

Simplifying Progress

Capital Markets Tutorial | November 2022:

Bioanalytics | Cell Culture Media | Chromatography





Simplifying Progress

Capital Markets Tutorial: Bioanalytics

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Lab Products & Services (LPS): premium supplier for Life Science research and quality control labs



~€720mn

Sales revenue 2021



17.6%

Sales CAGR¹2016-2021



26.1%

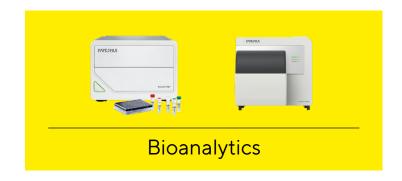
EBITDA margin² 2021



~50%

Recurring revenue

Portfolio includes lab instruments, consumables, software and services









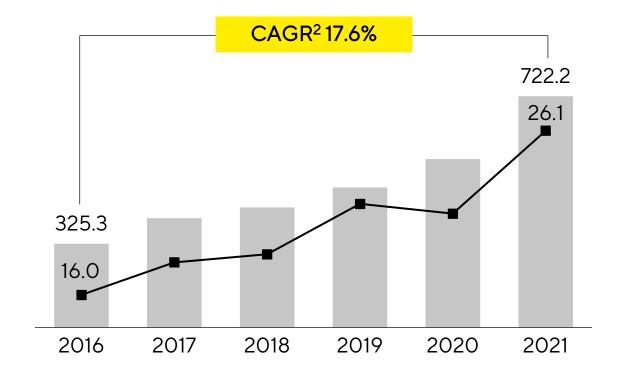


Lab consumables

1 In constant currencies 2 Excluding extraordinary items

Continuous transition to a higher growth and profitability profile for LPS

LPS sales revenue, € in millions; EBITDA margin¹ in %



Growth drivers



Attractive portfolio mix coupled with M&A

Launch of innovative products

Q Improved brand awareness

1 Excluding extraordinary items 2 In constant currencies



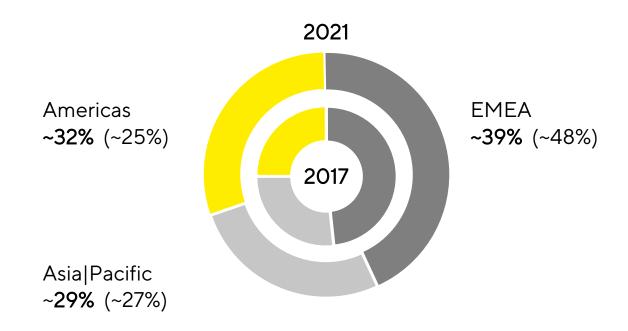
Focus on attractive Life Science market and more balanced regional profile

Sales revenue share by segment, 2021 vs. 2017

Life Science research ~55% (~42%)

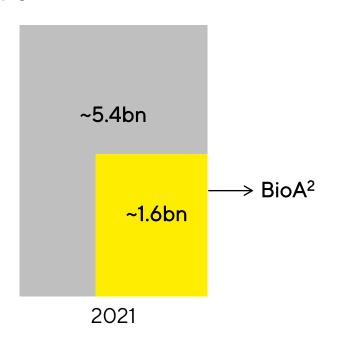
of which Bioanalytics >30pp (~14pp)

Sales revenue share by geography, 2021 vs. 2017



Bioanalytics portfolio strengthens position in Life Science research market

Total addressable LSR¹ market, in €



Strategic considerations

- Focus on Bioanalytics to address faster growing customer and product segments
- LSR market growing mid-to-high single digit while Bioanalytics in the teens
- Higher synergies between LPS and BPS³ in LSR than in AR⁴

Growth drivers

- Rich pipeline of novel molecules and proliferation of biosimilars
- Digitalization across all processes, from discovery to supply
- Al and big data continue to transform the industry

1 Life Science research 2 Bioanalytics 3 Bioprocessing Solutions 4 Applied research; Source: Various market and analyst reports and company financials



Bioanalytical tools address pain points of Life Science customers

Developing a new drug is costly, time-consuming, and involves a high risk of failure



~€500m average costs of drug discovery



>4-5 years time required for R&D and testing



Only 1 out of 10,000 molecules make it to the market

Bioanalytics improve R&D productivity by...

