



Bioprocess Platform in the Health Field

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Tofflon Science and Technology Group Co.,Ltd.

Trends in the field of Healthy











Biopharmaceuticals

Food

Medical apparatus and instruments

Cosmetics

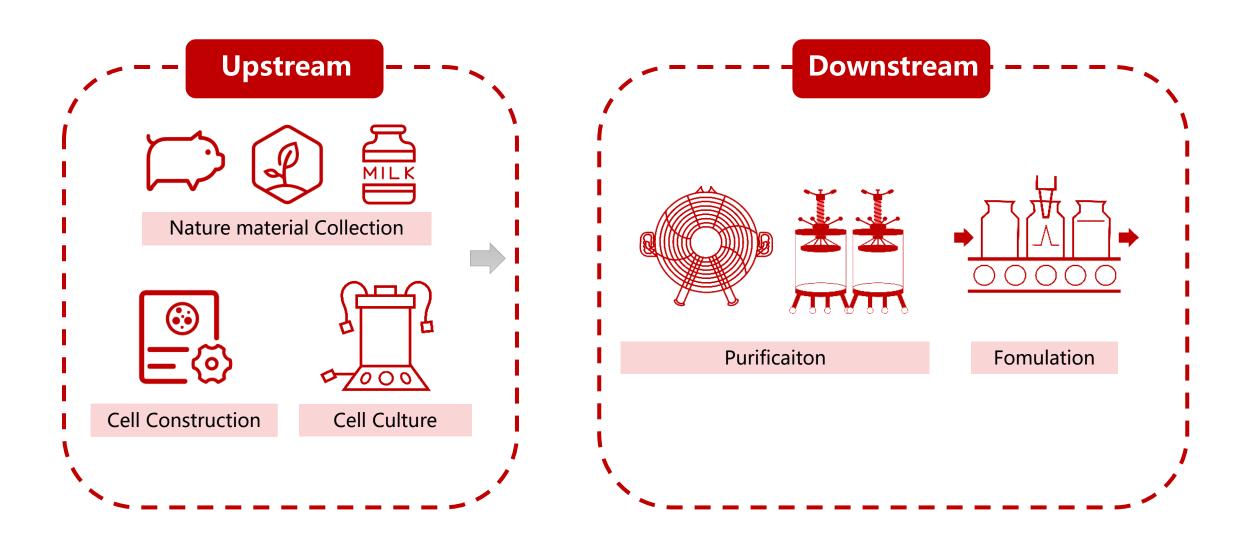
From Nature or Chemical synthesis, to Biotechnology

Biotechnology

Fermentation engineering Enzyme engineering **Metabolic Engineering** Cell Engineering Microbiology Synthetic biology

