

SARTORIUS

Simplifying Progress

G-CON



Collaborating for Success: Leveraging Platforms Solutions and Pre-Engineering to Simplify

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Speaker Information



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Head of Process Consulting |
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Peter Makowskyj
Senior Director of Design
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Meeting Our Industries Objectives to Be More Patient Centric



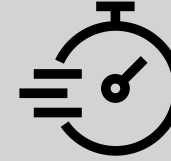
Efficient Supply Chain

- Lower Costs
- Adaptability to Market



Process Intensification

- Higher Productivity
- Improved Efficiency
- Adaptability to Market



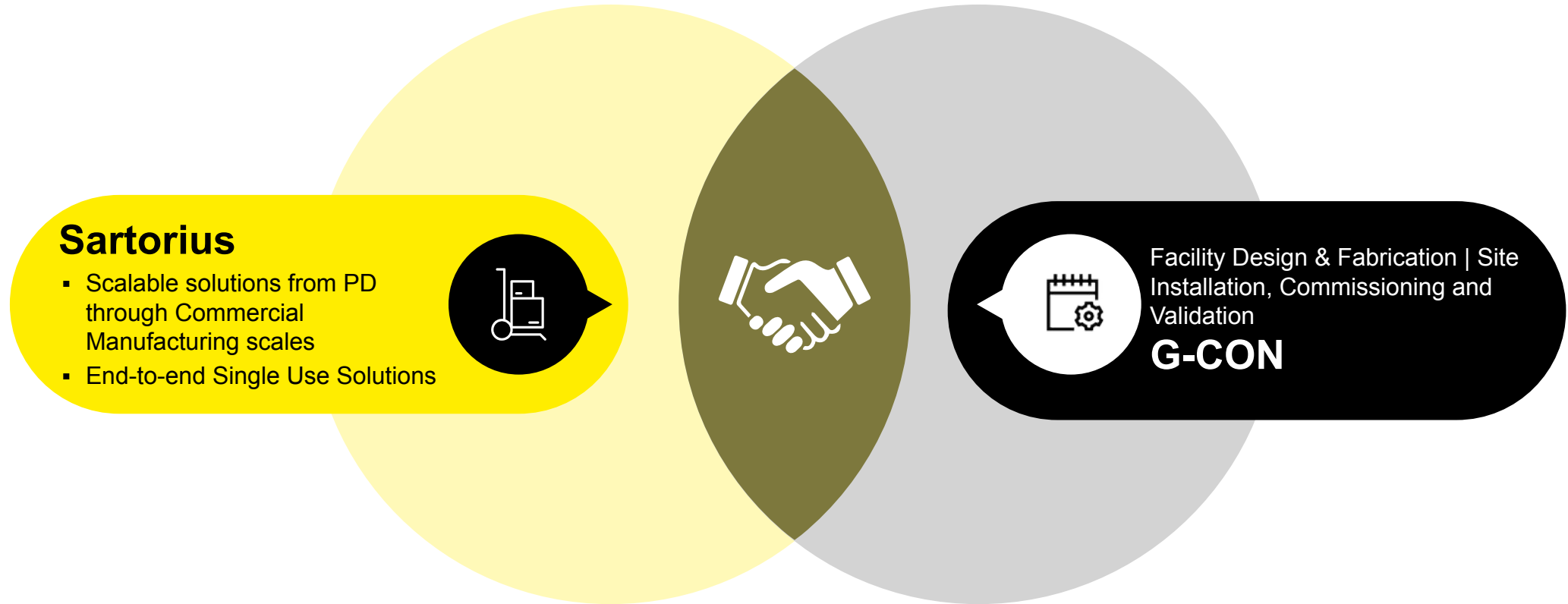
Speed / Time to Market

- Adaptability to Market
- Multi-Product Facilities
- Lower Costs

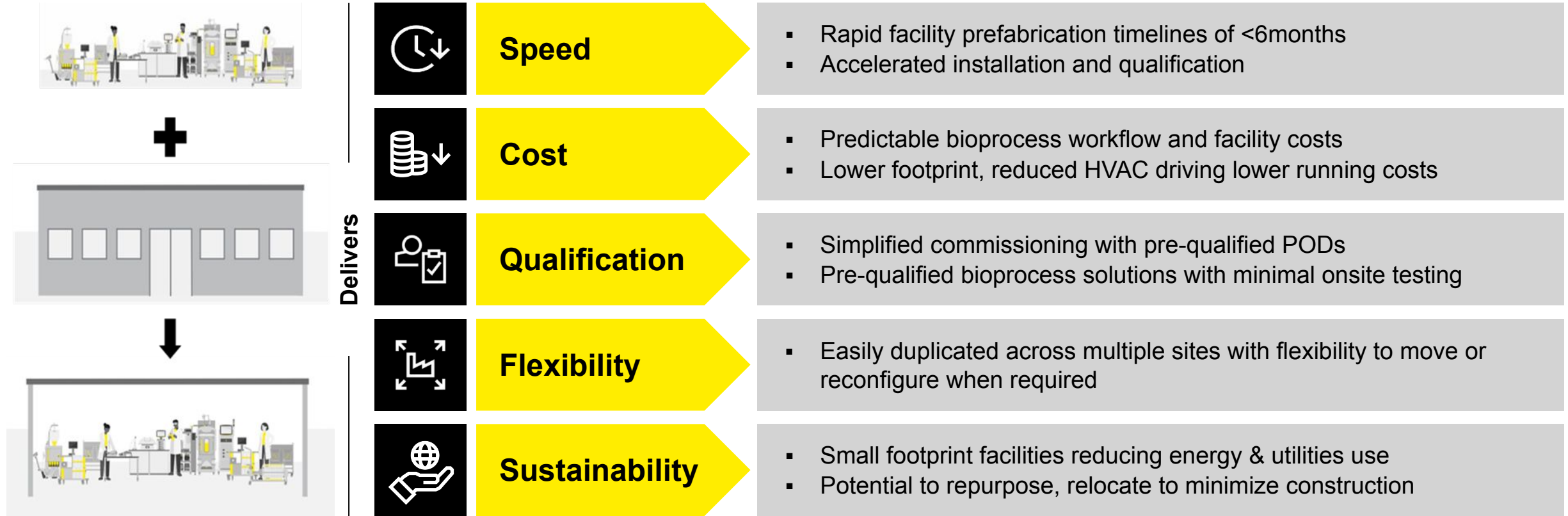
Market Objectives

- Higher Productivity
- Improved Efficiency
- Adaptability to Market
- Multi-Product Facilities
- Lower Costs

Sartorius and G-CON Collaborate to Deliver Sustainable, Flexible cGMP Facilities Faster



Combining G-CON Rapidly Deployed Cleanroom PODs® with Sartorius Integrated Bioprocess Solutions is a win-win!



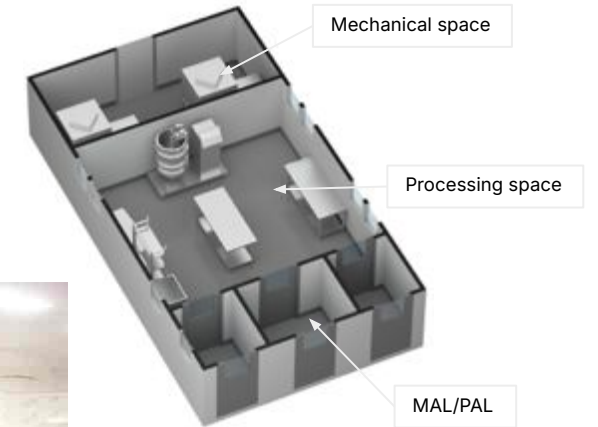
* Trademark registered in the European Union

