

Tailored Bioprocess Solutions for Diverse Vaccine Factories in the Developing Countries



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Affordability, Adaptability, Accessibility



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Vietnam Dengue Vaccine Factory



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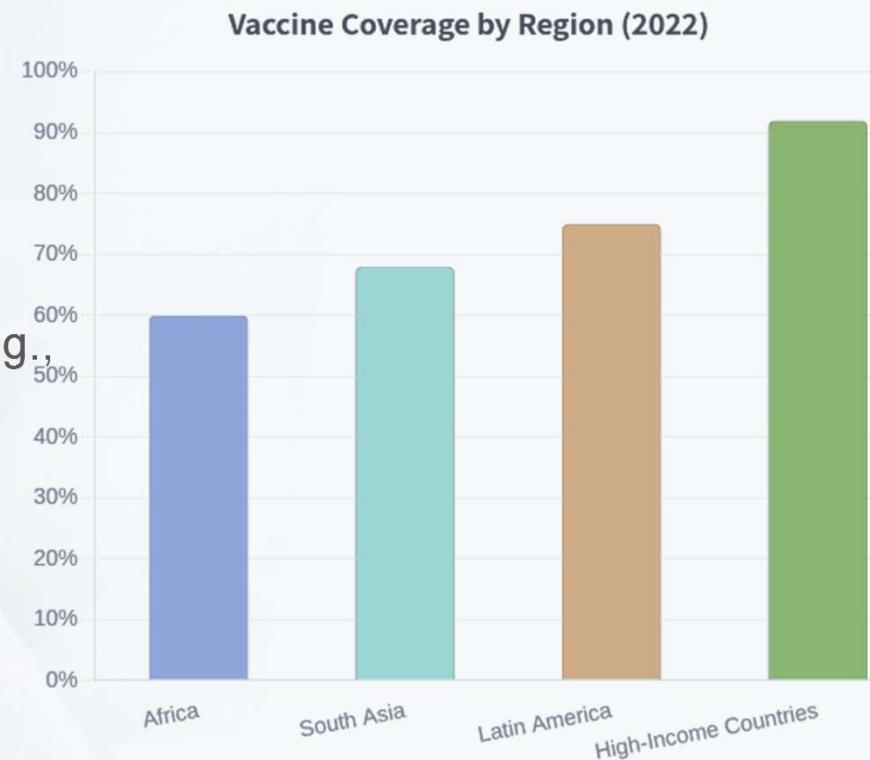
Value & Promotion of Customized Solutions

PART 01 ▶

Challenges in Vaccine Production for Developing Countries

Introduction: The Critical Need

- Addressing global health inequality through localized solutions
- ✓ Developing countries face significant barriers to equitable vaccine access and local production.
- ✓ Global health inequality highlighted by pandemics (e.g., COVID-19) and endemic diseases (e.g., Dengue).
- ✓ Africa CDC 2040 Vision: Target of 60% local vaccine production to enhance health security(AVMA).
- ✓ This presentation explores customized bioprocess solutions as a key enabler.



