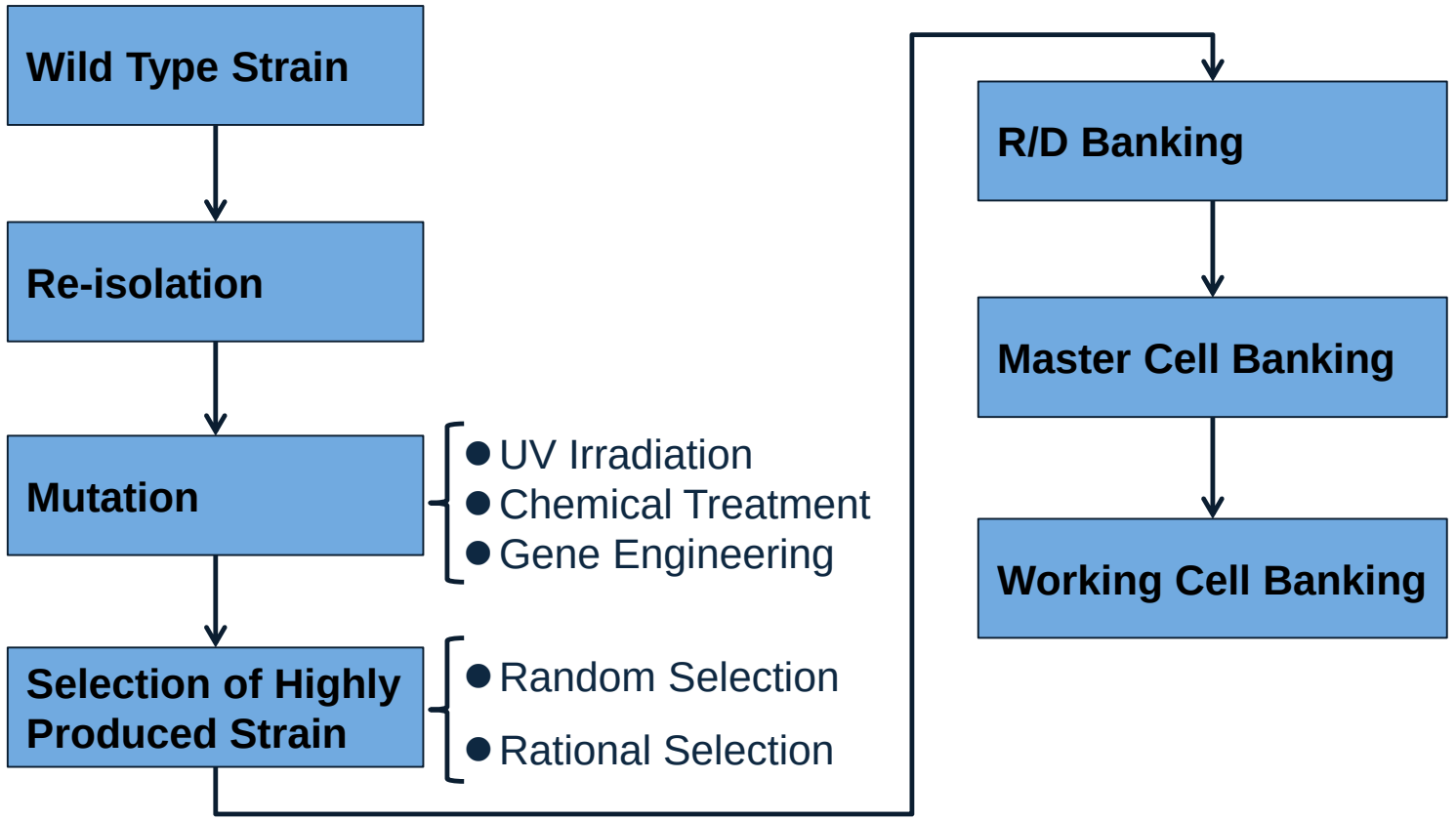
