

# SARTORIUS

Simplifying Progress

## Simplifying Science

Providing Technologies to Increase Productivity in Bioprocessing.

Webinar, April 24, 2024



UPR <sup>LA IUPI</sup>

# Agenda

1. Company Overview
2. Product Applications
3. Transfer of Product
4. Product Development
5. Engineering
6. Quality System
7. Continuous Improvement
8. Q&A



# Company Overview

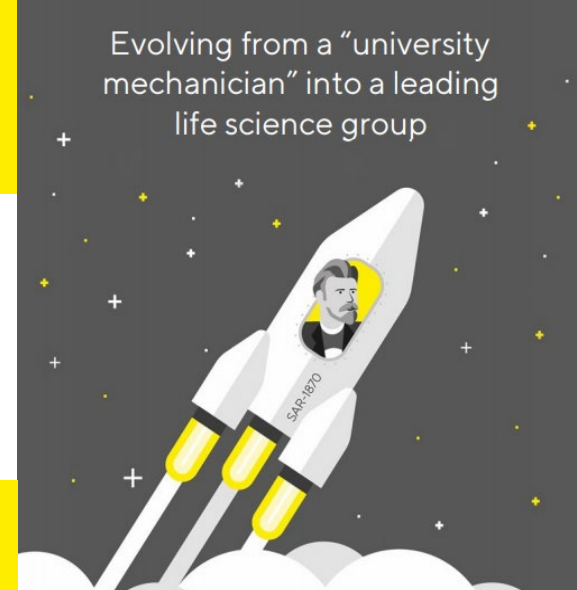
# Pioneers for around 150 years



1870-1926



1927-1949

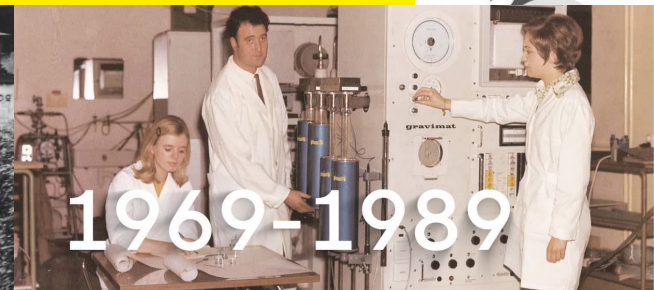


1870 At his precision machine workshop, 24-year-old Florenz Sartorius developed the short-beam analytical balance.

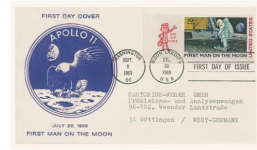
1927 A “joint venture” with Nobel Prize laureate Richard Zsigmondy expanded the Sartorius product portfolio by membrane filters.



1950-1968



1969-1989



2007 Biotechnology division of Sartorius merged with Stedim to become Sartorius Stedim Biotech.



1990-2006



2007-Today

2019 Sartorius acquired a majority stake in cell culture media specialist Biological Industries.



# Our ambition: Better health for more people

## Mission

We empower scientists and engineers to simplify and accelerate progress in life science and bioprocessing, enabling the development of new and better therapies and more affordable medicine.

## Vision

We are a magnet and dynamic platform for pioneers and leading experts in our field. We bring creative minds together for a common goal: technological breakthroughs that lead to better health for more people.



# Company Values

Sustainability, openness and enjoyment are the values that shape our work with colleagues, customers and business partners alike. By incorporating them into our thinking and actions on a daily basis, we create a positive corporate culture, which is an important source of long-term economic success, lasting motivation and above-average performance.

## Sustainability



Growing profitability and acting responsibly toward all stakeholders

## Openness



Driving change and progress internally and externally

## Enjoyment



Working in an energetic and rewarding environment

# At Home Worldwide

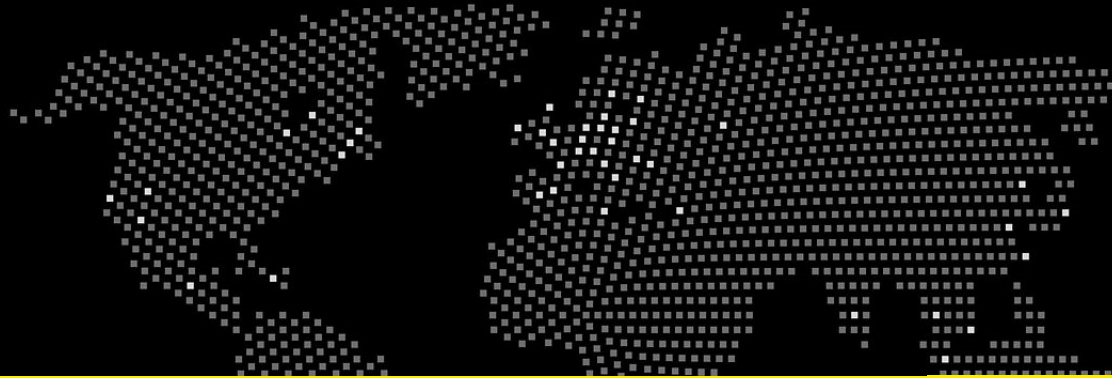


Sartorius has around 60 locations, some 30 of which are production sites (P), spread over 35 countries  
Including local commercial agencies, Sartorius is represented in more than 110 countries worldwide.

Americas

EMEA

Asia | Pacific



Sustainable Growth

~3.4 bn

Euros Sales Revenue 2023



International Workforce

~14,600

Employees in 2023



Global Footprint

60+

Locations Worldwide



SARTORIUS

Capacity Expansions

560 mn

Euros Investment in 2023



Climate Strategy

2045

Target for Climate Neutrality



Corporate History

1870

Year of Foundation



SARTORIUS



# Simplifying Progress



Biolayer  
Interferometry (BLI)



Bioreactors |  
Fermenters



Cell Culture Media |  
Buffers | Reagents |  
Plasmids



Cell Selection and  
Retrieval



Flow Cytometry



Fluid Management



Industrial  
Microbiology



Lab Data & Fleet  
Management  
Software



Lab Filtration &  
Purification



Live Cell Imaging &  
Analysis



OEM



Pipetting



Process Automation  
Platform and  
Software



Process  
Chromatography



Process Filtration



Surface Plasmon  
Resonance (SPR)



Water Purification



Weighing

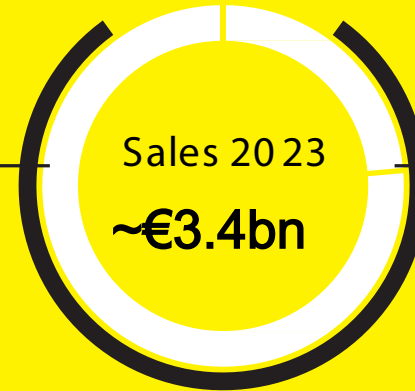
## Sartorius Global Product Portfolio

# SARTORIUS

# Two divisions with a clear focus on the life science industry

Offers a wide array of innovative technologies for the manufacture of biopharmaceuticals and vaccines as well as cell and gene therapeutics

**79%**  
**Bioprocess Solutions**  
Division



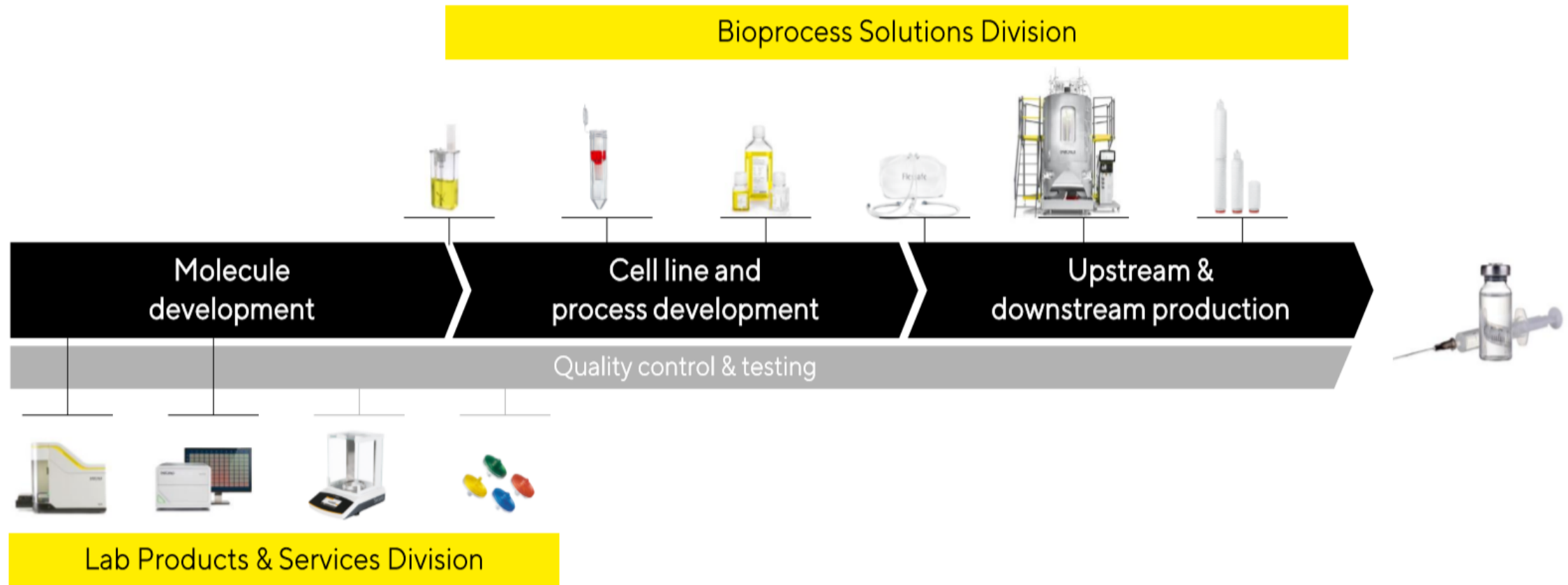
**~85%**  
with life science  
customers

