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Tailored Bioprocess Solutions for Diverse Vaccine Factories in the Developing Countries



202510/29

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Challenges in Vaccine Production for Developing Countries



Core Principles

Affordability, Adaptability, Accessibility



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Vietnam Dengue Vaccine Factory



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Value & Promotion of Customized Solutions

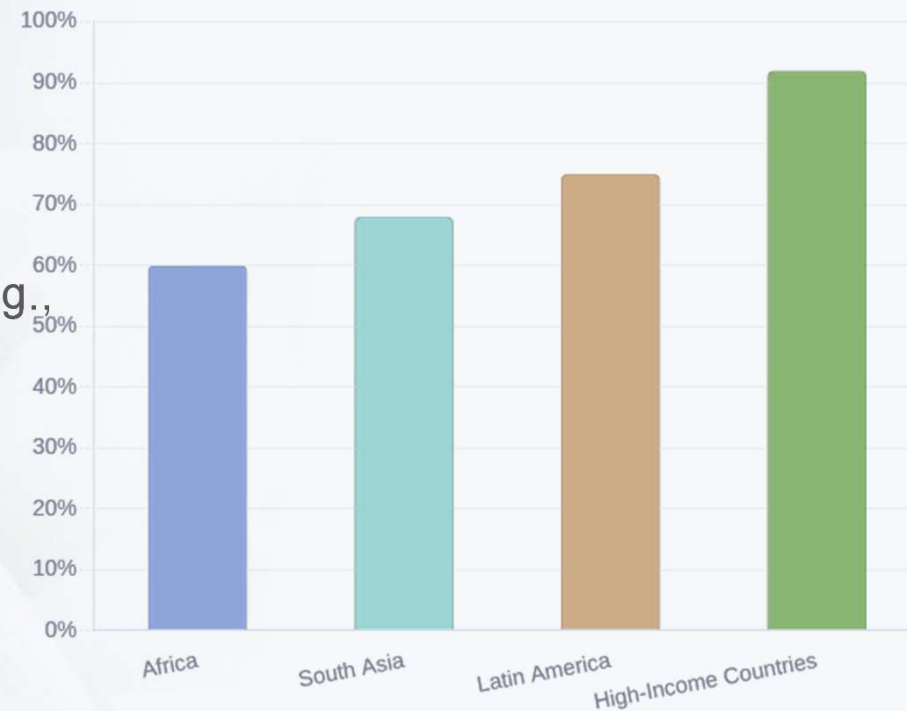
PART 01 ▶

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.

Vaccine Coverage by Region (2022)