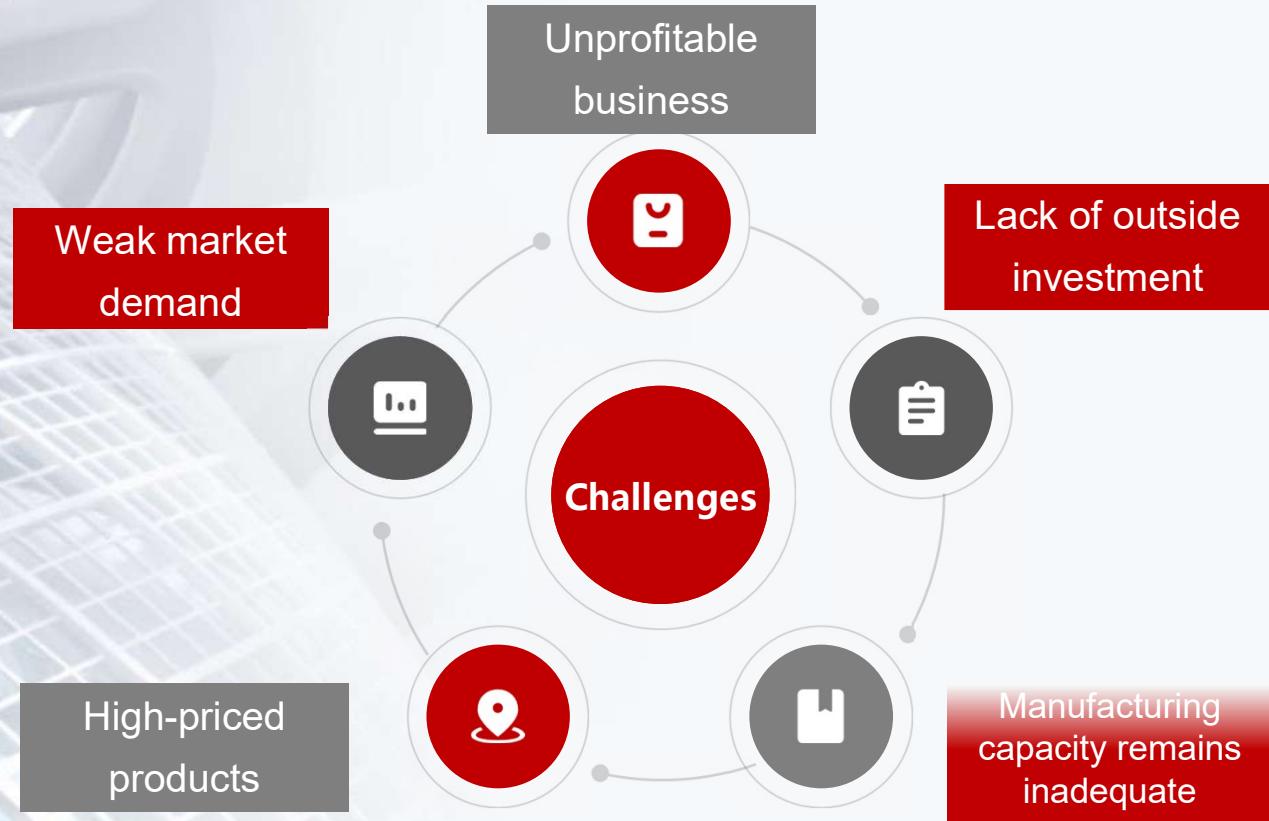
[Sources : Vaccine Accessibility and Global Equity, 2023]

Unique Constraints in Developing Countries

Challenges:

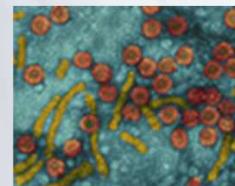
- High production costs due to **small-scale** operations.
- Limited R&D and **substance** manufacturing capabilities.
- Over-reliance on fill and finish (F&F), risking oversupply and commercial unviability.
- Weak public procurement forecasting and financial support
- shortage of specialized **technical talent**

■ The challenging cycle

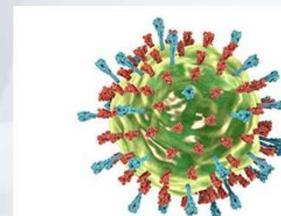


Challenges

Bacterial



Virus



01

- Bioprocess Technology
- Technology Transfer
- MST Capability



02

- Facility Design
- Multi-Production
- Combined vaccine



03

- Product lines tactic
 - DP
 - DS



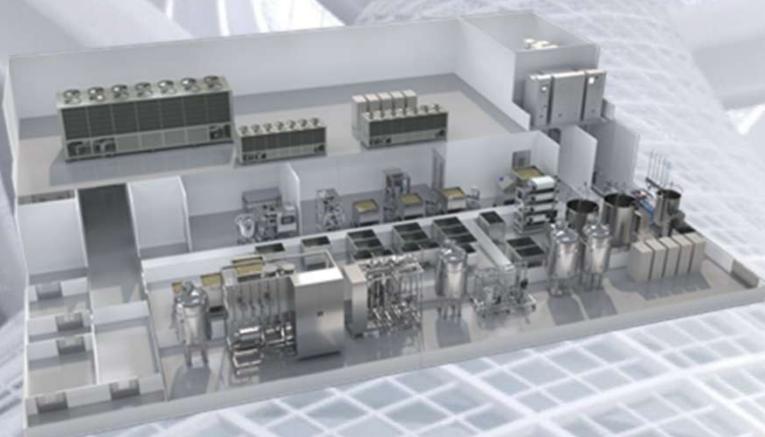
| Phase One | Phase Two |
|-----------------------------------|-------------|
| BCG(Fermenter ,IA) | PCV |
| Tetanus(Fermenter ,IA) | ACW135 |
| Measles(Egg Base/Cell Factory,LA) | HPV |
| Rabies(Vero/Diploid,IA) | DTP-HIB-HEP |
| Yellow Fever(Egg Base ,LA) | IPV |
| OCV(RP) | Others |