**21%**  
**Lab Products & Services**  
Division

Specializes in equipment and technologies for life science research and pharmaceutical laboratories



# Strategic Focus on the biopharma market



# People at Sartorius



People at Sartorius



Share



SARTORIUS

Automated,  
GMP-  
Compliant  
Welding



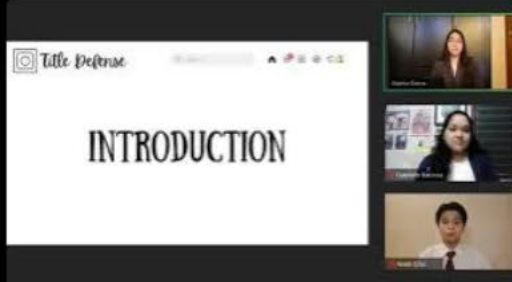
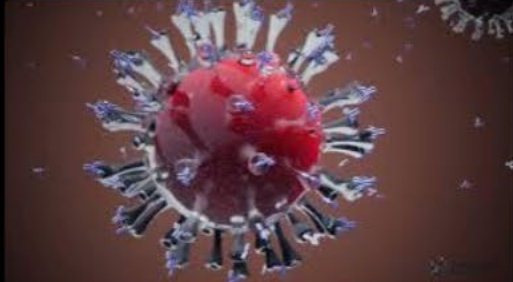
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Menschen  
bei Sartorius  
Sartorius entdecken



SARTORIUS

Simplify  
Large-Volume  
Frozen BDS  
Management



SARTORIUS

Campus in  
Göttingen  
Discover Sartorius



3:27 / 3:27



HD

YouTube





40 Years in Yauco Puerto Rico



**2013** – Start up Filter Assembly  
(Separation Technology) in ECO 1 Building

**2019** – Expansion of Bag Manufacturing  
(Sterile Bags Technology) in ECO 2 Building

**2023** – Start up Cell Culture Media  
Manufacturing in ECO 2 Building

**1983** – Start up Separation Technology  
start up in Main Building



**2012** – Start up Bag Manufacturing  
(Sterile Bags Technology) in ECO 1 Building



**2020** – Expansion of Membrane  
Casting in MC Building



# Explore Our Yauco Portfolio



Separation Technology

Lab Filtration & Purification



Fluid Management Technology

Safeguard Bioprocessing Fluids



Cell Culture Media

Cell, Viral, & Protein-Base  
Therapies





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Separation Technology Process

SARTORIUS



# Yauco Separation Technologies Overview

## Laboratory Applications

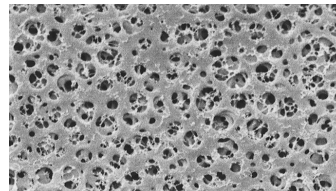
- Flat Filters



## Membrane Casting

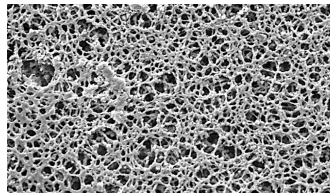
- Cellulose Acetate
- Polyether Sulfone

Membrane manufacturing done according to  
Precipitation and Evaporation Technologies



Cellulose Acetate

Polyether Sulfone



## Filters

- Capsules
- Cartridges
- Maxicaps







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Fluid Management Technology Process

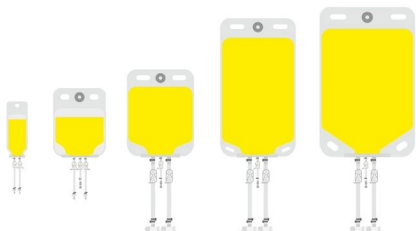
**SARTORIUS**

# Yauco Fluid Management Technologies Overview

America's Region Supplier for all Product Families

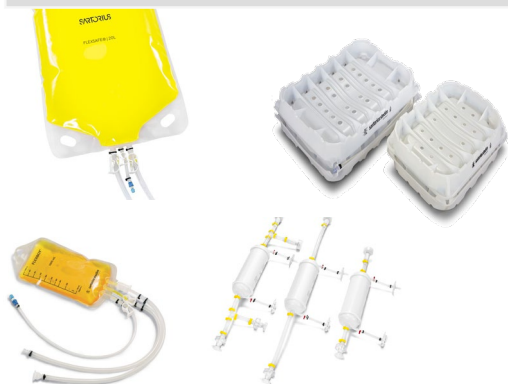
## 2D Bag Chamber

- Flexsafe 2D 250 ml to 50 L



## 2D Assembly

- 2D Flexsafe
- 2D Flexel
- Flexboy
- Celsius
- Transfer Sets
- PUPSIT
- FFU, FSL & VFU
- Sartoflow



## 3D Assembly

- Flexel 3D Storage & Mixing
- Flexsafe 3D & Mixing



## Smart Consumables

- Quickseal (Sil & TPE)
- SmartLink
- MyCap
- OPTA Connectors



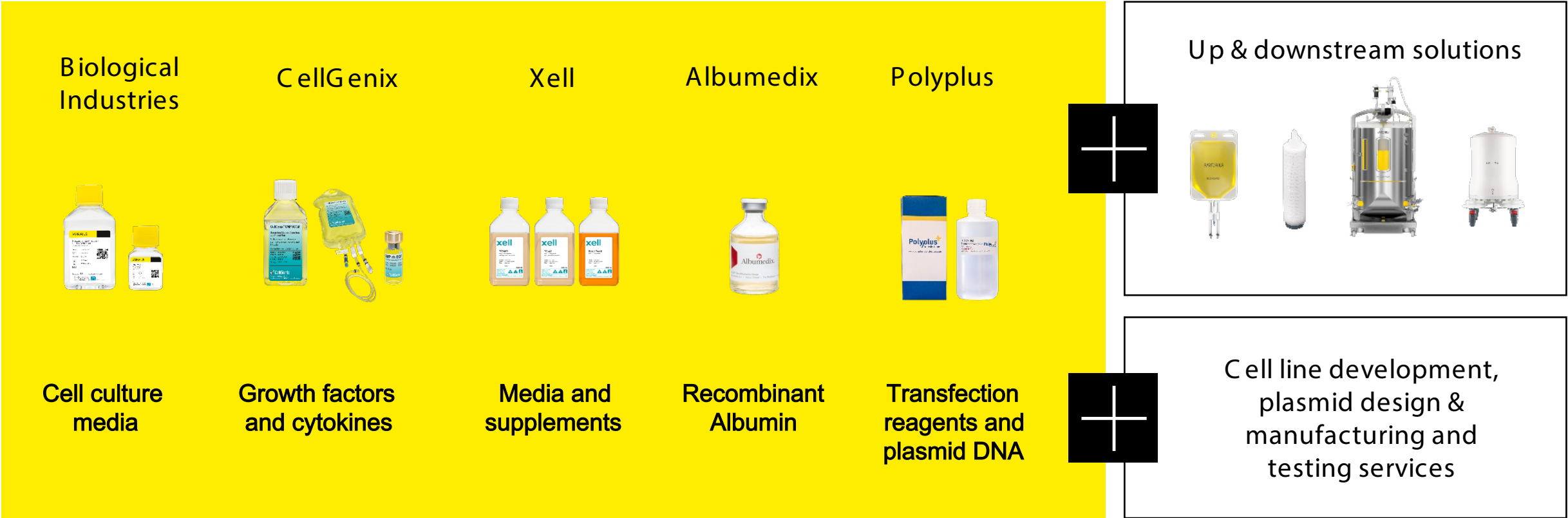
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Cell Culture Media Process

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# Creating a technology platform for cell and gene therapy applications