G-CON POD Cleanroom[®] Solutions

Global Leader in Prefabricated and Modular Cleanroom Solutions

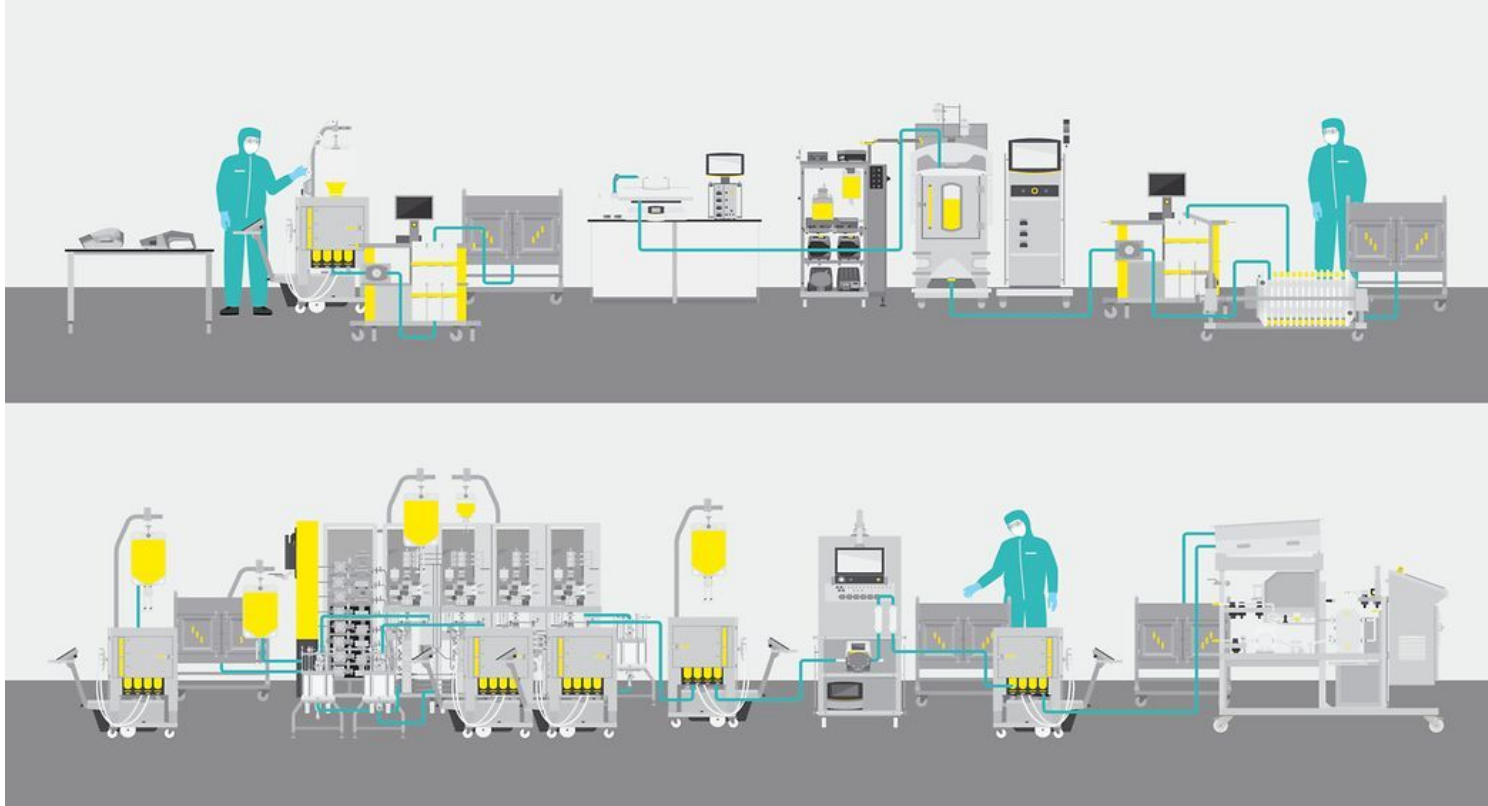
Adoption of prefab methodologies, enabling PI with the following benefits:

- ☑ Shorten timelines
- ☑ Reduce footprint
- ☑ Simplify project execution
- ☑ Reduce operational expenditure
- ☑ Adapt and Scale without interruption
- ☑ Transportable for relocation