PART 02 ▶

Core Principles

Core Principles: Customized Bioprocess Solutions

Customized bioprocessing addresses these challenges through three fundamental pillars:



Affordability

Reducing production and infrastructure costs



Adaptability

Enhancing flexibility and operational efficiency



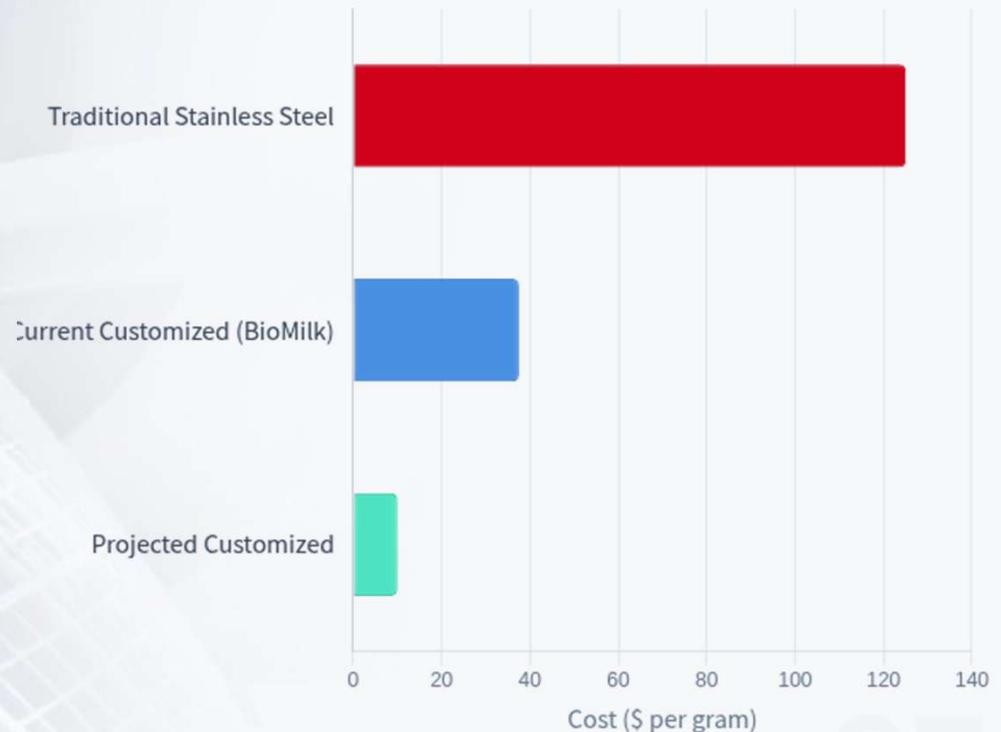
Accessibility

Promoting local production and equitable distribution

Principle 1: Affordability

- ✓ Single-Use Bioreactors (SUBs): XXX Biologics achieved 15-ton mAb production with 5000L SUBs, 3x capacity increase at cost parity.
- ✓ Low-Cost Platforms: BioMilk goat mammary bioreactor reduces mAb cost to < \$35-40/g (60% reduction vs. traditional).
- ✓ Reduced capital expenditure: SUBs require 20-50% lower initial investment than stainless steel systems.

Monoclonal Antibody Production Cost Trend (\$/g)



[Source : Gene-Edited Goat Mammary Bioreactor Technology, 2025]

Designing for rapid response and diverse production needs

Principle 2: Adaptability & Flexibility

 **Rapid Product Switching:** SUBs eliminate CIP/sterilization downtime, enabling **48-hour product changeover**.

 **Modular Facilities:** XXP™ process reduces deployment timelines by **40%**, adaptable to small-batch and multi-product needs.