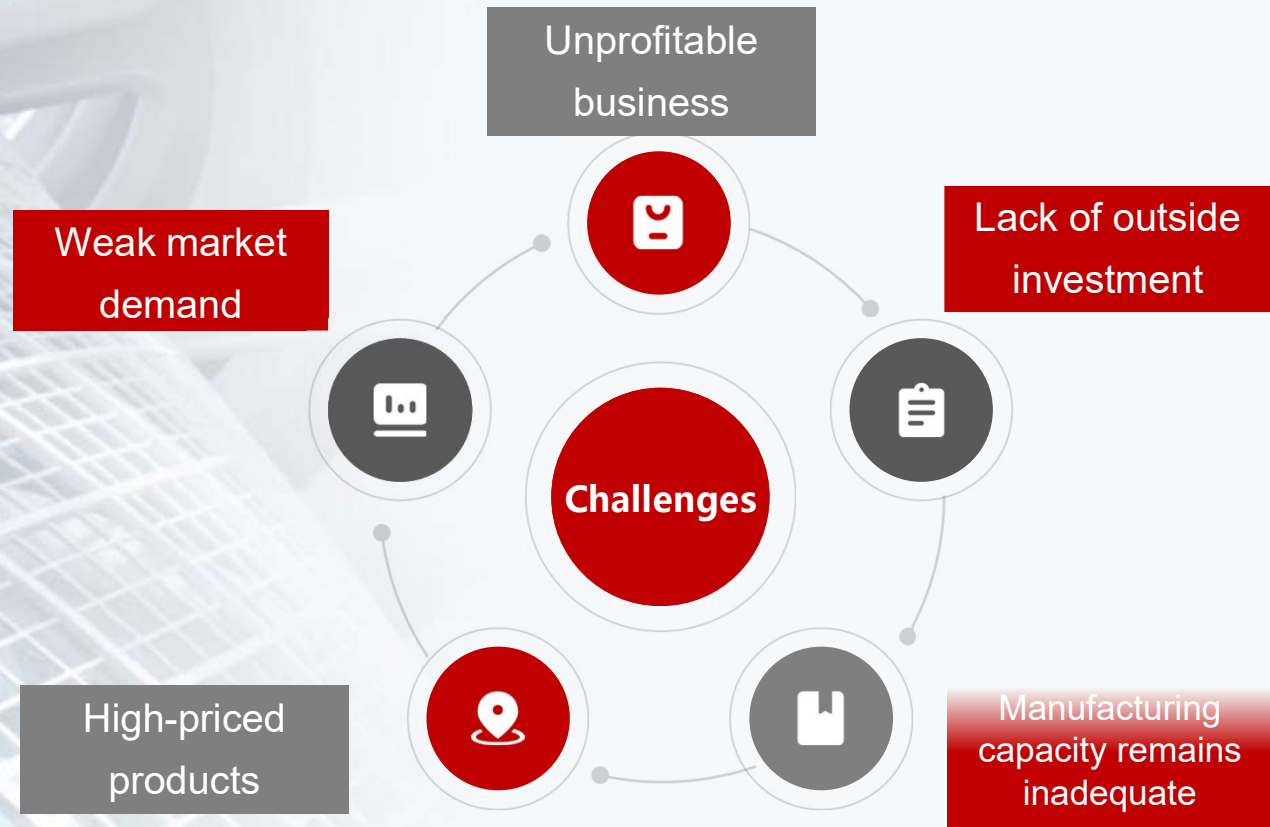


[Sources : Vaccine Accessibility and Global Equity, 2023]

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**

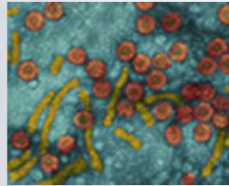
■ The challenging cycle



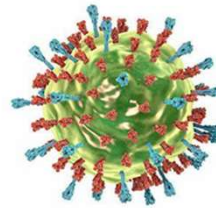
What are the Challenges in NEW VACCINE Facility Project?