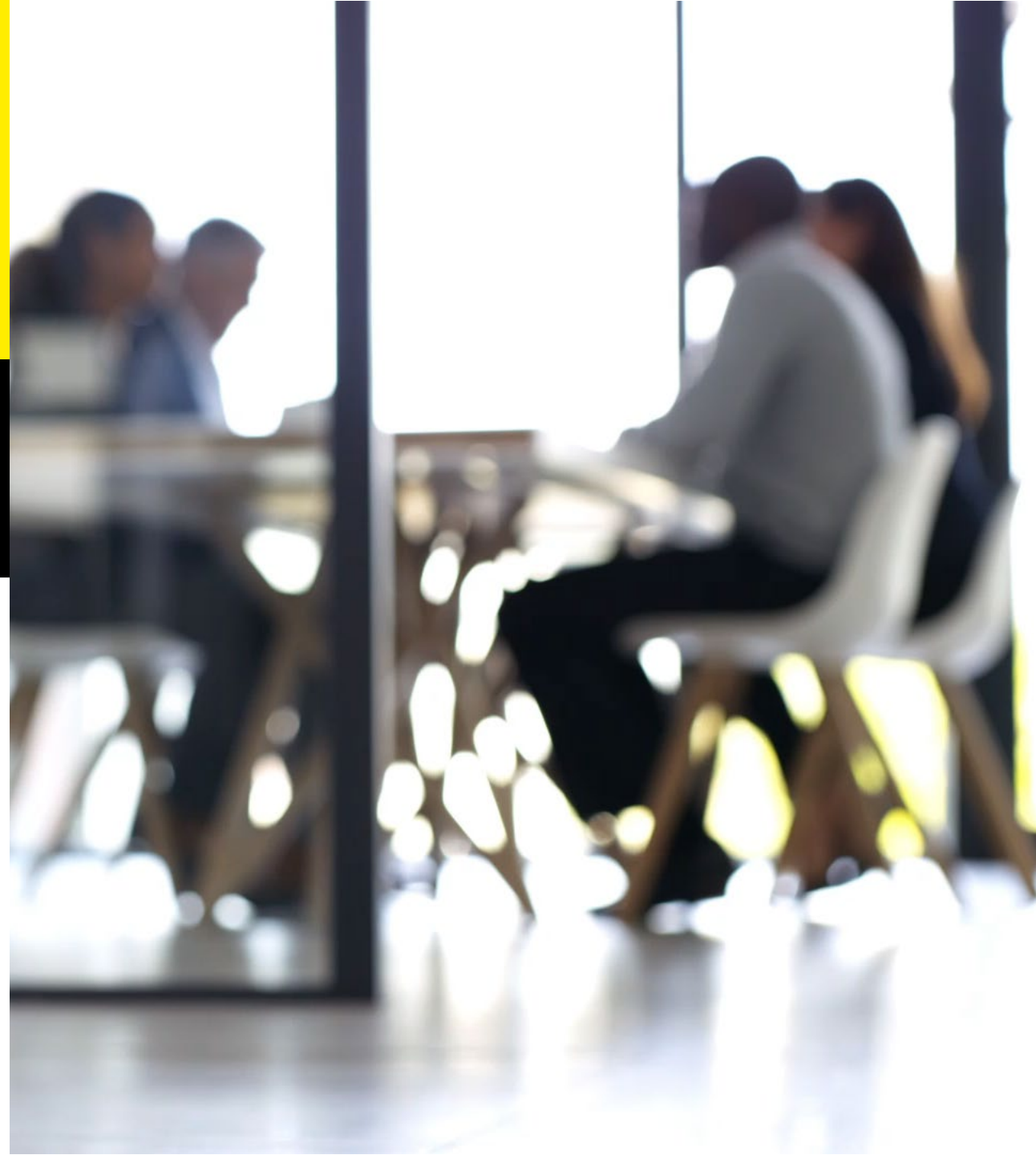




# SARTORIUS

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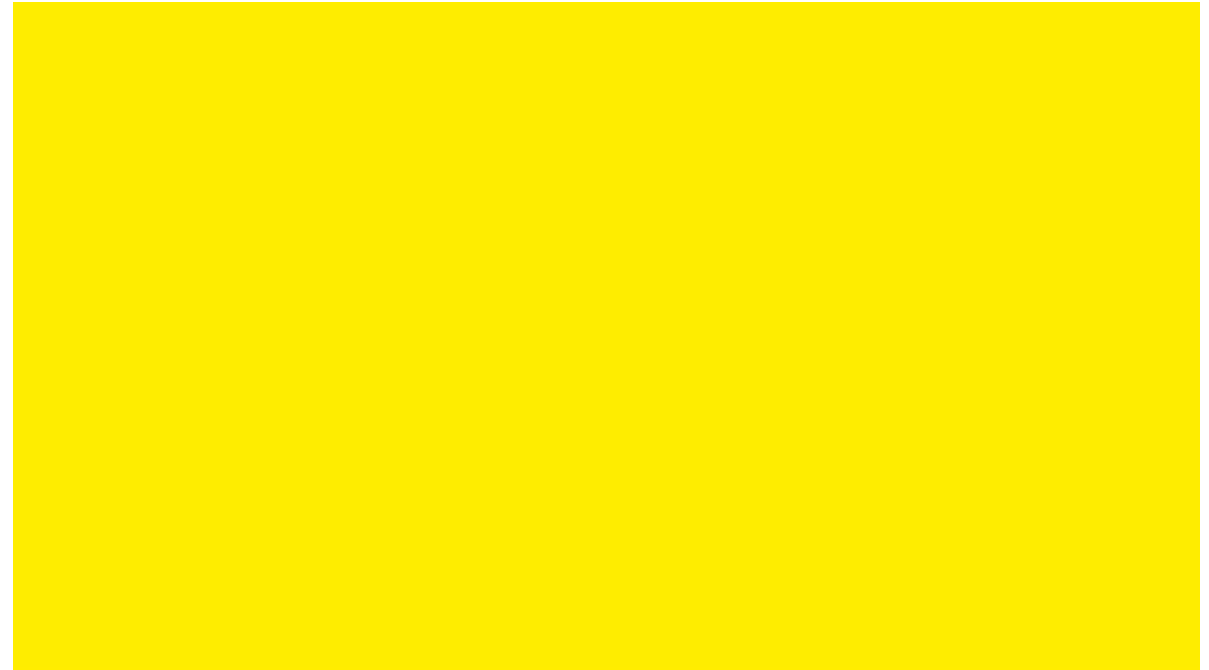
Investigations that we are  
part of the Solution





# We are part of the Solution

- Product Portfolio aligned on gene therapies solutions for the treatment of **rare genetic diseases**
- Sartorius products were part in the development of the world's **first FDA -approved vaccine against the mosquito - borne chikungunya virus**
- Sartorius support the **biotechnological manufacture of insulin** to treat the diabetes
- Sartorius products are involved in the production of several **hepatitis B vaccines** , including high-throughput cell culture systems, purification technologies, and sterile filter
- Sartorius technologies are laying the grounds for maybe one day overcoming the shortage of donor organs, by **3D bioprinting**

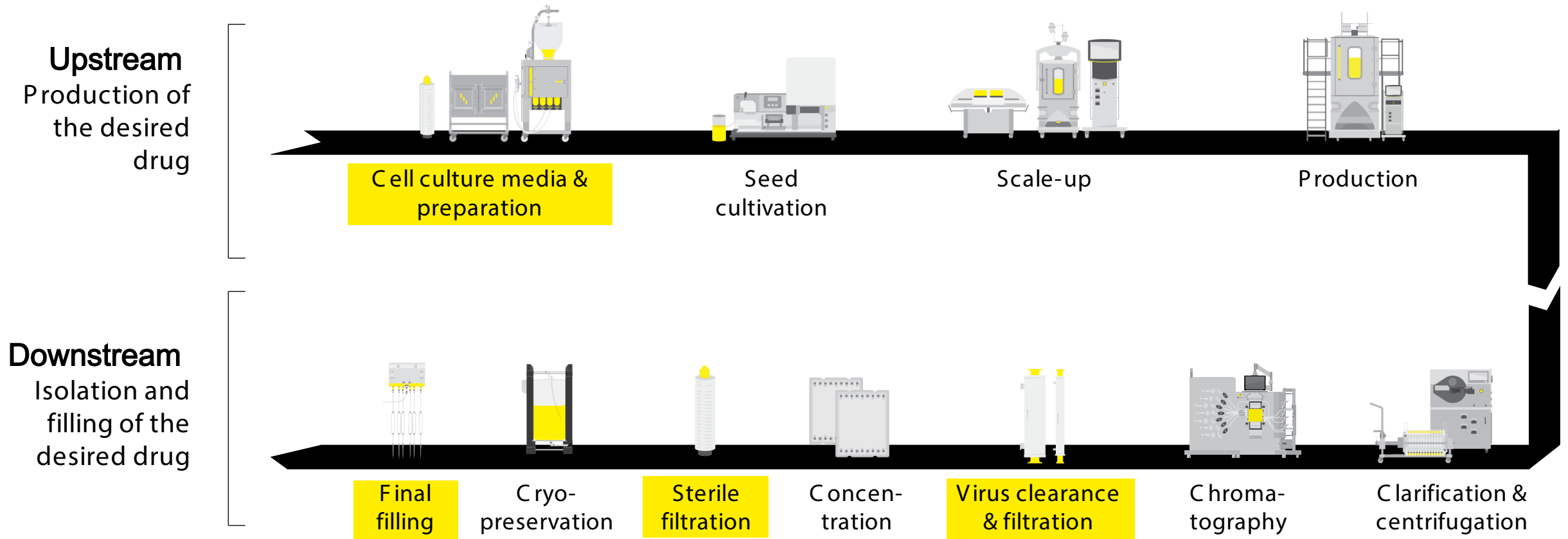






# Product Application

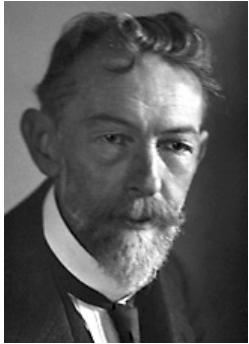
# Offering integrated end-to-end manufacturing solutions