 **Customized Analytics:** Enzyme conversion and GMP-grade reagents optimize yields by **30%** while reducing waste.

80%

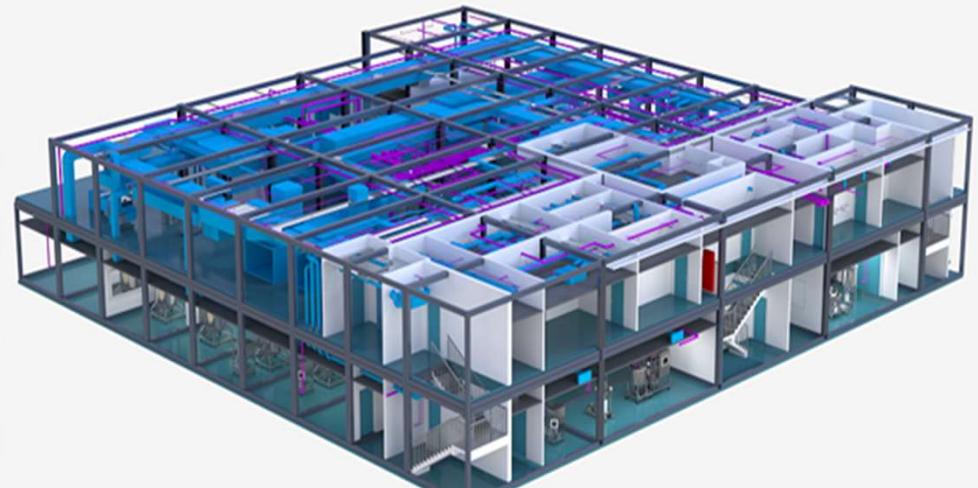
Off-site: 80%

10

Turn-key: 10 Month*

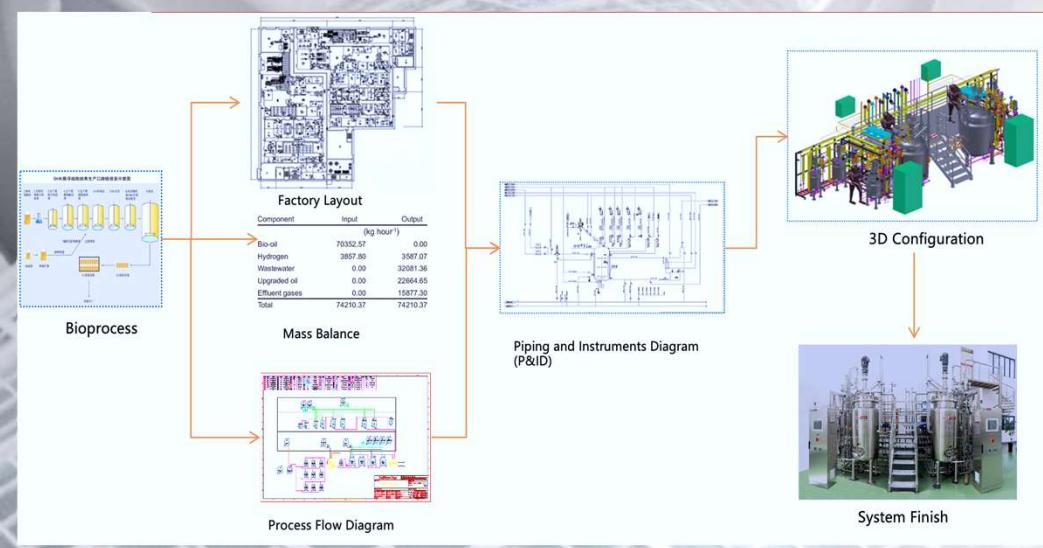
5%

Cost predictability: 5 %



- Modular construction eliminates 80% of site construction activities
- It includes all structural parts, building fixtures, clean room, HVAC, process equipment, utilities, power supply system, auto-control system etc.
- By Modular approach, we can deliver your project like an equipment.