...digitizing and automating key steps in molecule and cell line development

...providing customers with valuable data and analytics to make better decisions earlier in the process

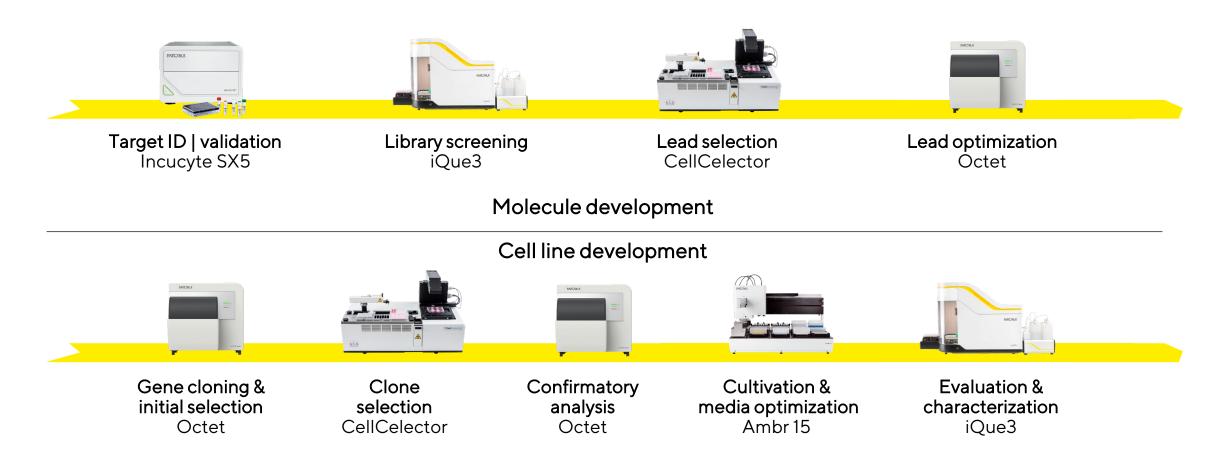
...decreasing likelihood of late-stage failure, shortening time-toclinic, and achieving better results faster

Time-to-market is key for customers: being first-in-class is more important than being best-in-class

Source: Association of the British Pharmaceutical Industry; Duxin Sun et al.: Why 90% of clinical drug development fails and how to improve it?, July 2022



Powerful solutions to enhance molecule and cell line development processes



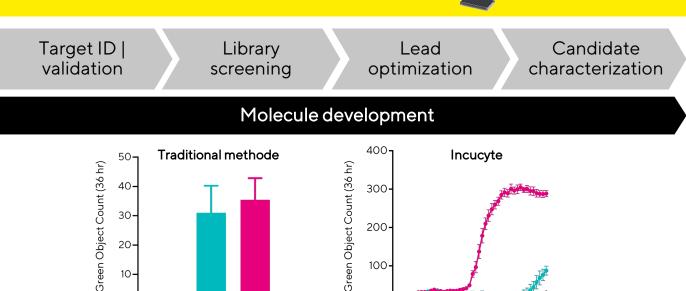
Case study: Incucyte reveals biology over time for deeper insights



Incucyte allows for deeper understanding of cellular behavior to accelerate drug discovery and research



- More information about drug candidates
 Time-dependent effects of experimental treatments
 in living cell models to reduce late-stage drug failures
- More relevant testing
 Leverage advanced cell models to recapitulate
 physiological and pathological conditions
- Boost productivity
 Parallelize experiments with 6x more capacity than traditional approaches