# Separation Technology - Filtration through History



1927



Richard Zsigmondy  
Ultrafiltration

1979



Sartobran®

1995



Sartopore®

2012



Sartopore®  
Platinum

2017

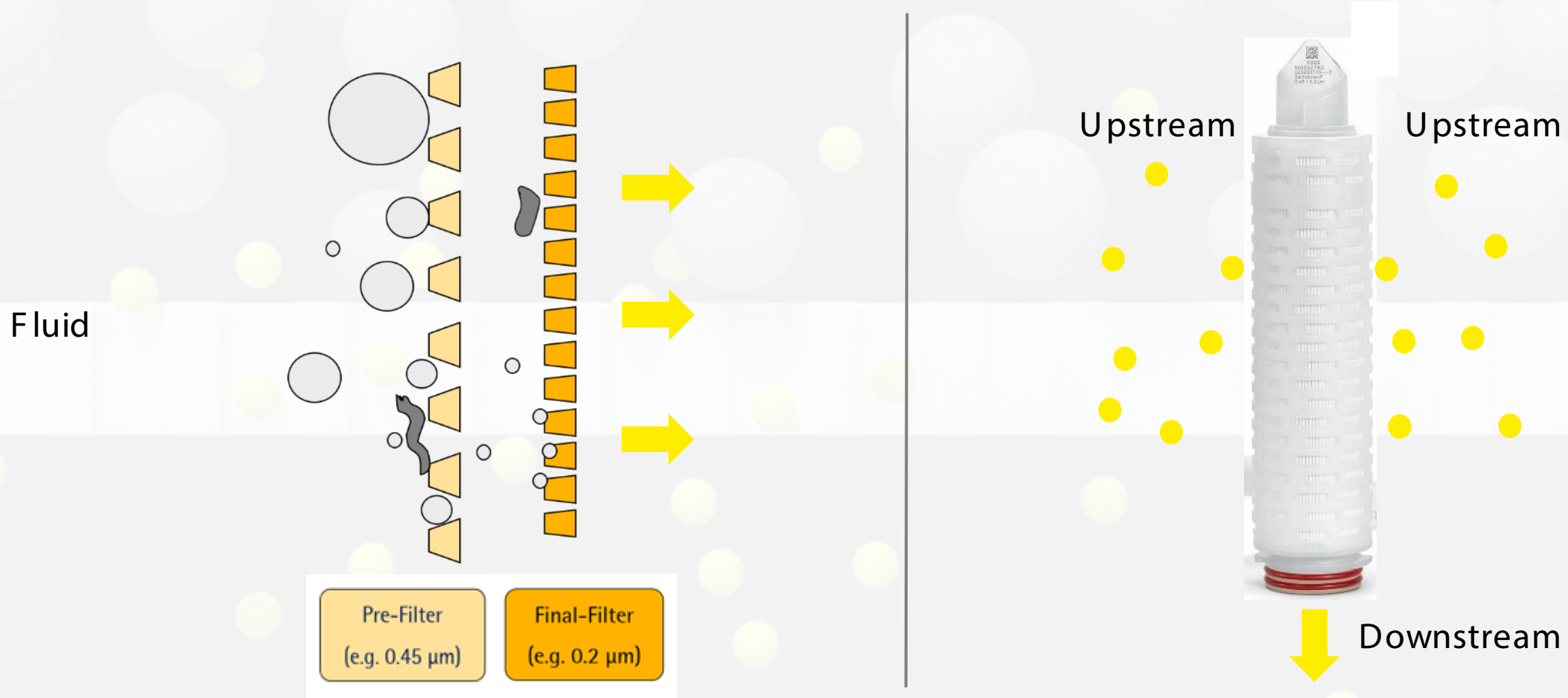


MaxiCaps® MR

- Hungarian chemist from Austria.
- Nobel Prize in chemistry in 1925.
- In 1927, the company (under the name Membranfiltergesellschaft m.b.H.) began the industrial production of membrane filters

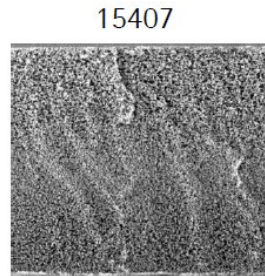


# Filtration Principles



# Separation Technology Application

- Therapeutics
- Biological Fluids
- Ophthalmic solutions
- Injectables
- Media
- Antibiotics
- Buffers
- Chemicals
- Cleaning and sanitizing agents



↓ + pre-filter  
15445



- Reusable (50x)
- p: - 5 bar
- hydraulic shock/ autoclavable
- 4°C - 80 °C



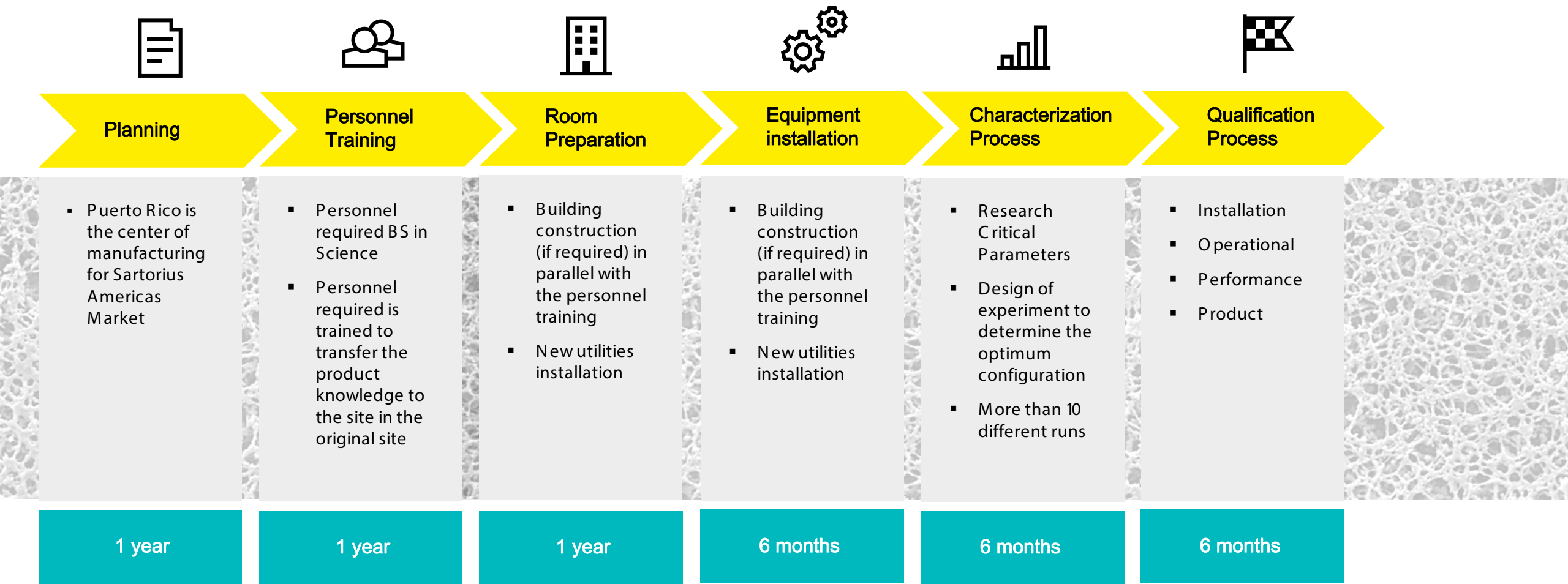
# Fluid Management Technology Application

- Chemical and Consumer Care
- Food & Beverage
- Cell therapy
- Biologic Discovery
- Sample preparation
- Vaccine