Principle 3: Accessibility



Optimization

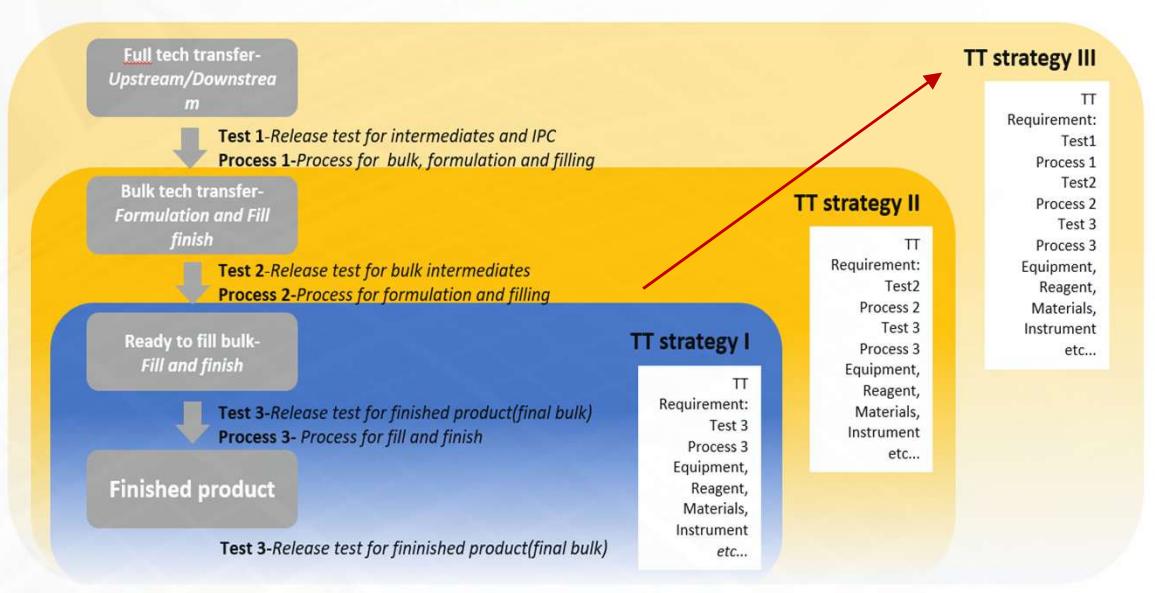
- ✓ **Localized Production:** Chinese vaccine companies in Egypt/Colombia, South-South reduced import dependency by **60%**.
- ✓ **End-to-End Support:** China's 'vaccine + cold chain' packages for Iraq increased coverage by **45%**.
- ✓ **Regional Hubs:** XXX factory to serve **100M doses/year** domestic and export markets.

PART 03 ▶

Case Studies

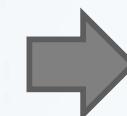
From BD to Facility Setup

■ Tech Transfer Strategies

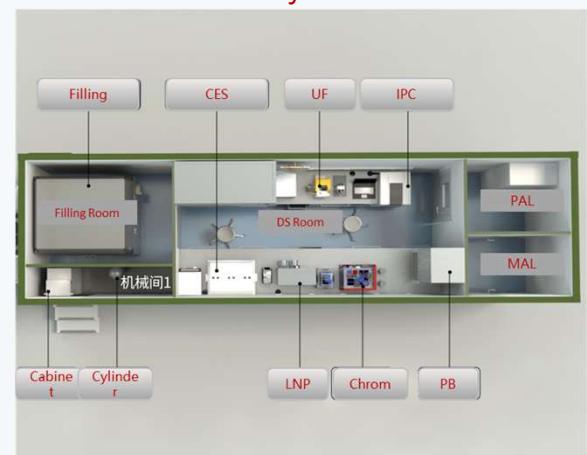


■ Facility

Phase 2

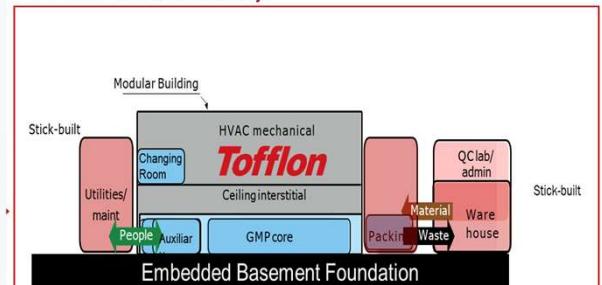


□ DS New Facility



Phase 1

■ DP New Facility



□ Product Pipelines:

- New Tech Vaccines mRNA/Adv/Recombined Protein /
- Tradition Vaccines

Case Study: Hybrid System-EPC SCOPE

XXX Biopharma Co., Ltd.

Established on July 14, 2020

Produce **Recombinant Protein Vaccine**

Annual capacity of **100 million** doses of vaccine

Project scope

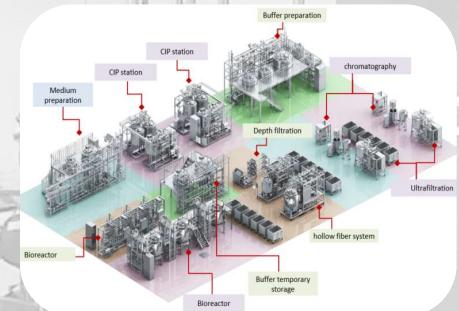
Tofflon **EPMV** project. FAST TRACK

DS+DP+DC+DE of a 12000m² factory

CES, SSB, SUM, BIN, SS. Bio-process system, HF, DF, TFF, Chrom., filling machine, inspection machine, packing machine