Challenges

Bacterial



Virus



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

01

- Bioprocess Technology
- Technology Transfer
- MST Capability



02

- Facility Design
- Multi-Production
- Combined vaccine



03

- Product lines tactic

- DP
- DS



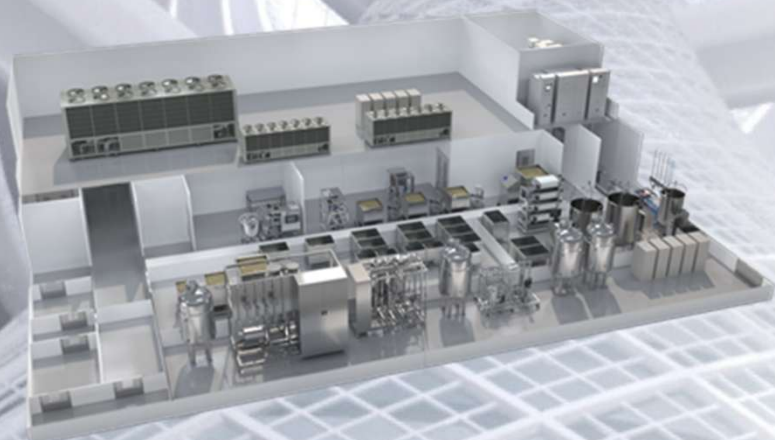
PART 02 ▶

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

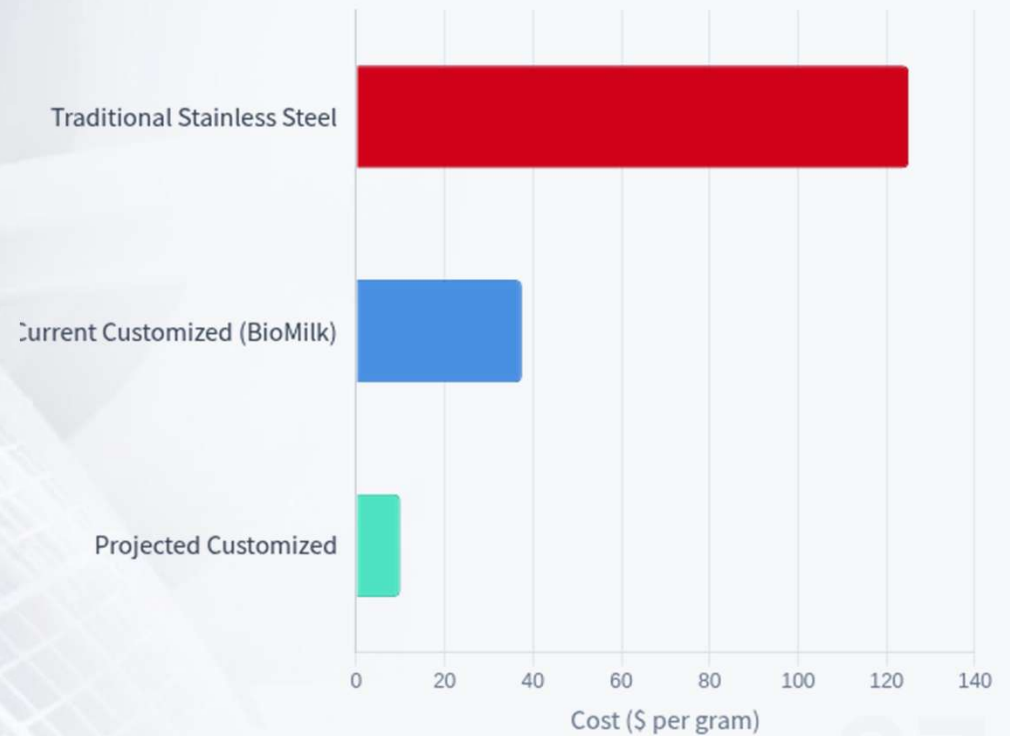
Promoting local production and equitable distribution



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]