# Transfer of Product

# Transfer Product Process

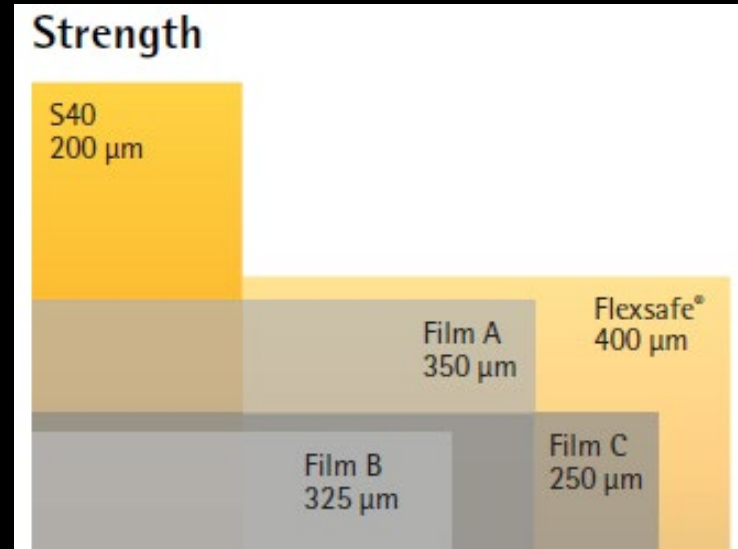


# Product Development

# Product Development

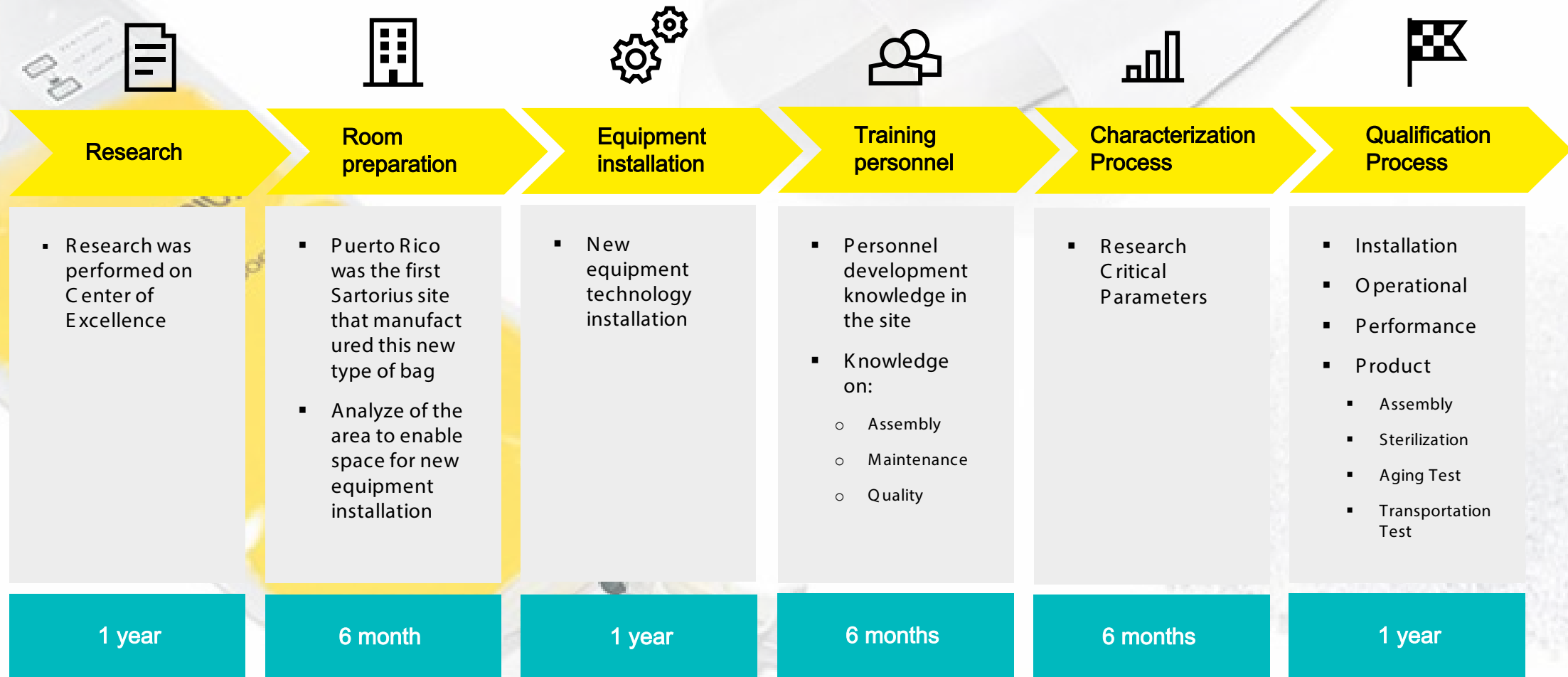
## ▪ Product Overview:

- Made of the new polyethylene S80 film. It utilizes a multiple layers of different materials which provide a strong, robust and flexible 400 µm structure.
- Number of Ports: 2 and 3
- Volumes: 50 mL - 50 L
- First Manufacturing site: Yauco.





# Development Process



# Engineering



# Integrity Test Process to Filters Units

A non-destructive physical test to determine the presence of oversized pores or other defects that may compromise a given filter's retention capability.

Two (2) test were performed:

## Diffusion test

Applies a constant pressure of air on the upstream side of a filter saturated with liquid and measures the volume of air over time that diffuses through the filter.

## Bubble Point

It is used to separate solids from liquids, making the liquid pass through the pores of a membrane, which is known as a filter.





# Steam Sterilization Process

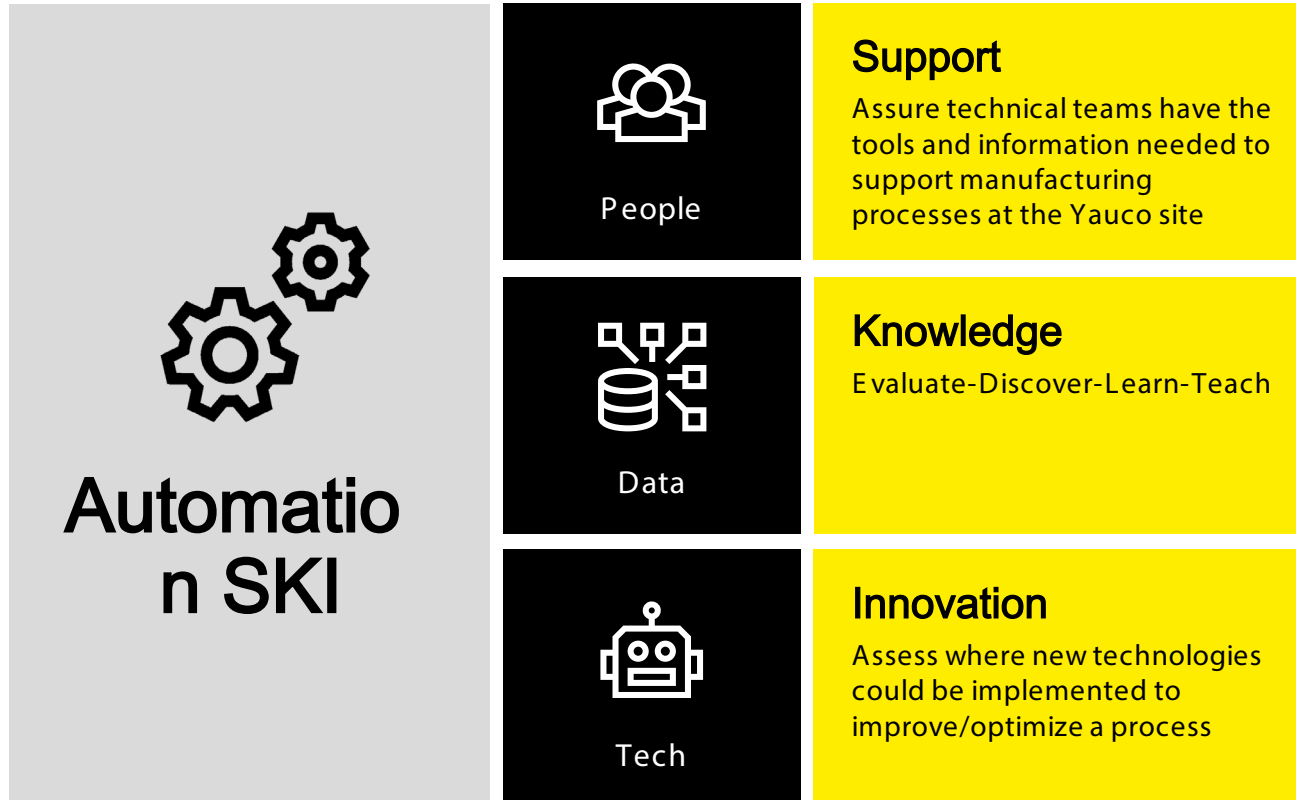
Killing and eliminating bacteria, viruses, and spores using heated, high-pressure steam with  $\geq 97\%$  of steam quality.

Does not involve any toxic liquids or fumes, and it's relatively inexpensive, quick, and effective.

Corrosive in some materials, combustive in some lubricants, may reduce material ability to transmit light, and may increase hardening time in plaster-cast



# Engineering Automation Program



- Automation can make processes more **efficient, convenient, and faster**.
- Can achieve higher production rates and increased productivity.
- More efficient use of materials.
- Better product quality and process control.
- Reduces process variability.
- Improved safety.
- Minimizes paperwork.
- Organizations can improve their resource allocation by freeing employees from time-intensive, low-skill tasks.