Sartorius Process Consulting

Configurable and Modality-Specific end-to-end Solutions

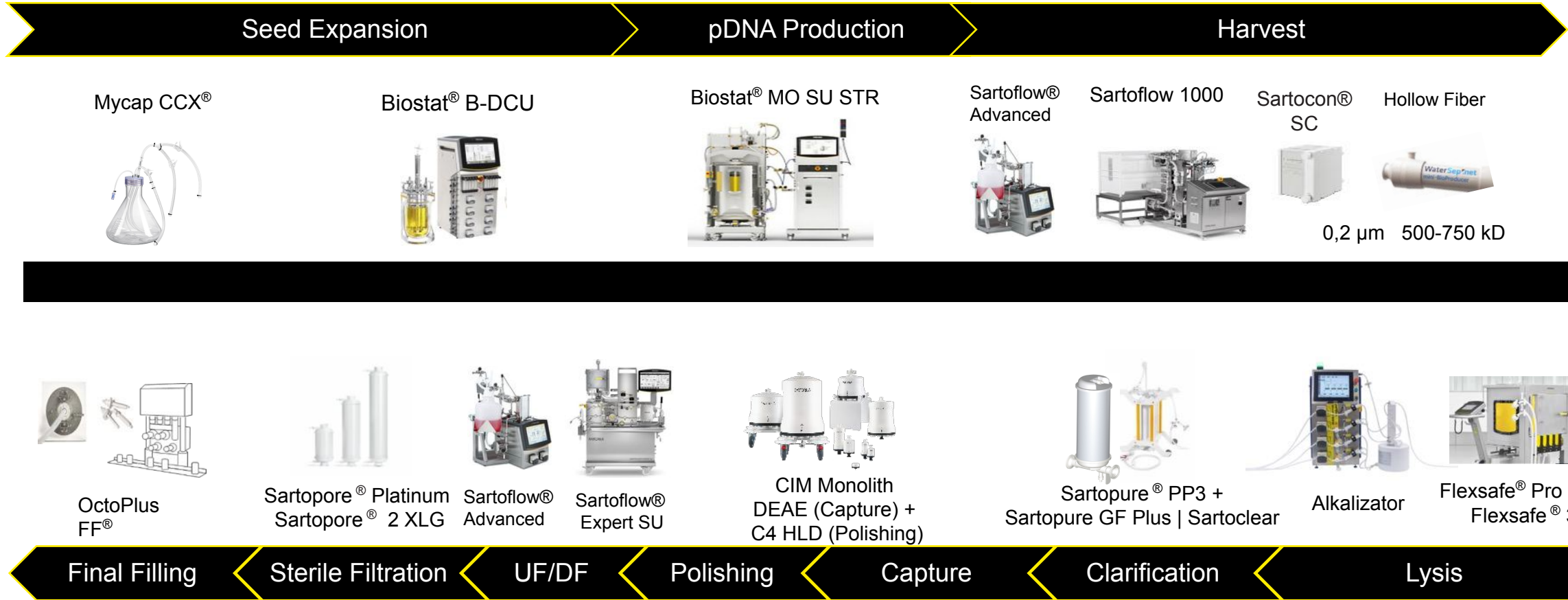


Sartorius Conceptual Designs

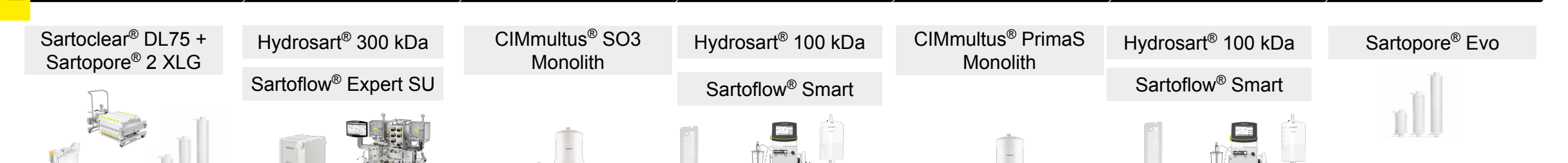
- ✓ Configurable, Modular Equipment
- ✓ SU Consumables including Flow Kits
- ✓ Automation & Data Acquisition
- ✓ Service, Training & Support