Principle 2: Adaptability & Flexibility

Designing for rapid response and diverse production needs

⚡ **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%

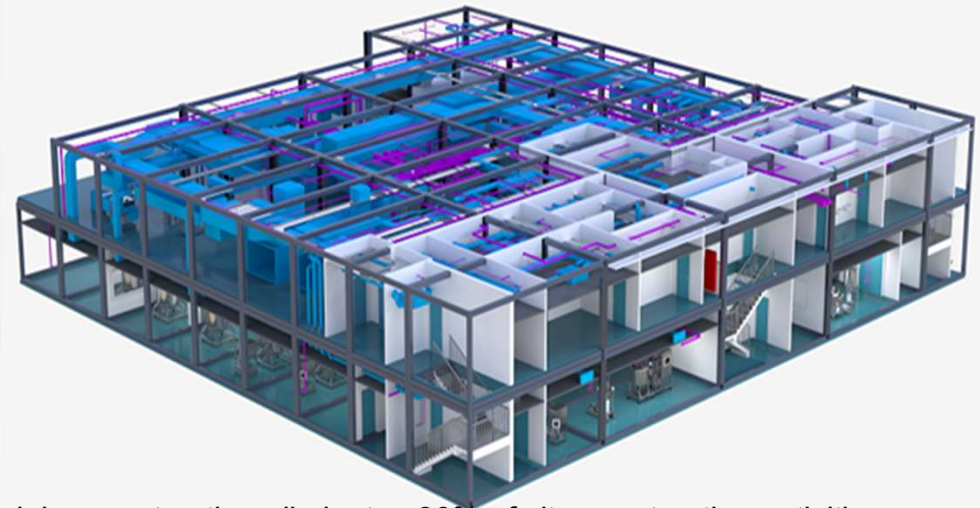
Off-site: 80%

10

Turn-key: 10
Month*

5%

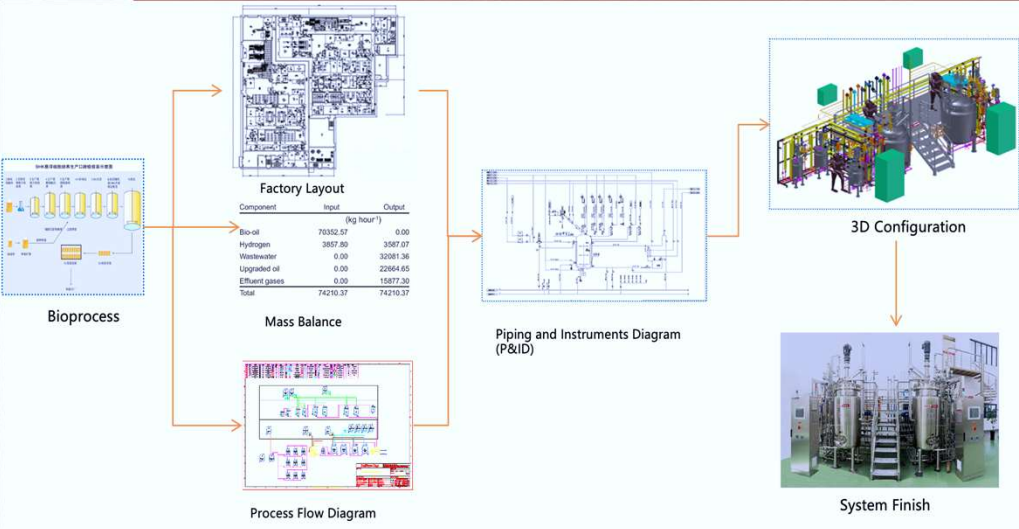
Cost predictability:
5%



- 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.