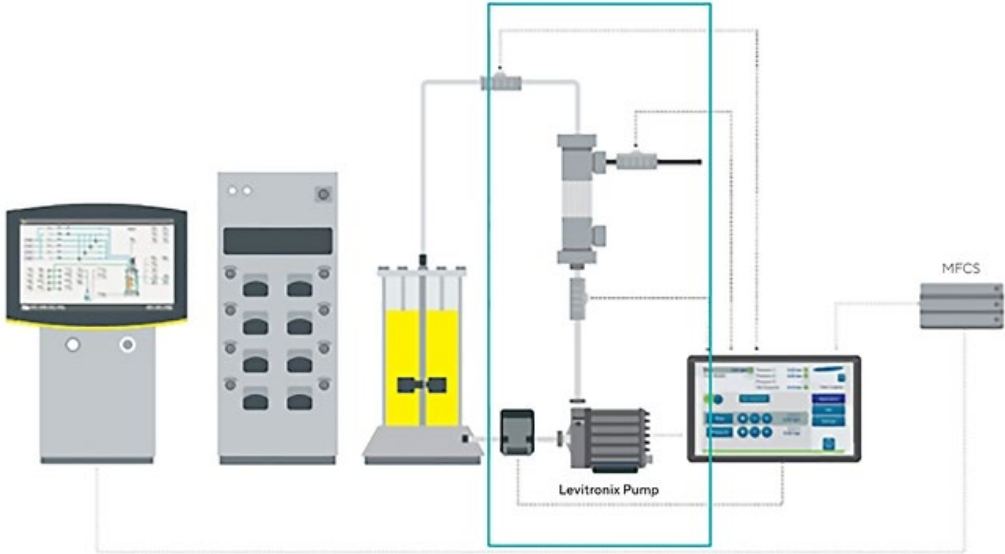




# MES Software - Siemens Opcenter

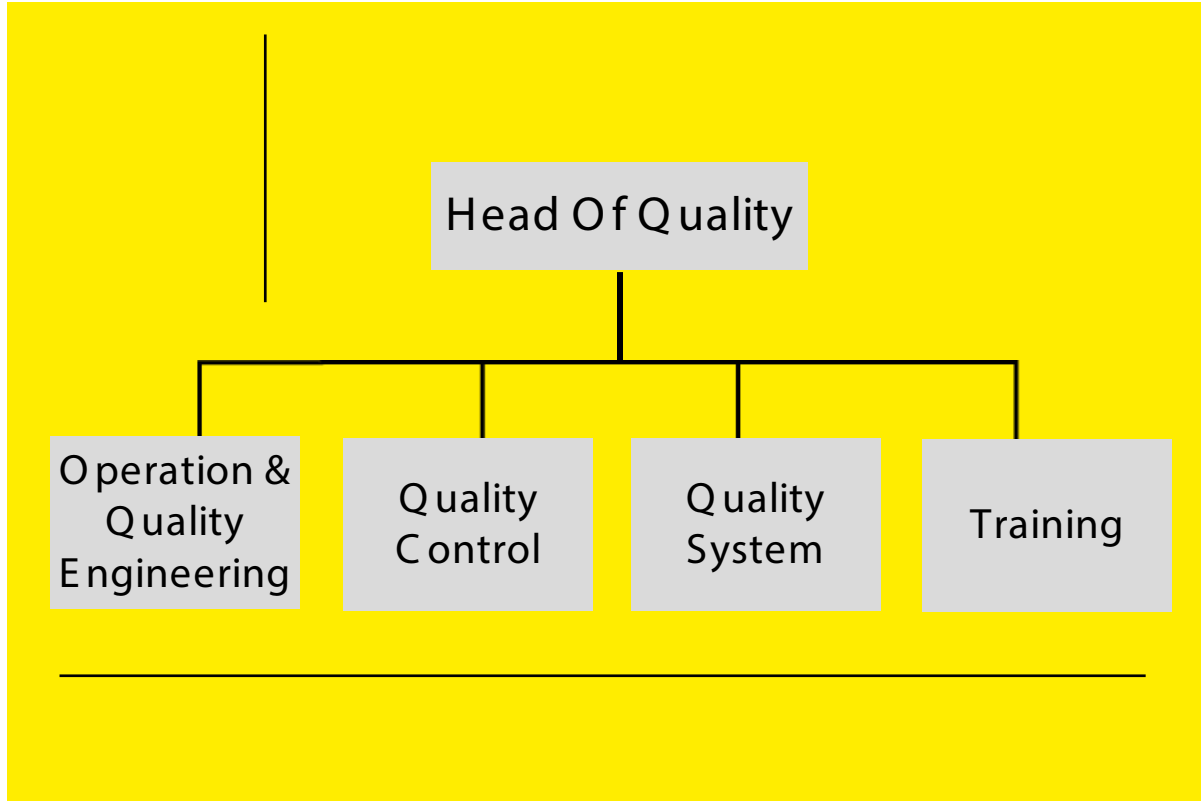
Siemens Opcenter (*formally known as SiemensCamstar*) is a manufacturing execution system (MES) that enables a complete digitalization of manufacturing operations.

- Provides end-to-end visibility into production.
- Automatic enforcement of manufacturing processes.
- Self-auditing, paperless manufacturing.
- Complete manufacturing audit trails across the enterprise.
- Continuous feedback to operators.
- Interoperability with enterprise resource planning (ERP) and third-party systems.



# Quality System

# Quality System



## Quality Roles

- + Quality Engineers
- + Analysts: Chemistry, Microbiology
- + Investigators
- + Training
- + Quality Auditors





# Quality System



Documentation  
Training



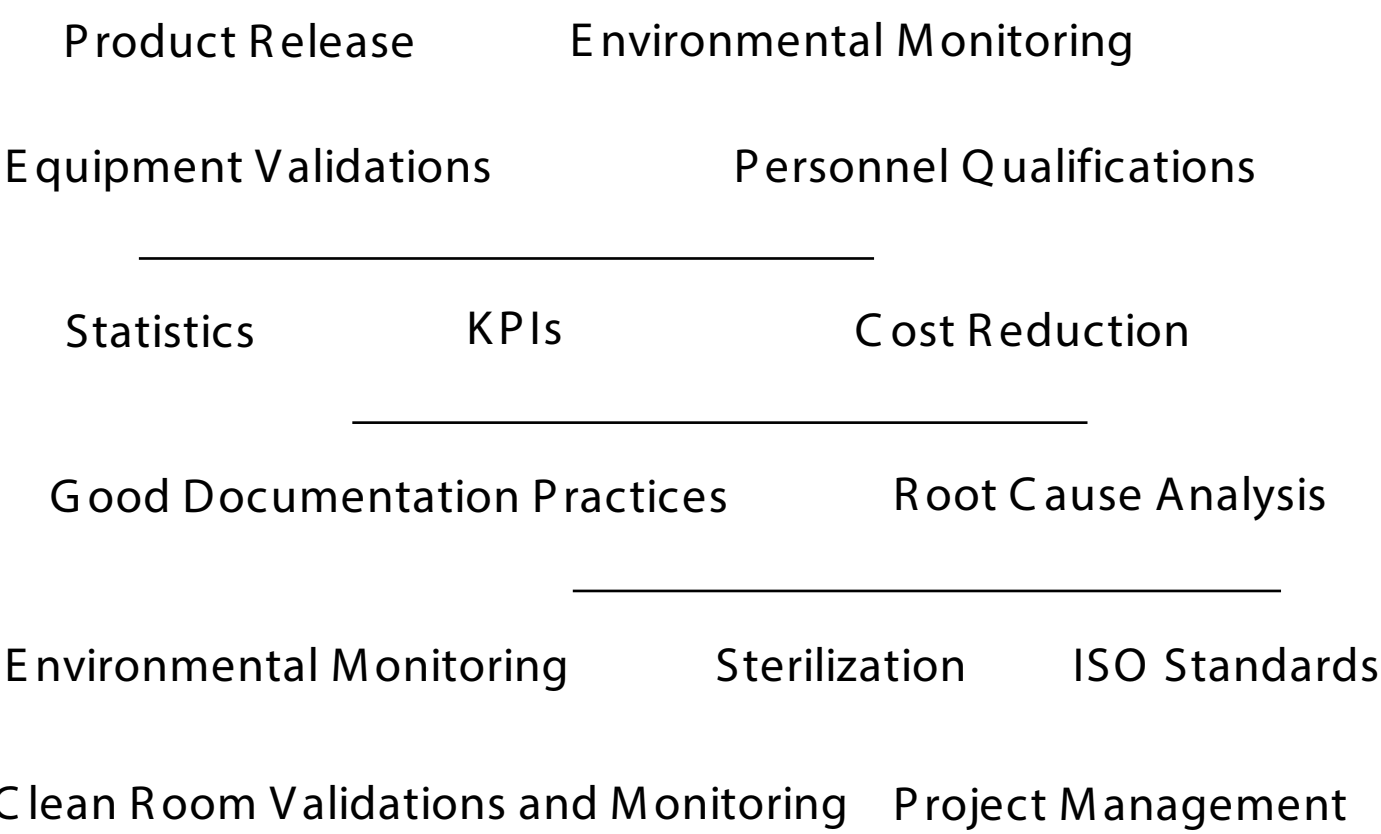
Q/A Q/E



Investigators: Complaints  
& Non-Conformance



Analyst: Chemistry  
& Microbiology





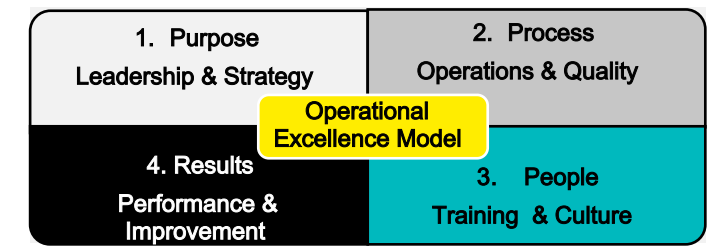
Quality  
System


# Continuous Improvement

# People – Talent Management & Culture

## Cultural Enablers – systems

*Cultural enablers: focus on the foundation of an organization: its people .*

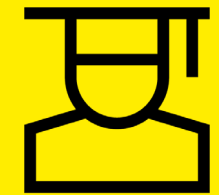


1	Talent Capability	<ul style="list-style-type: none"> <li>CI Academy <ul style="list-style-type: none"> <li>Lean Basic Tools Program</li> <li>Kaizen Program</li> <li>CIA Belts Program</li> </ul> </li> </ul>
2	Reward and recognition	<ul style="list-style-type: none"> <li>Recognition Program</li> <li>Competition Participation (PRMA QUEST Event)</li> <li>Ideas Program</li> </ul> 
3	Communication system	<ul style="list-style-type: none"> <li>Townhall Meeting(Exempt) And All Hands</li> <li>Visual Management (Visual boards)</li> <li>Entry Level Meeting("Café con Leche"), Recognitions communications</li> <li>Skip Level Meeting</li> </ul>
4	Leader Standard Work	<ul style="list-style-type: none"> <li>Tier Management Meeting</li> <li>Gemba Walks</li> <li>Creating Accountability</li> <li>Mentoring People</li> </ul>





Simplifying Progress



## CI Student Program + Collaborations

UPR RUM – 10 Capstone Projects / 5 Coops  
 UPR Ponce – 1 Industrial Engineering Visit / 1 Coop  
 CROEM – 2 Biotechnology Interviews

SARTORIUS

# Line Balance – Cost Improvement & Increase Productivity (2D)



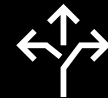
Define  
Phase

Goal: Productivity Increase for L11 and L12 at FMT CR 3 at Sartorius Yauco of at least 1.1N/hr by Q3 '24.