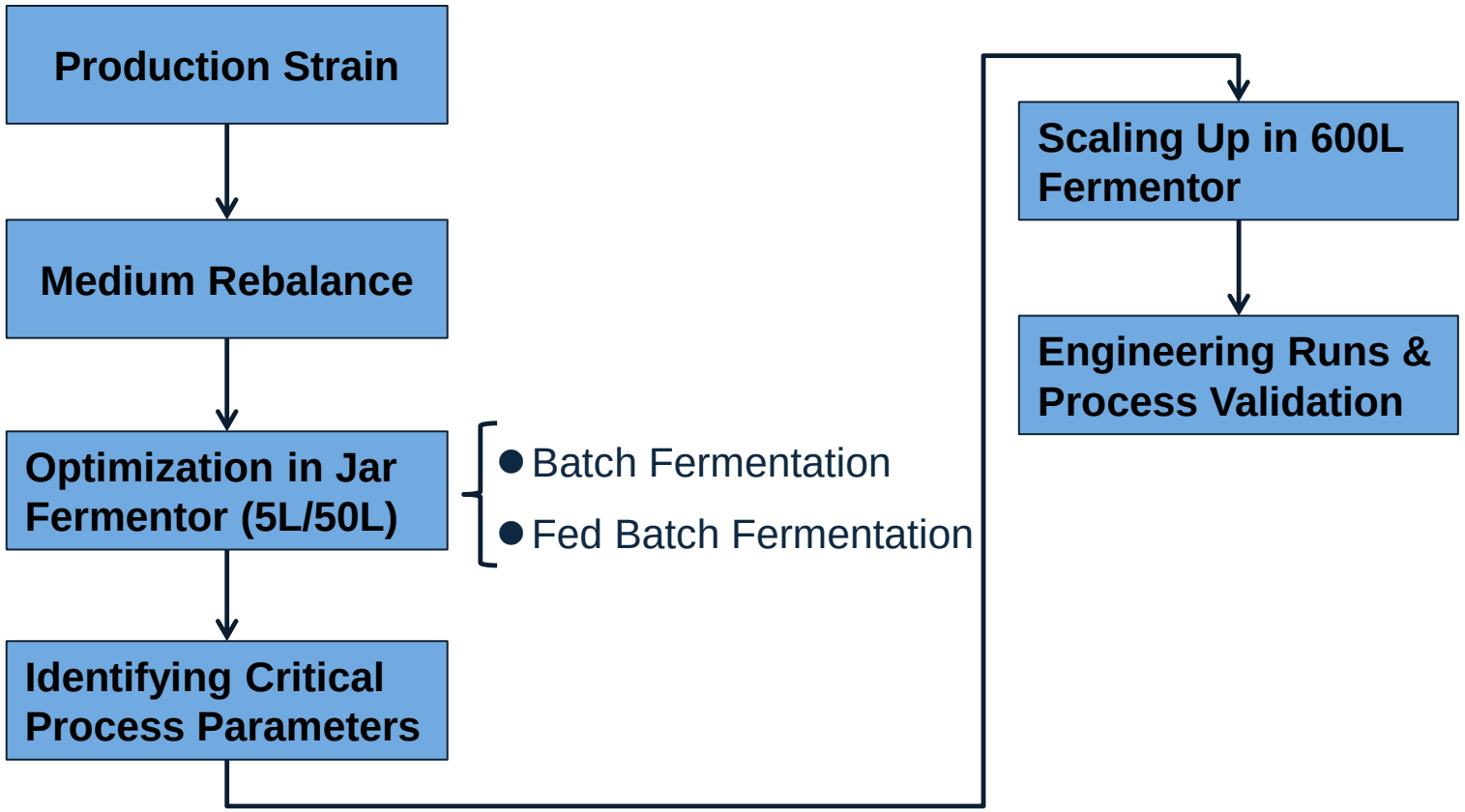
Fermentation API Development