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

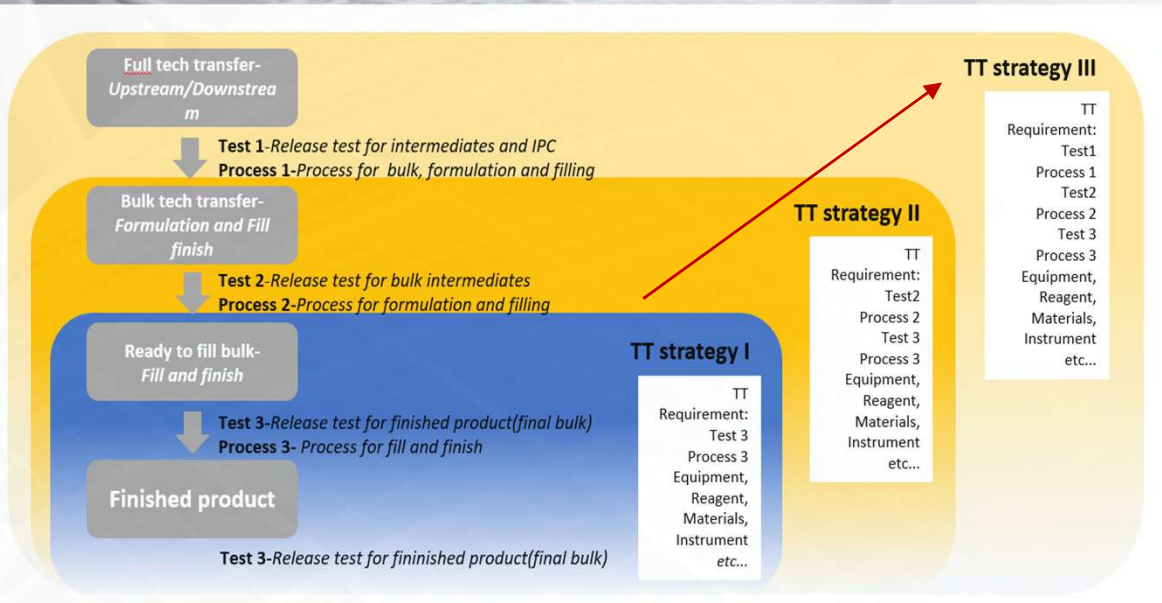
■ Tech Transfer Strategies

■ Facility

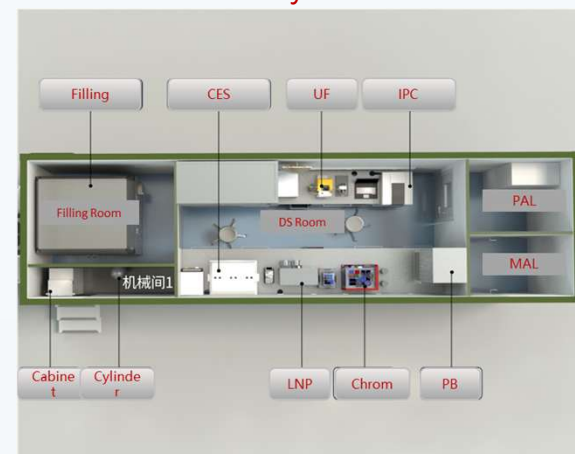
Phase 2



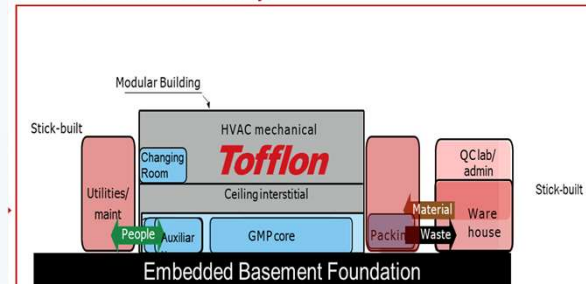
Phase 1



□ DS New Facility



■ DP New Facility



□ Product Pipelines:

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

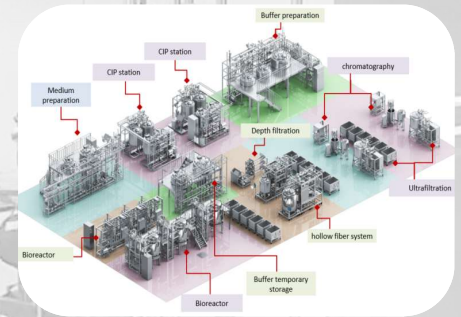
Tofflon **EPMV** project. FAST TRACK

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

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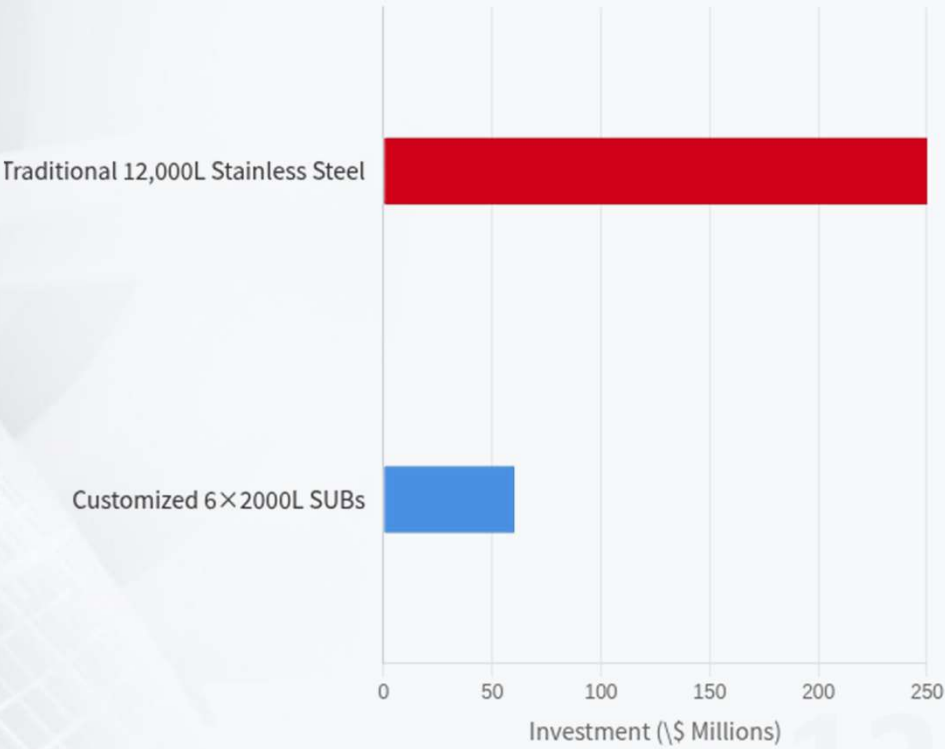