Measure  
Phase

- Order Intake/Demand (Pareto)
- Cycle Time /Bottleneck/Changeover
- 8 Waste Analysis



Analyze  
Phase

- Ishikawa Diagram
- 5 Why's
- VSM



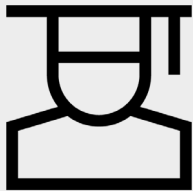
Improve  
Phase

- Line Rebalancing
- Station Standardization
- Planning/Scheduling improvements




Improve  
Phase

- Trend Charts
- Visual Management
- 5s




Capstone Student  
Name

UPRM-Student  
Industrial Engineering




Capstone Student  
Name

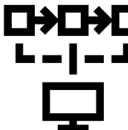
UPRM-Student  
Industrial Engineering



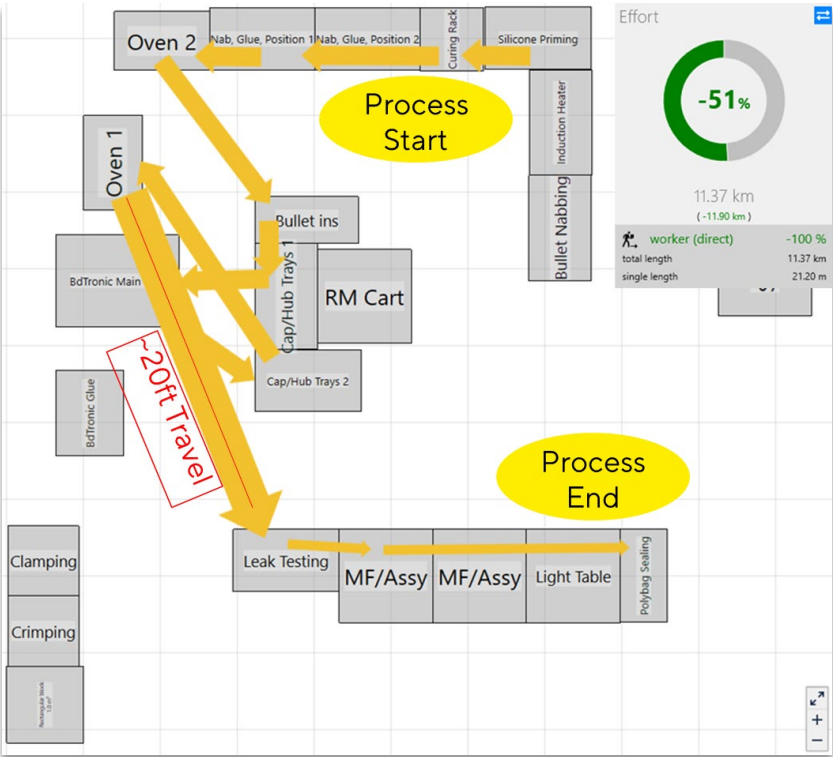
Expected  
Savings with  
Productivity  
Increase:  
~14k€



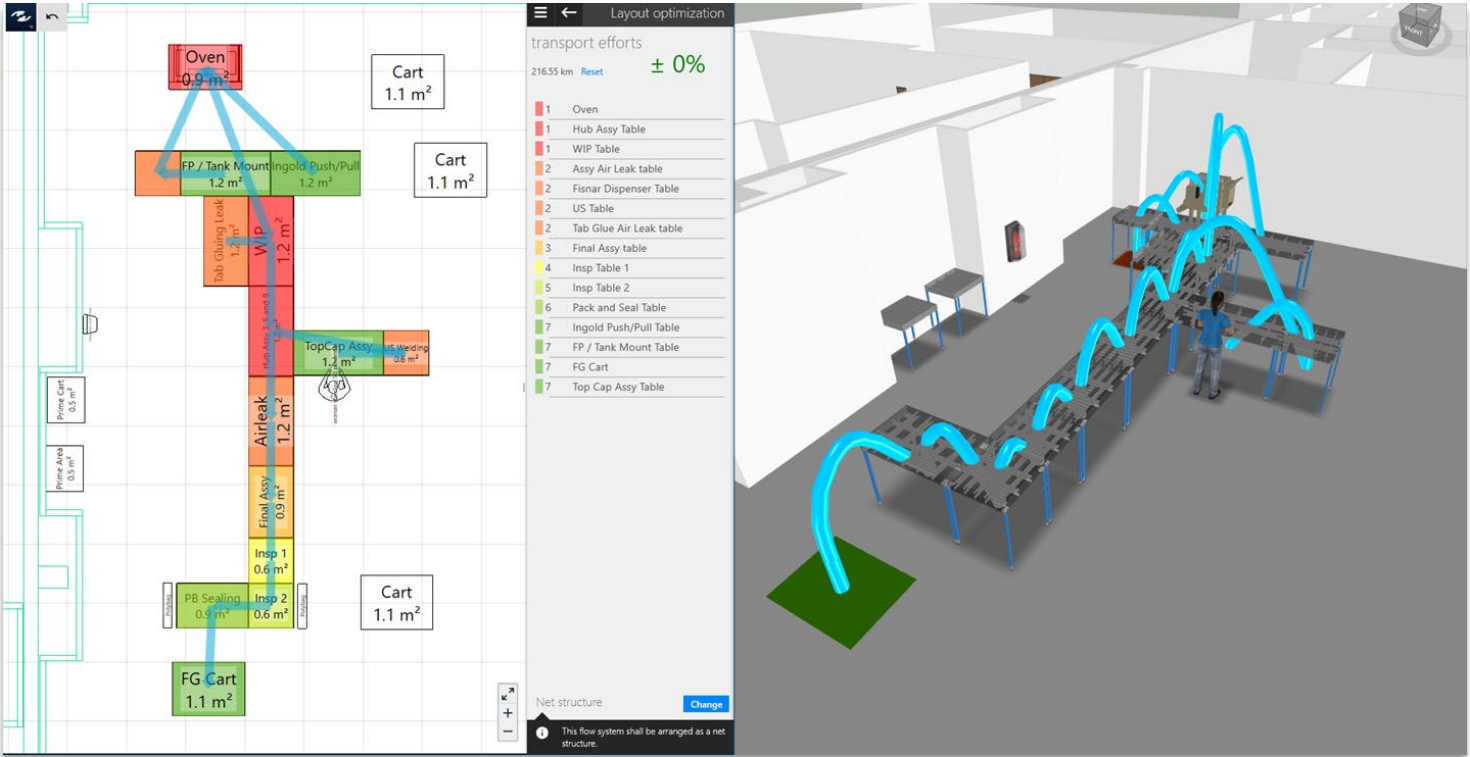




# VisTable Software for Layout Improvement.



Re-Layout Improvement reduce work effort and increase process efficiency



New Line Proposal Layout Load & Flow Visualization

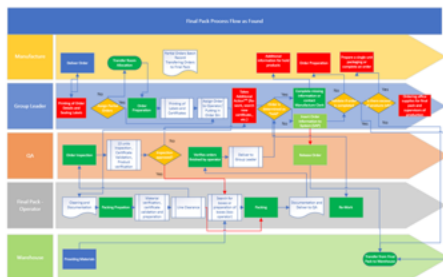
## Control

**Control:** Improved Packaging layout applying FIFO for each individual line. Implement a Lead Time KPI to manage the QA Release times. Monitoring the ST Delivery Reliability.

**Tools:** Visual Management, FIFO, 5s.

Figure 1 is a schematic diagram of a warehouse layout. The warehouse is represented as a grey-shaded area with various internal structures like shelves and workstations. Colored lines of different colors (red, blue, green, yellow, orange, purple, brown) represent the movement paths for different tasks. A legend on the right side of the diagram lists the tasks corresponding to each color:

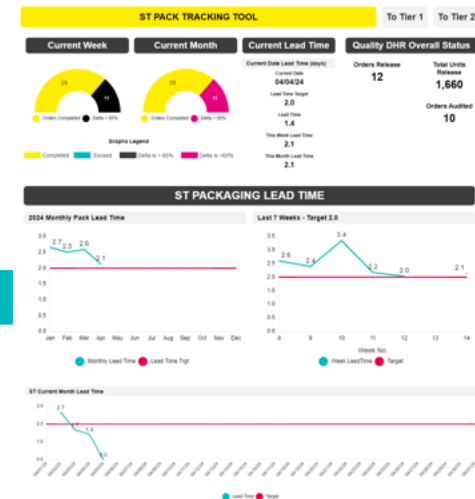
- Red: Checking certificates
- Blue: Adding certificates
- Green: Deliver case order to QA
- Yellow: Deliver empty cart
- Orange: Break
- Brown: Searching raw material
- Purple: Deliver FG to bins
- Dark Purple: Deliver boxes to operators
- Light Blue: Inspection of LC
- Light Green: Delivery order to GL
- Light Purple: Inspection of FG to release order
- Light Red: Searching order in mfg
- Light Blue: Printing labels & certifying
- Light Green: Bring product to operator
- Light Yellow: Delivery order to QA



The figure contains two bar charts. The left chart, titled 'External %', shows a Target of 90% (black bar) and an Actual of 100% (yellow bar). The right chart, titled 'Internal %', shows a Target of 90% (black bar) and an Actual of 65% (yellow bar). The y-axis for the left chart ranges from 0% to 150% in 50% increments. The y-axis for the right chart ranges from 0% to 100% in 20% increments. A legend at the bottom indicates that black bars represent 'Target' and yellow bars represent 'Actual'.