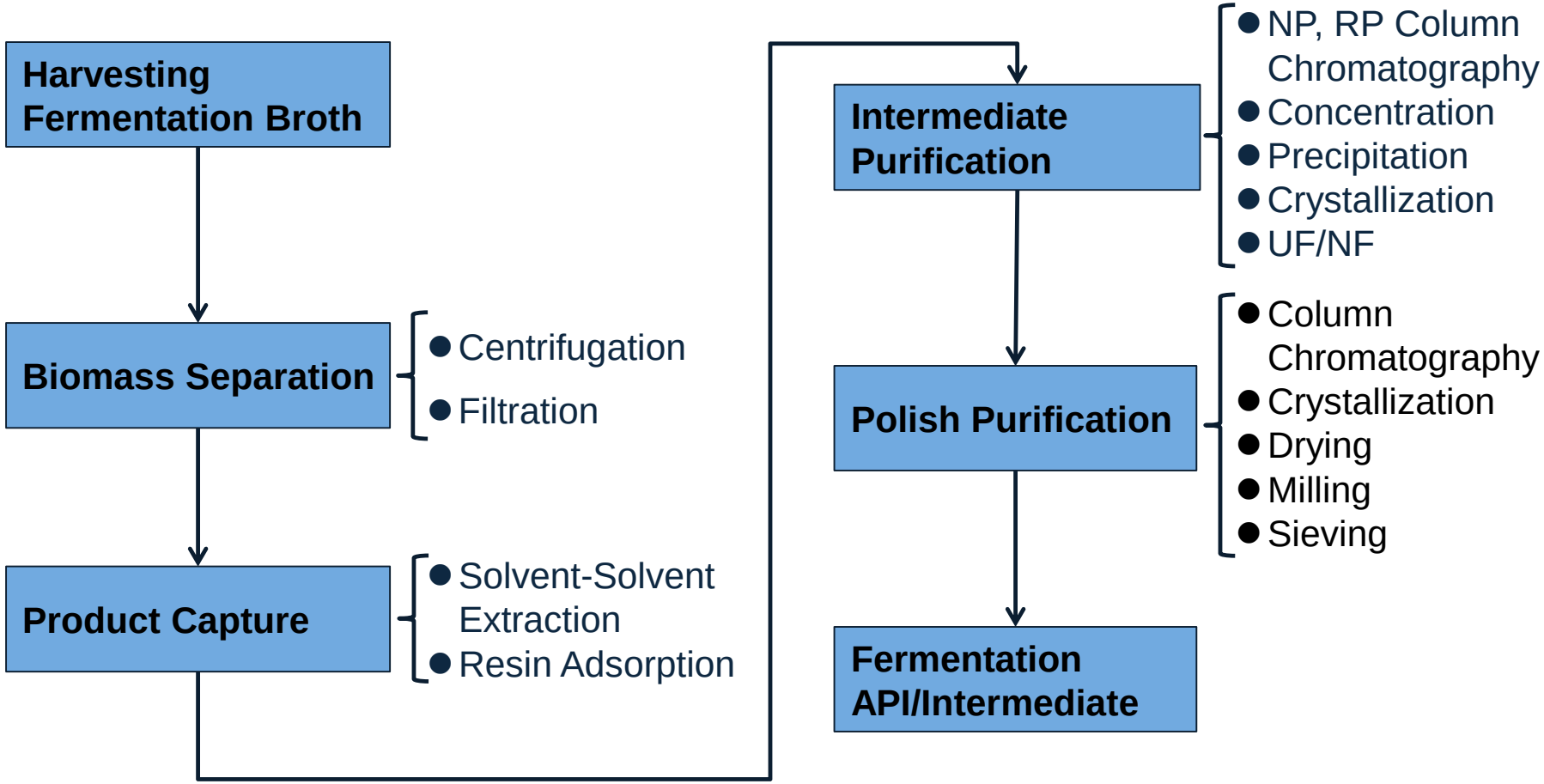
Strain Improvement Program



Fermentation Process Optimization



Down-Stream Processing



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Systematic Approach to Recombinant Peptide