Protein Functional sugar oligonucleotide

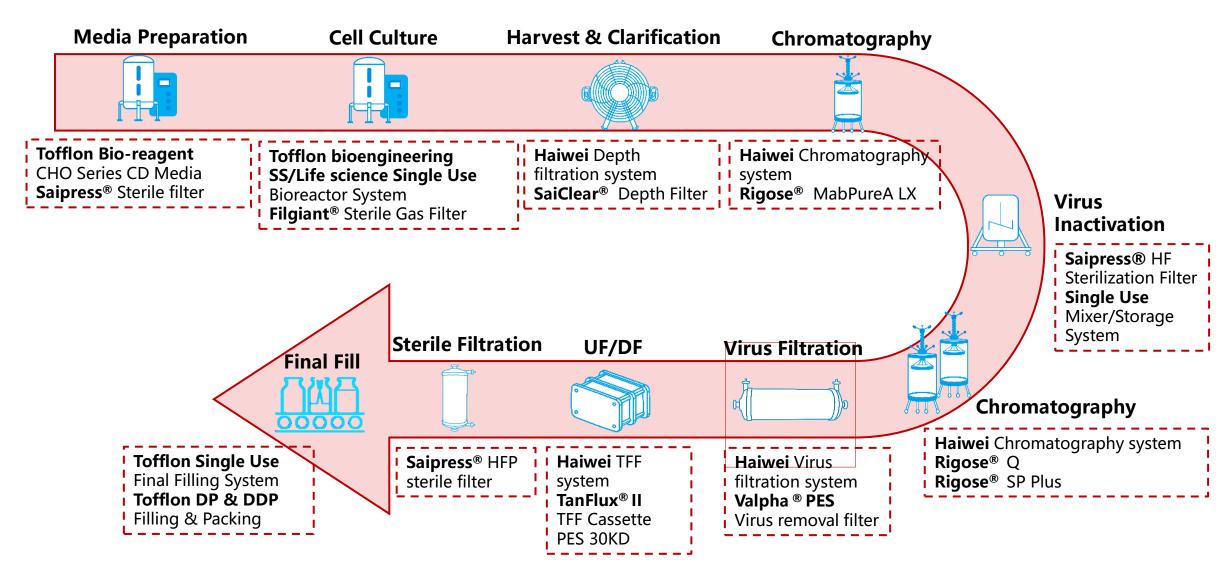




Mature Process Solution in Biopharma



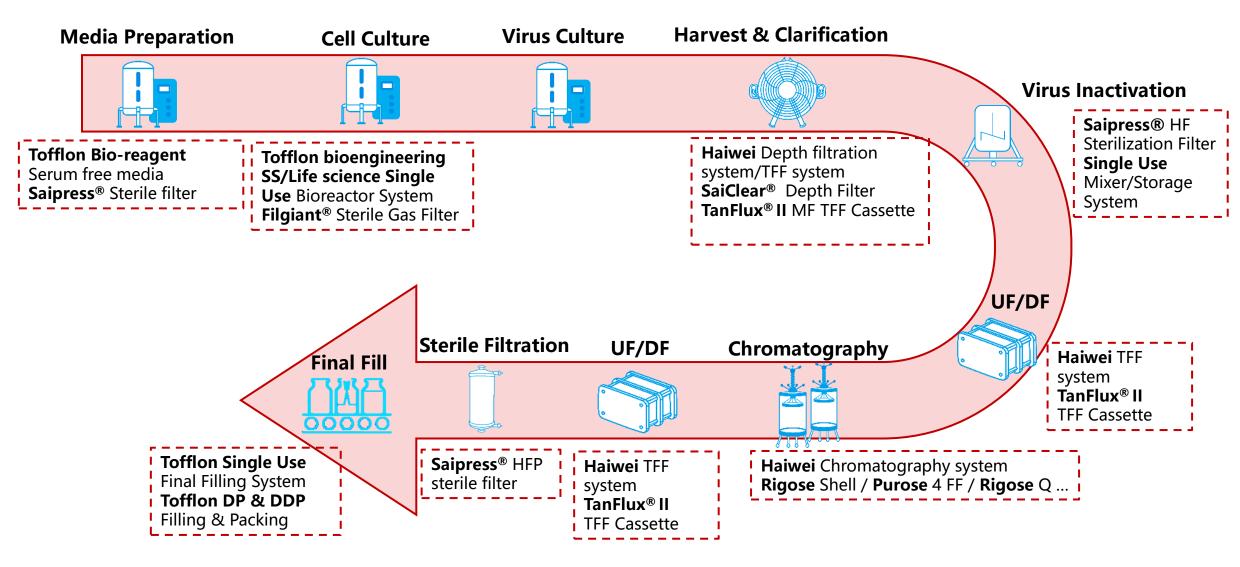
Process Solution for mAb



Mature Process Solution in Biopharma



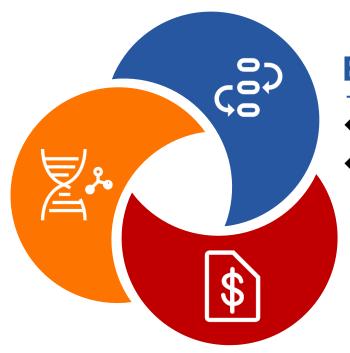
Process Solution for Inactivated Vaccine/attenuated live vaccine





Technology

- ◆ UpstreamGenetic Technology;Culture/FermentationTechnology
- **♦** Downstream Bioseparation Technology (Centrifugation, Filtration, Chromatography, Drying)