* Trademark registered in the European Union

Commercial Scale Solutions for pDNA Production



50L End-to-End AAV8 Production Process



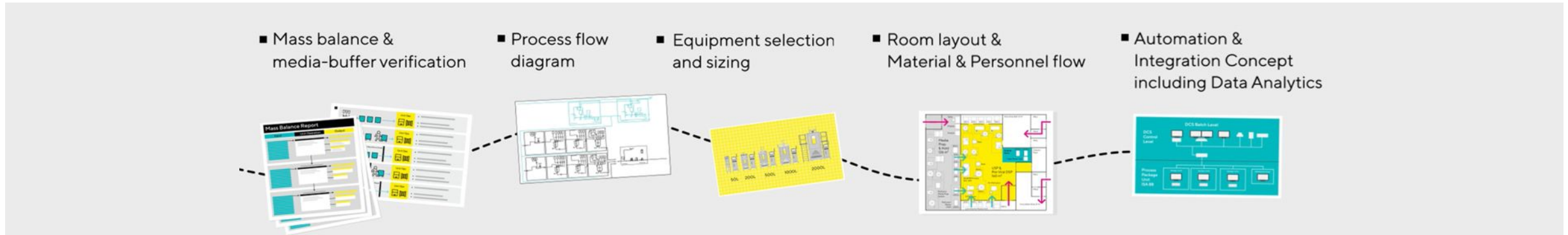
Analytics:
 Capsid titer – ELISA
 Genome titer – ddPCR
 HCP – ELISA
 HCD – ddPCR
 E/F – PATfix, Octet



Case Study

Project Blackhawk

Setting out with a Plasmid DNA Process to Establish the Parameters for Optimal Process Layout and Facility Design



Expertise

- Facility Design & Manufacture
- Bioprocess Solutions & Services
- Seamless Project Execution
- Early Regulatory Feedback

Deliverables

- Fabrication & Installation
- Efficient & Cost-effective Processes
- Automation & Data Strategy
- Sustainable Construction & Operation

GMP facility ready for production

Integrated GMP production facility with process equipment, dedicated air handling, building management system (BMS), fire protection, and electrical and process utility distribution.

Project Overview

Owner

§ NIIMBL

Location

§ STAR Campus, University of Delaware (Newark, DE)

Funding Sponsor

§ NIST, Department of Commerce (under 70NANB21H085)

Project Stakeholders

§ Project Manager: University of Delaware

§ EPCM: IPS Engineering

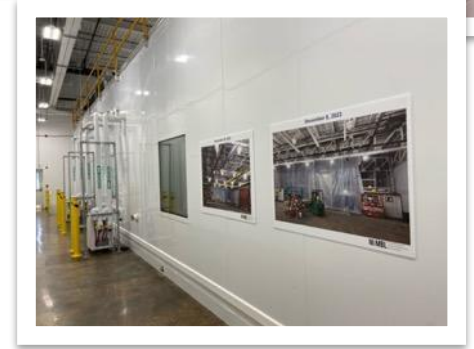
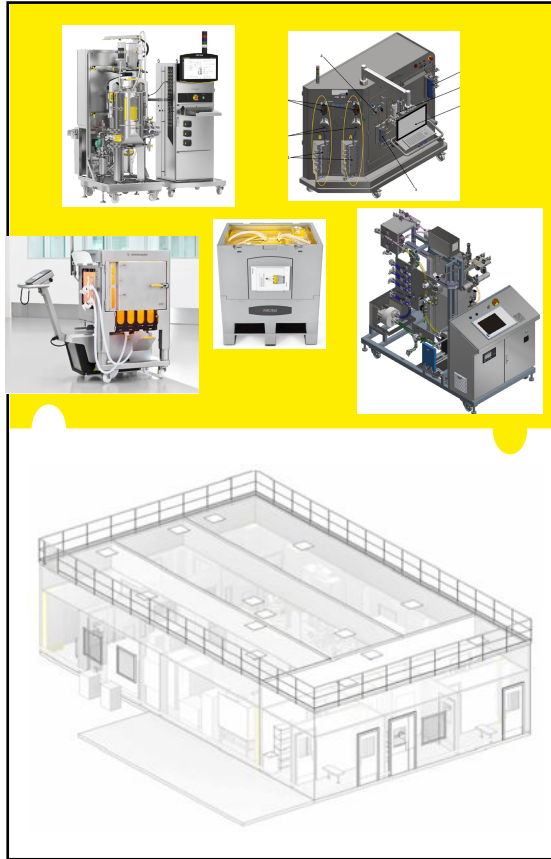
§ Prefab Cleanroom Provider: G-CON