Cell line Development	• Expression system selection • Vector preparation • Stable clone generation • Scale-up • Development bank • Clone characterization • Stability • Bioreactor evaluation
Cell Culture/ Fermentation Process Development	• Cell line • Media development • Cell expansion • Parameter optimization • High cell density culture • Robustness study • Scale-up

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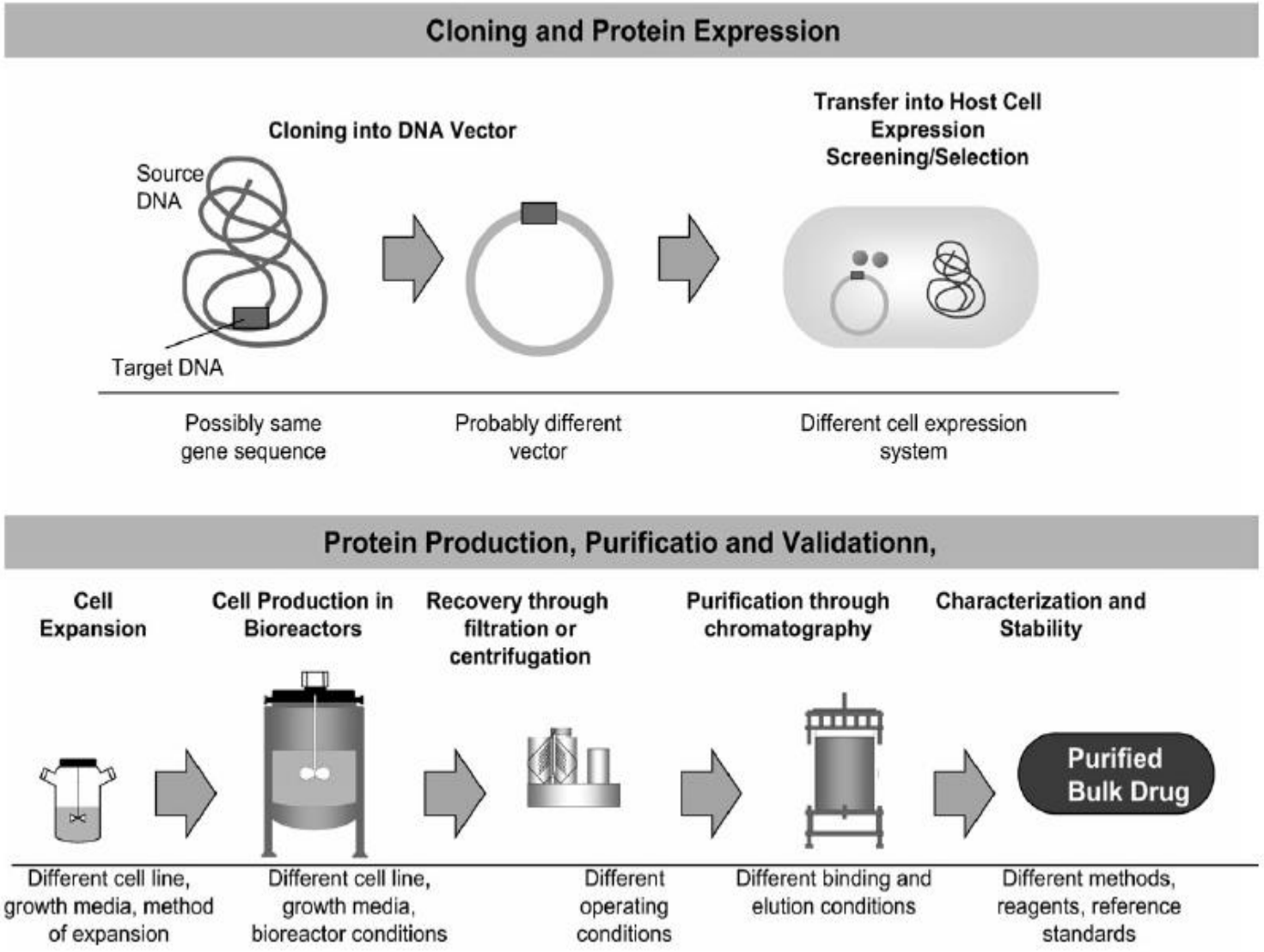
Systematic Approach to Recombinant Peptide