Engineering

- **♦** Process design;
- Equipment selection and assembly

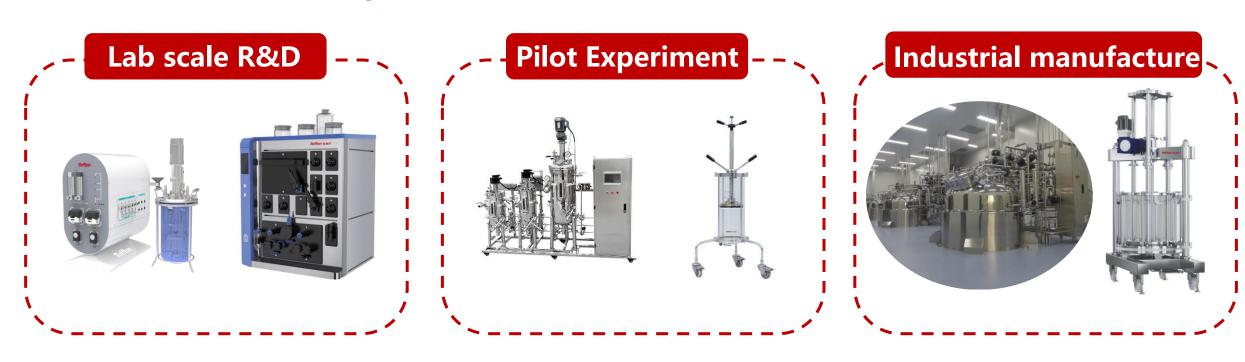
Economic evaluation

- **◆** Material balance
- **♦** Cost and economic benefit assessment

How to Develop a Bioprocess



How to get Finished Product from Natural Raw Material / Cell?

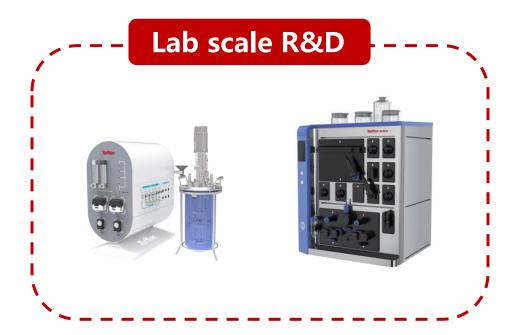


- **◆** Rational experimental scheme
- **♦** Complete experimental equipment
- **◆** Abundant experimental experience

- **◆** Accurate economic accounting
- **♦** Accurate process control
- **◆** Accurate process amplification

How to Develop a Bioprocess





Upstream Cell culture / E.coli or yeast fermentation

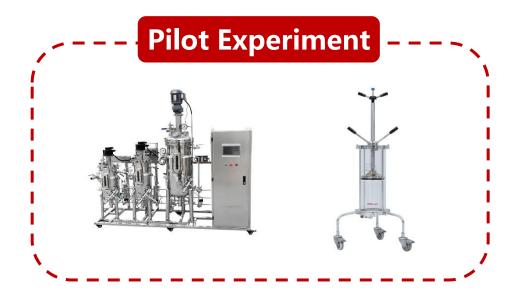
- ◆ Tofflon Life Science/ Bio-reagent Technical team (provide Media with **Cell culture technology**)
- ◆ Tofflon Bioengineering Technical team (provide fermenter with **fermentation technology**)
- ◆ Technical team from Jiangnan University (provide optimization of fermentation process)

Downstream Bio-separation & Purification

- ◆ Tofflon Qianchun Technical team (provide Resins with **chromatography technology**)
- ◆ Tofflon Saip Technical team (provide Filters with filtration technology)

How to Develop a Bioprocess





- ◆ Technical team for the project transfer from lab scale development
- ◆ Standard pilot site conditions, complete pilot equipment and pilot consumables



- ◆ Precise engineering design, full set of production equipment and consumables, ensure consistency with pilot experiment
- ◆ Technical team to site, ensure the success of the whole project



Case Share: Food Protein by Yeast Fermentation

Fermentation

Clarification

Chromatography

Ultrafiltration

Freeze/Spray Drying











- ✓ To get high concentration of target protein
- ✓ From 50L Up to 130T
- ✓ To remove bacteria and solid impurities
- ✓ Centrifugation, or Ceramic Filtration
- Critical step, to obtain the high purity of the target protein by optimizing the resin purification process
- ✓ Ion-exchange Chromatography

- Concentrated and replaced solutions
- Ceramic Ultrafiltration,
 Plate membrane Ultrafiltration