§ Process Technology Provider: Sartorius

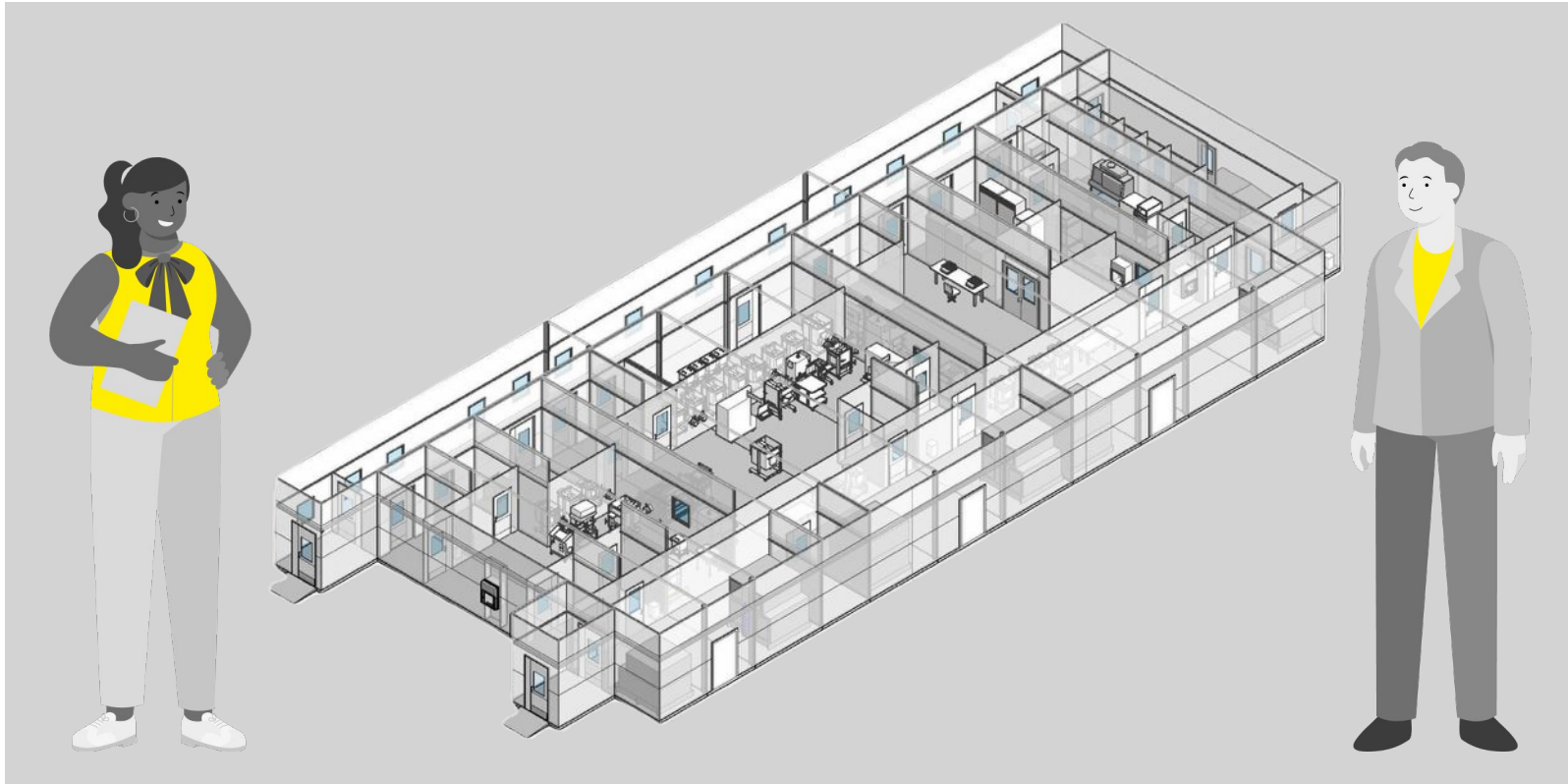


The Solution

Combining of Sartorius and G-CON platform technologies



Sartorius and G-CON Collaborate to Deliver Sustainable, Flexible cGMP Facilities Faster



Process-first Approach



Standardization



GMP Manufacturing Ready



From Concept to Execution

Thank You

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