Purification Process Development	• Ion Exchanger Column • Affinity Column • HIC Column • SEC Column • Refolding • Preparative HPLC • Lyopholization • Scale-up
Analytical Method Development	• Characterization • Chemical Assay • Bioassay • Bioburdens • Impurity Profiling • Degradation Profile • Method Validation

Recombinant Protein Production



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Recombinant Peptide Production

Pros

- Relatively inexpensive and simple to perform
- Versatile hosts and expression vectors
- Extensive knowledge regarding DNA manipulation
- Easy manipulation of expression host system
- Efficient and cost-effective high production yields
- Mature scale up and purification system

Cons

- Expression of all natural amino acid peptides
- Purification of low molecular weight peptides
- When Met is not the first amino acid in mature peptides
- Aggregation
- Host cell proteins and DNA

Strategy of Recombinant Cell Line Construction

Fusion protein technology

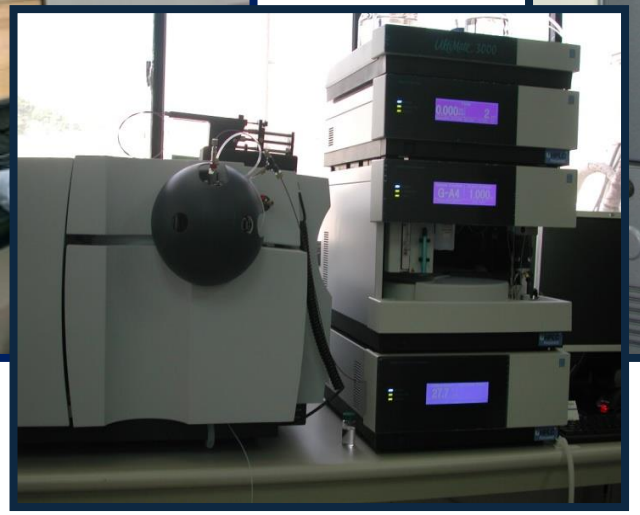
- Enhance expression of target protein
- Improve protein solubility
- Easy to be purified via tag
- Highly solubility in native buffers

Innovation technology platform

- Construct novel fusion protein expression vector
- Enhance peptide expression level, improve solubility
- Fusion protein can be efficiently cleaved by inexpensive enzymes

Instrumentation (cont.)