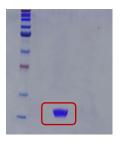
Case Share: Food Protein by Yeast Fermentation



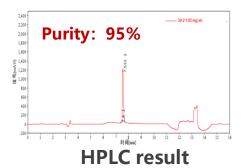
- Determine the main process especially Chromatography for downstream process
- Requirements for finished products: Recovery >80%, Purity> 90%



Freeze-dried product

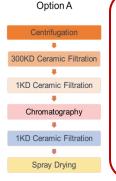


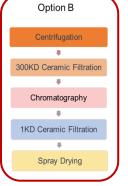
SDS-Page





- Determine the clarification method for Large scale manufacture
- Verifying the data from lab scale experiment







Factors to consider

- ✓ Protein purification
- ✓ Protein recovery
- ✓ Process time
- ✓ Cost

Option B is the best: Purity: 94.6%

Recovery: 85.0%



- ◆ Expanding to large scale such as 25T and 130T
- ◆ Output the Integrated Solutions (M+E+C)

Proposal designing in Progress



Case Share: Food Protein from Nature Resource

Anion Cation Micro-**Cation Ultra-Degrease** exchange1 exchange2 exchange filtration filtration IgG Milk α-lactalbumin Casein Lactoferrin **β-lactoglobulin**

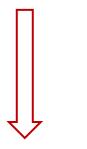


Case Share: Food Protein from Nature Resource

Lab Scale

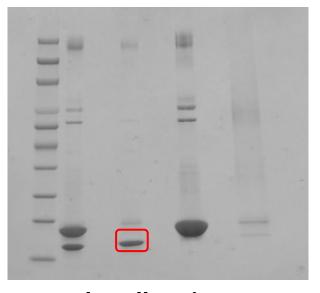


Pilot Scale

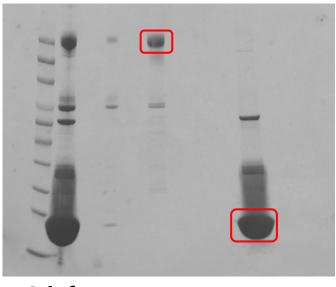




Lactoferrin Purity: 83.2% Recovery: 87.8%



α-lactalbumin Purity: 72.1% Recovery: 91.4%



IgG(left) Purity: 86.9% Recovery: 58.4%

β-lactoglobulin (right)

Purity: 80.2% Recovery: 73.5%

Capacity(for One of the top five dairy producers in the world):