Project delivered in 10 months for meeting the urgent requirement

Tofflon



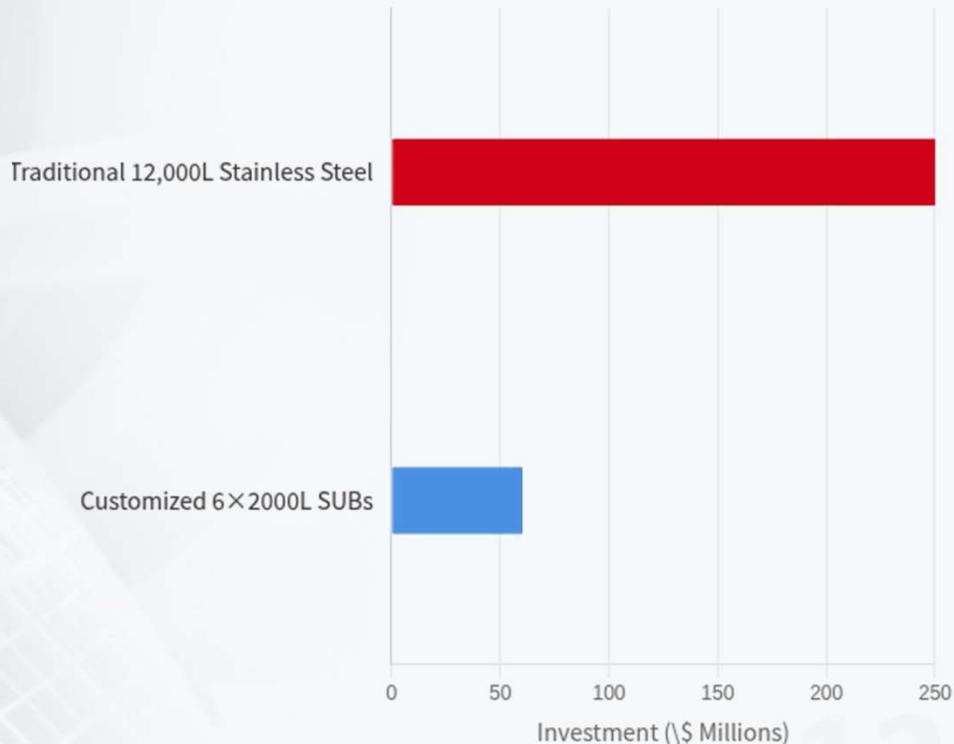
Traditional vs. Customized Bioprocess

Cost Comparison Analysis

Key Takeaway This comparative analysis highlights the key differences in cost, flexibility, and operational efficiency between traditional stainless steel bioprocesses and modern customized solutions using Single-Use Bioreactors (SUBs) and BioMilk technology.

| Dimension | Traditional (Stainless Steel) | Customized (SUBs/BioMilk) |
|--------------------|--|--------------------------------------|
| Initial Investment | \$100-400M (12,000L reactor) | \$40-80M (6×2000L SUBs) |
| Flexibility | <40% utilization, high changeover cost | >85% utilization, 48-hour switch |
| Operational Cost | High (CIP/sterilization, labor) | 50% reduction (water/energy savings) |
| Yield | 30% lower vs. affinity chromatography | 30% higher yields, shorter cycles |

Initial Investment Comparison (\\$M)



[Source : Bioprocess Equipment Cost Analysis, 2025]