GC/MS

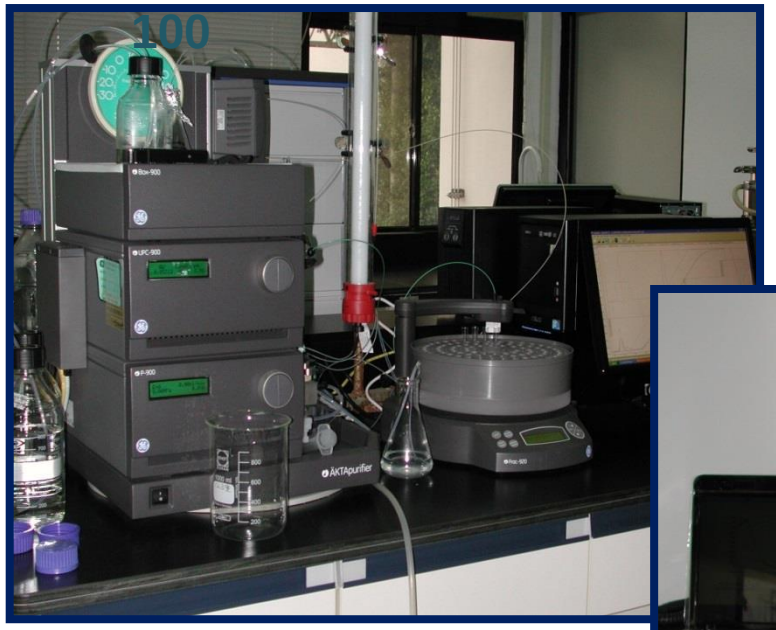


LC Mass

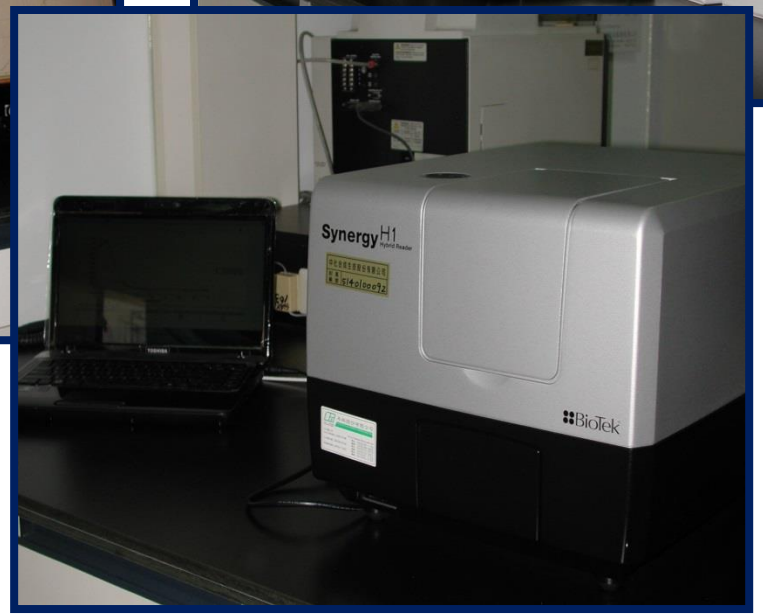
UPLC

Instrumentation (cont.)

GE AKTA Purifier UPC 100



KvickLab Cross Flow System



BioTek Synergy H1 Hybrid Reader

Instrumentation (cont.)

Mbraun Glove box

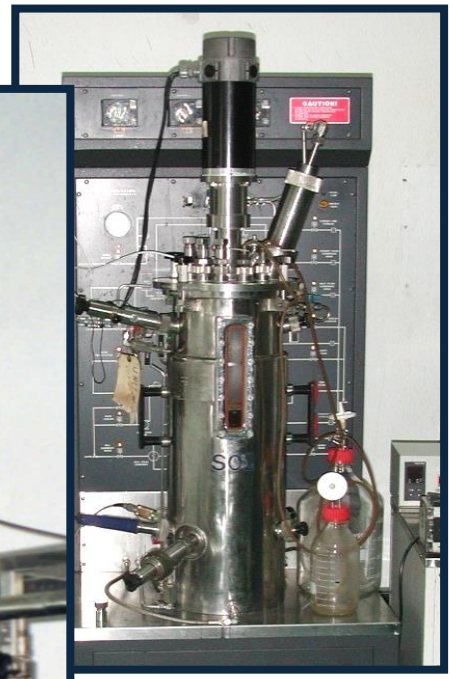
Type: UNILAB-B

Bio Rad ChemiDoc XRS+ Imaging System

Biotech Pilot Plant

5 L Fermentor

600 L Fermentor



22 L Fermentor

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