Industrial Scale 60 Tons of Milk /Day

300 Tons of Milk /Day in the future

Tofflon

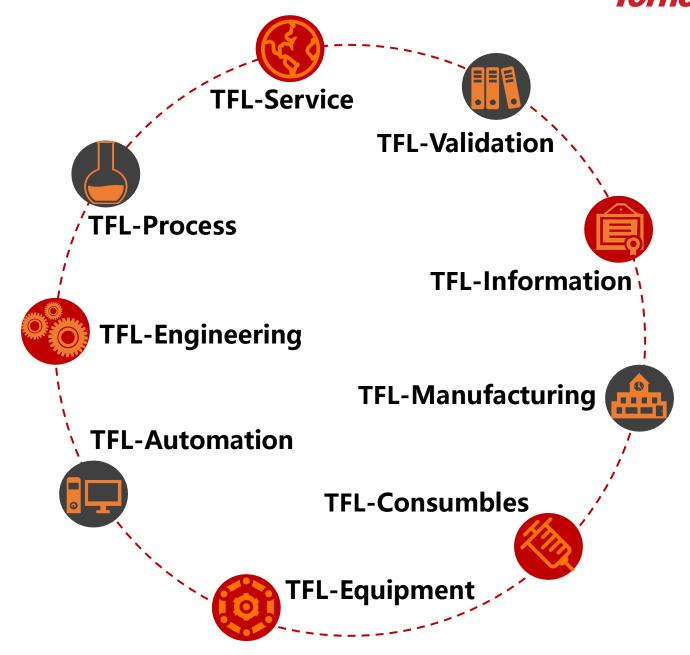
♦ Global Regulation Compliance

♦ Satisfied Process

♦ Successful Engineering

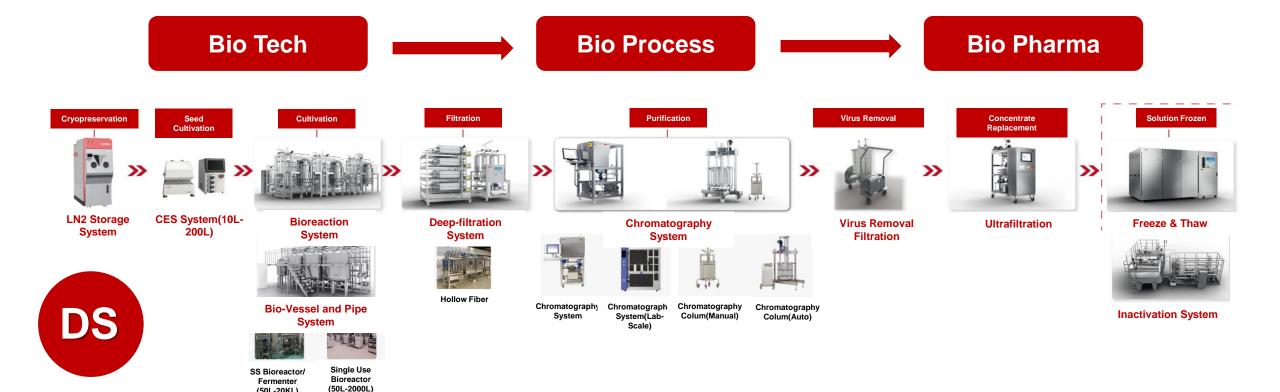
♦ Cost-Competitive Production

♦ Easy Operation & Maintenance



Tofflon Biopharma Enterprise Solution









(50L-20KL)



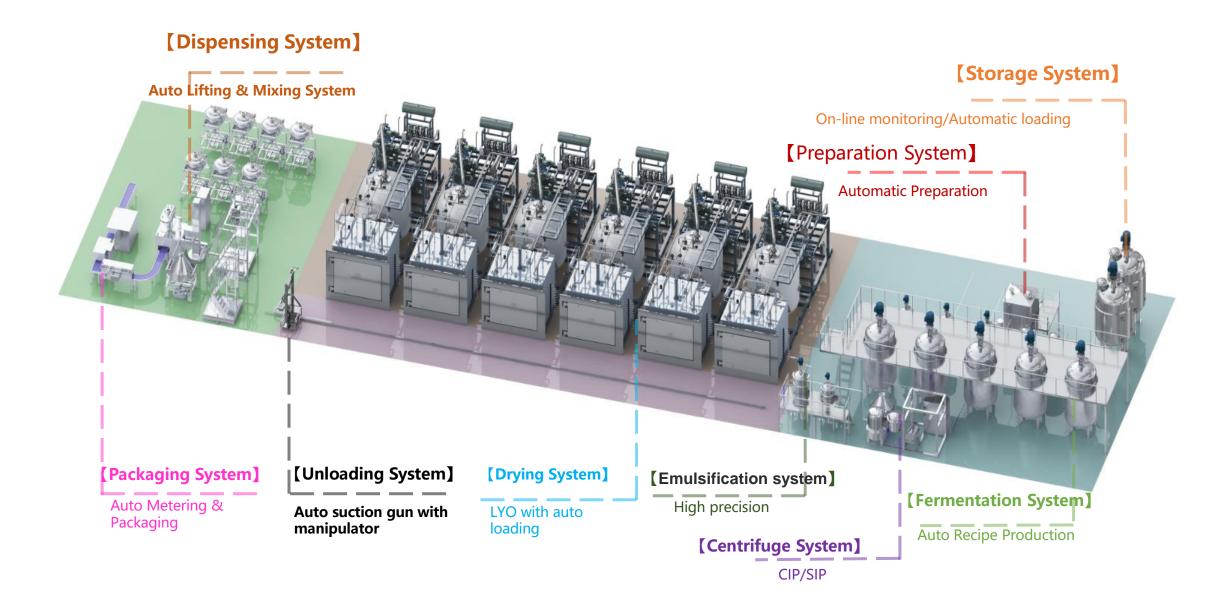






Tofflon API Enterprise Solution







Tofflon

Tofflon India



worldwide

All for Customers