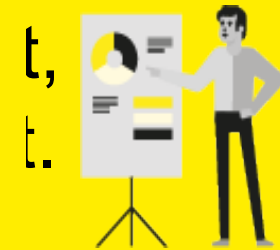
Category	Target (%)	Actual (%)
External %	90%	100%
Internal %	90%	65%

Before \$14k → After \$33k (Wk)





# Simplifying Progress



Projects	Participants
Kitting Improvements	Fernando Vera, José Guevarra, Mayte García, Marlon Báez
Quickseal Capacity Improvement	Angel Acosta, José Albarrán, Julio Caraballo, Eva Rosado
Flowkits Improvements	Ernestor Hernández, Suleira Torres, Victor Ramírez, Andy Sáez
Flexel Line Optimization	Tayra Soto, Ernestor Hernández, Brenda Rivera, Irving Sánchez
MyCap Improvements	Richard Gómez, José Albarrán, Tayra Soto, Margie Rivera, Kristian Muñiz, Glendy Ortiz
Sterilization Improvements	Norgelie Figueroa, Richard Gómez, Rafael Suárez, Eric Toro, Virgen Torres
ST Pack Improvements	Angel Acosta, Juan Oliveras, Edwin Sinigaglia
Oven Optimization	Edwin Sinigaglia, Carlos Nieves, Mariset Agostini, Eddie Salinas
IPA (Non-Bulk) Reutilization by Solvent Recovery	Kervin Santos, José Ortiz, Angely Questell, Wilnia Sepulveda
RFP Sample Reduction	Alexis Hernández, Eileen Rivera, Ernestor Hernández, Cindy Ortiz



Conozcan a nuestro representantes para el **Evento Quest 2023**



**29 de septiembre** | Costa Bahía Hotel & Convention Center  
Guayanilla, PR

\*Fecha límite de registro para empresas y academias participantes: 18 de septiembre de 2023

Para más información:

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Ernesto Cabrera | [ecabrera@prma.com](mailto:ecabrera@prma.com) | 787-346-2148

Elisabet Ortiz | [eoritz@prma.com](mailto:eoritz@prma.com) | 939-246-7793

AMGEN |  |  | WorldNet | Medtronic | SARTORIUS | Coca-Cola | Johnson Scientific | PRIME | HYTEL

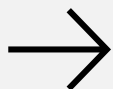
**10 Equipos** que tendrán la oportunidad de representar el talento profesional de Sartorius a nivel Isla.

**10 Proyectos** que nos mueven en la ruta de la **Excelencia Operacional**.

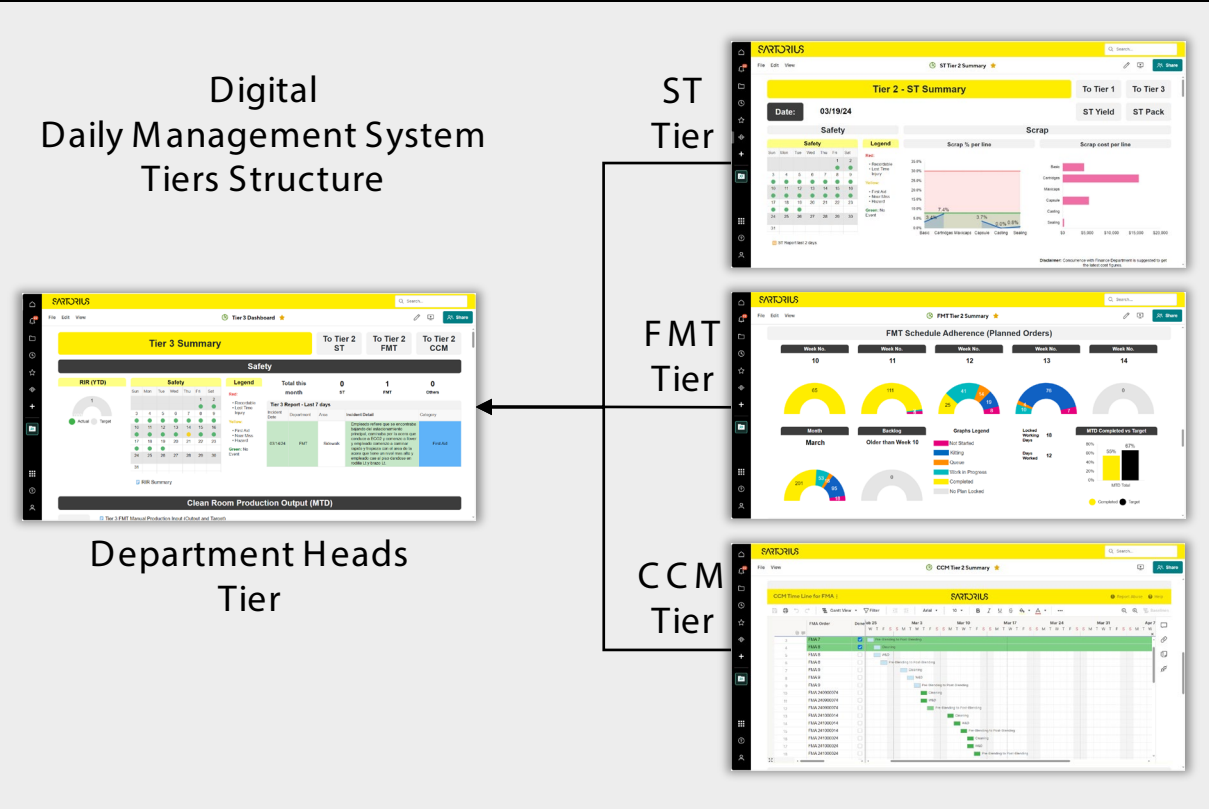
**1 Cultura** de Mejora Continua.

Éxito y Gracias!

# SARTORIUS



# KPI Digitalization + Data Centralization



SQDC Digital Hierarchy Structure for Tier 2 (Department Management) & Tier 3 (Department Heads)

**Digital Trends**

How can we leverage our outcome by building new business models or simplify our daily work operations?

- Information Access
- Employees Direction
- Actions Driven
- Scrap Cost Impact
- Q/A Compliance & Continuous Monitoring
- Safety Standards
- Metrics Attendance
- Process Improvement & Monitoring

**Tech**

**Data**

**People**

**Digital Visual MGMT**

Digital SQDC infrastructure that makes it possible to identify opportunities and interact with an instant actions escalation between Tiers to remove roadblock.

**Data Centralization**

Consolidate SAP reports to visualize data from the ERP System enabling a mechanism to monitoring and improve each business units daily KPI's.

**Staffing Optimization**

KPI Digitalization helps MGMT to enhance workforce agility and accountability by quickly responding to business behaviour.

Stepping into the Industry 4.0

# SARTORIUS

Simplifying Progress





# CI Academy Roadmap



CIA Certified Lean Badges



CI BPS Lean Basic Toolkit Assessment Alignment

CIA Certified Lean & Sig Sigma Badges

Six Sigma Certifications

# CIA Lean Badges Program

Badges for each Certification of Completion  
 Module Outcome:

- Trained
- Certified: Action Implementation + Badge Metal Pin

CIA Certified Lean Badges	Requirements
8W +3M	
5S	8W +3M
Standard Work	8W +3M +5S
Problem Solving	8W +3M +5S +SW
Kaizen Program	8W +3M +5S +SW +PS
Yellow Belt (CIASSYBC)	All Lean Badges + 1Kaizen Impl.
CIA Coach (CIACC)	YB +Provide Lean Trainings
	YB +3 Kaizen Impl.



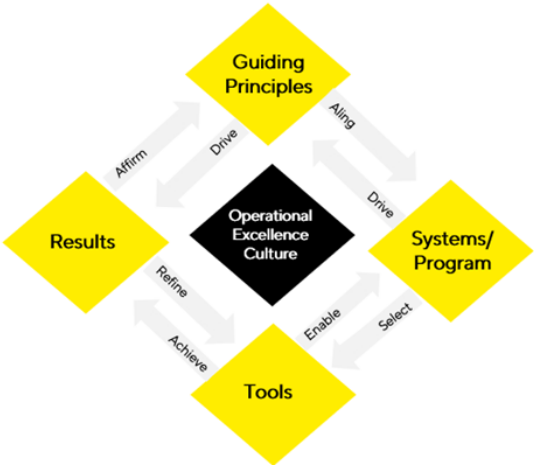
# CIA 6 Sigma Badges Program– Based in the Shingo Model

Badges for each Certification of Completion

Module Outcome:

- Certified: Action Implementation
- Badge Metal Pin

CIA Certified 6 σ Badges	Requirements
Yellow Belt (CIASSYBC)	All Lean Badges + 1 Kaizen Impl.
CIA Coach (CIACC)	YB + Provide Lean Trainings
	YB+3 Kaizen Impl.
Green Belt (CIASSGBC)	YB or Coach + Savings Proj.
Black Belt (CIASSBBC)	GB + Capital Project



CONTINUOUS IMPROVEMENT



SIMPLIFYING PROGRESS

• CIA •  
2024

ACADEMY

# Q & A



# Thank You

SARTORIUS



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