Cost Comparison Analysis

 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 ▶

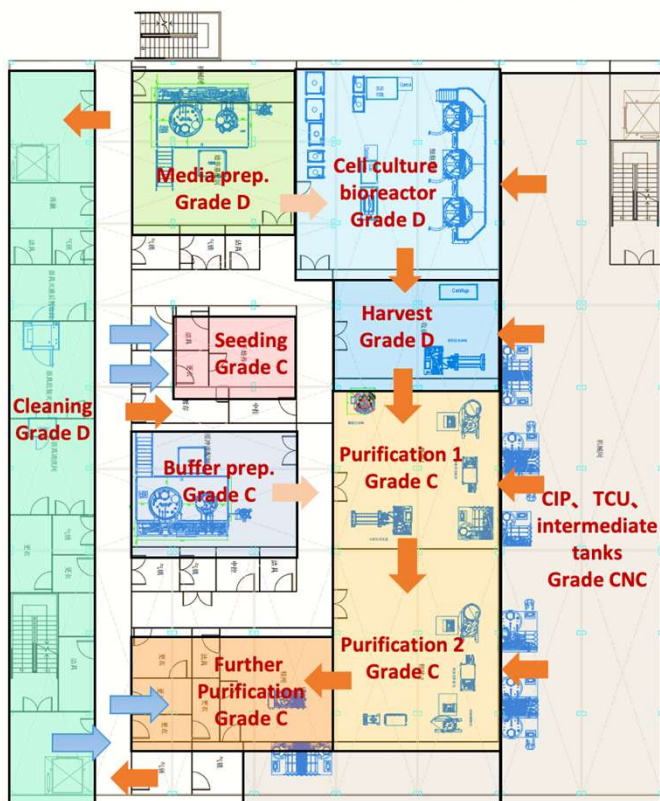
Conclusion

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Core Conclusion:

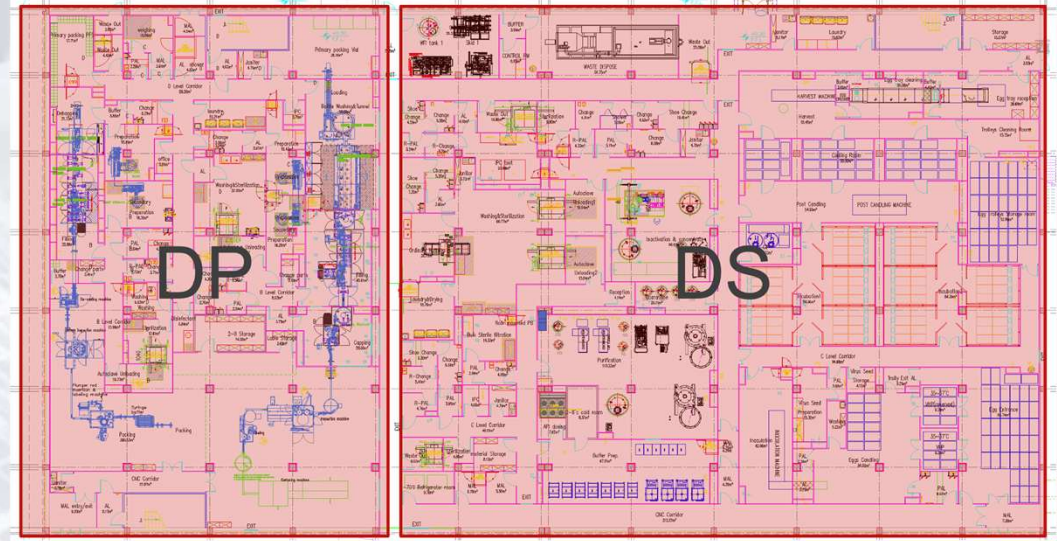
Customized solutions are the key to sustainable localized vaccine production

■ Hybrid DS Facility Layout With Modular



■ Multi-Product collineation

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Vial line

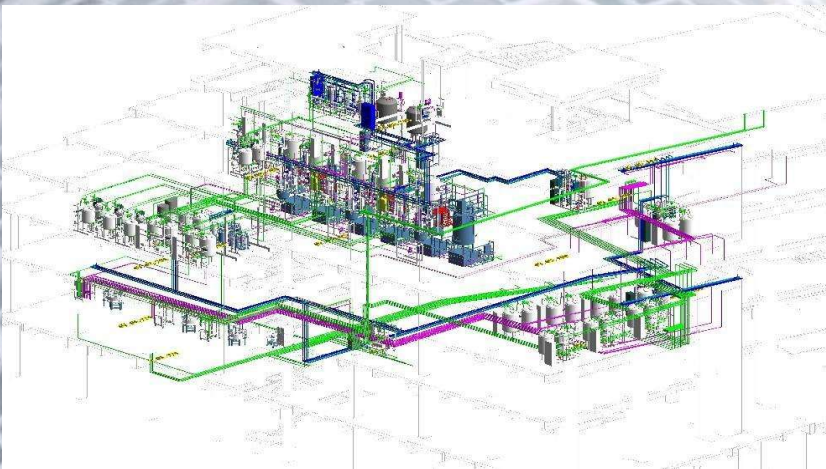
Combo Line(Vial+Syringe)