PART 04 ▶

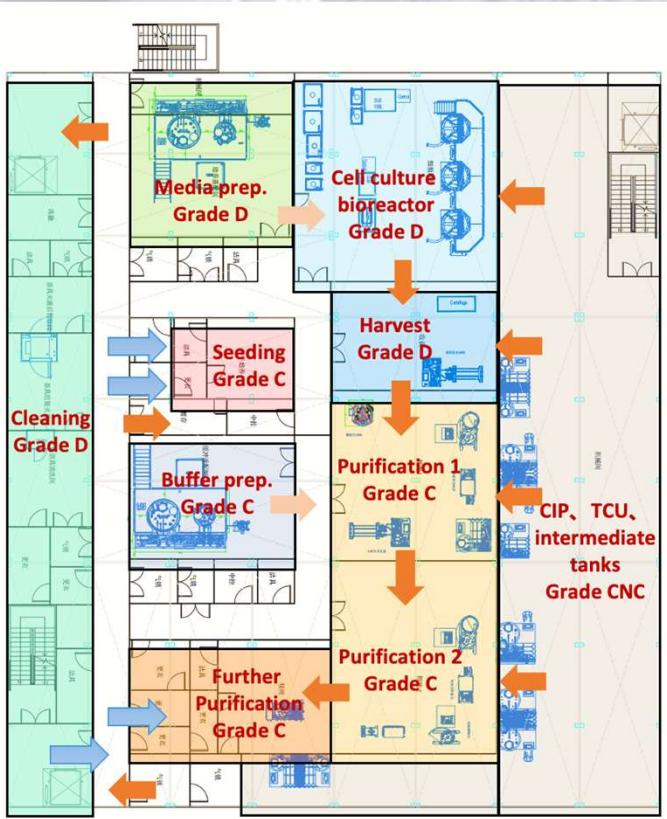
Conclusion



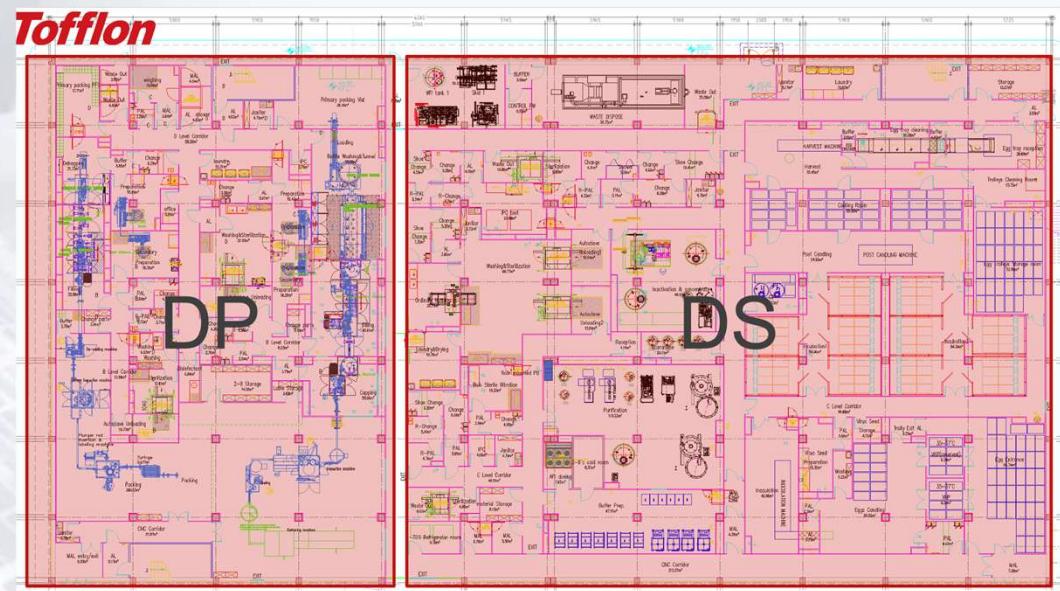
Core Conclusion:

Customized solutions are the key to sustainable localized vaccine production

■ Hybrid DS Facility Layout With Modular



■ Multi-Product collineation



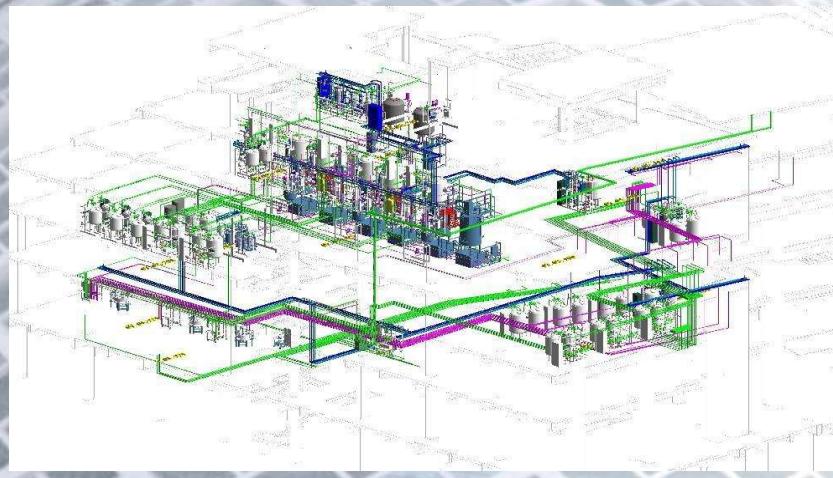
Vial line
Combo Line(Vial+Syringe)