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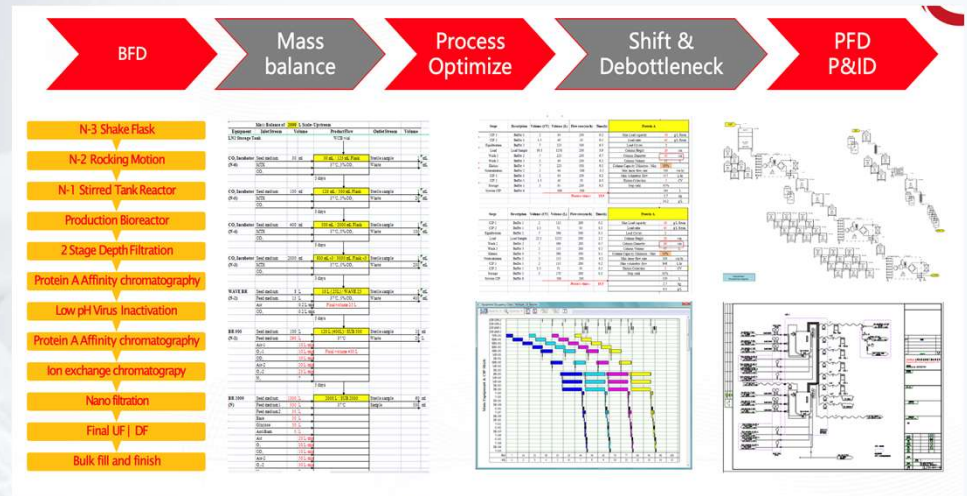
PILOT DESIGN



Engineering Design



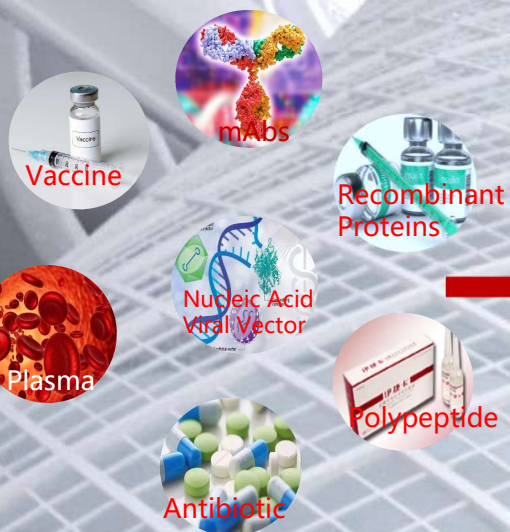
Bio Process Design



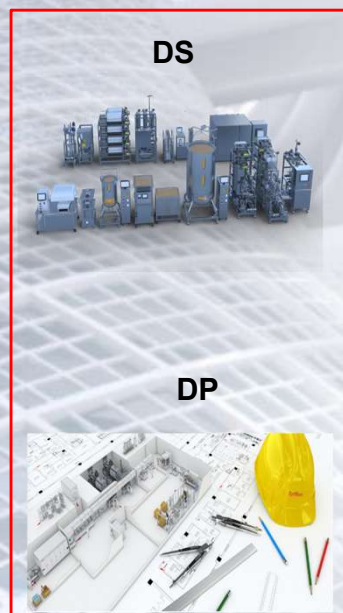
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Enterprise Solution For Your Biopharma MFG

Biopharma/CGT

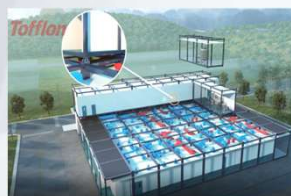


Machine



+ **E**ngineering

Modular Facility



Site Built Construction



+

Services

BD



TT



+

Consumables

DC



R&D/Pilot Scale

Large Scale

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**Tofflon Vision:
Smart Pharma Factory Builder**



Thank You