Tofflon

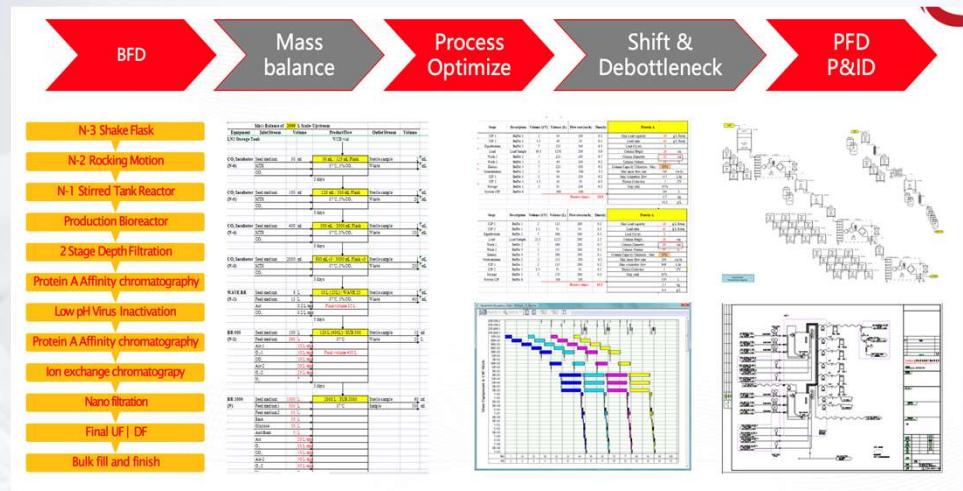
PILOT DESIGN



Engineering Design

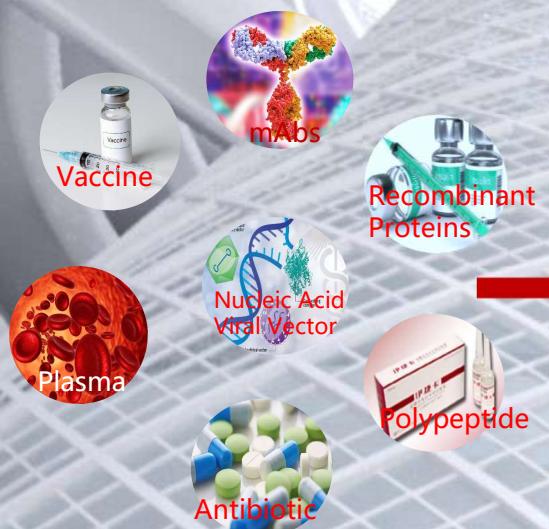


Bio Process Design

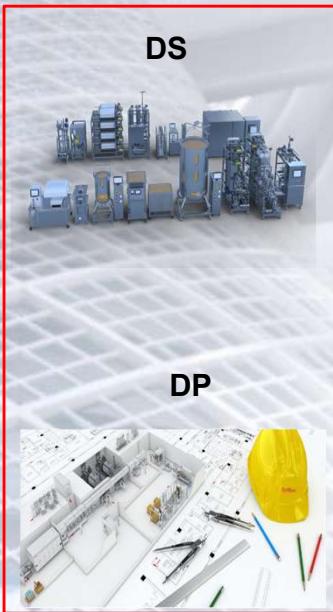


Enterprise Solution For Your Biopharma MFG

BioPharma/CGT



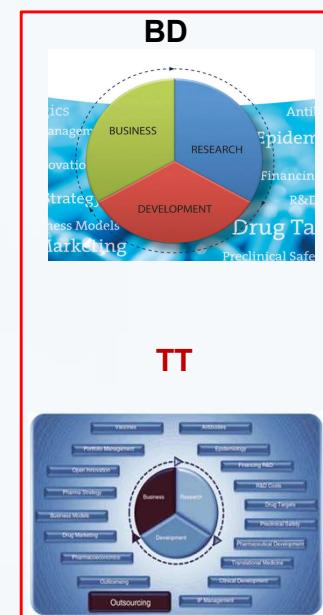
Machine



+ Engineering



+ Services



+ Consumables



R&D/Pilot Scale

Large Scale

ACROSS ALL SCALES

Tofflon Vision:
Smart Pharma Factory Builder