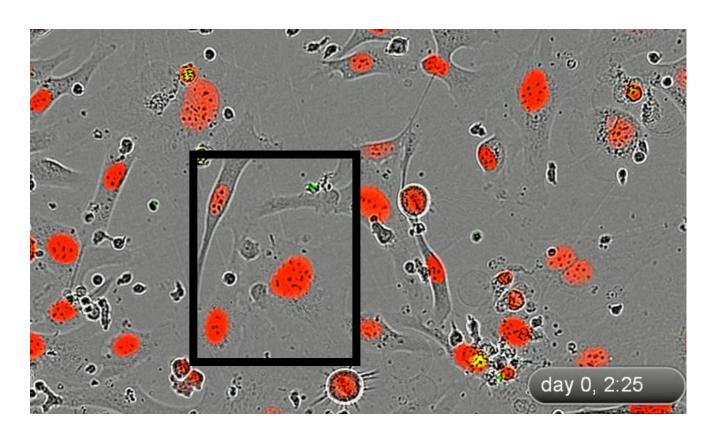


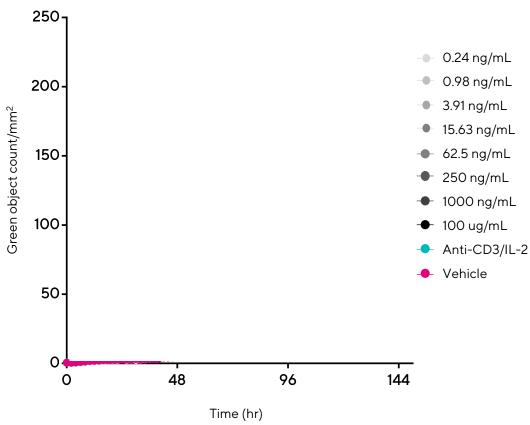
A549 +PBMC +PBMC

(CD3/IL-2)



Dive deeper into accurate and reproducible results with Incucyte







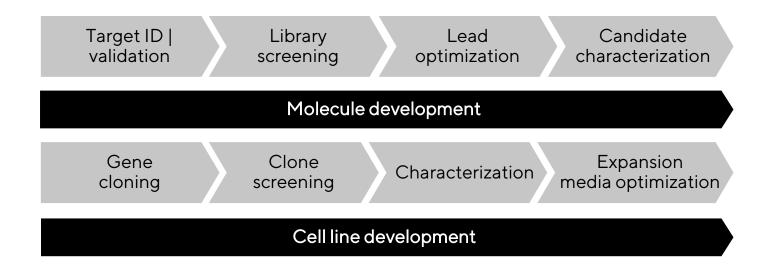
Case study: Octet reduces screening time and increases throughput



Octet BLI solutions reduce titer and CQA screening time during cell line development by up to 99% vs. traditional methods



- Fast time to results
 Protein titer measurements in <2 minutes
- Rapid, detailed information on molecular interactions
- Simplified characterization of workflows Robust, easy-to-use platform





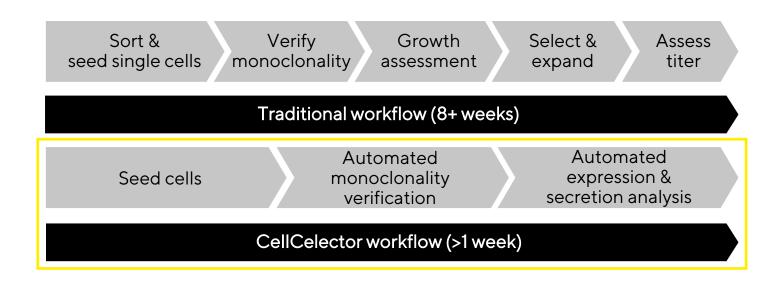
Case study: CellCelector picks best cells reducing time for clone selection



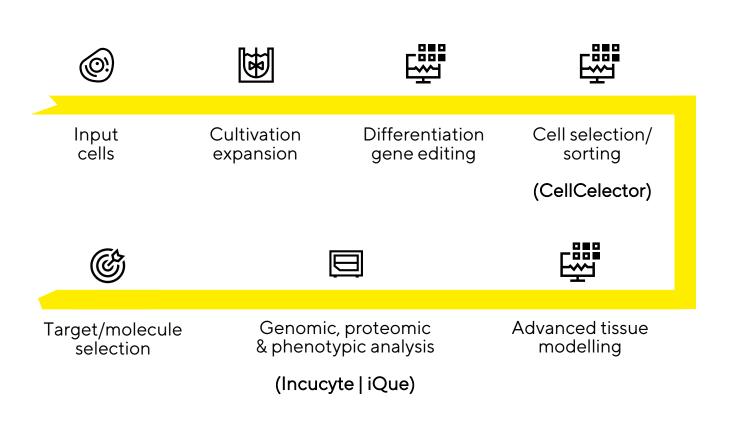
CellCelector integrated workflow saves 5+ weeks, compared to traditional method

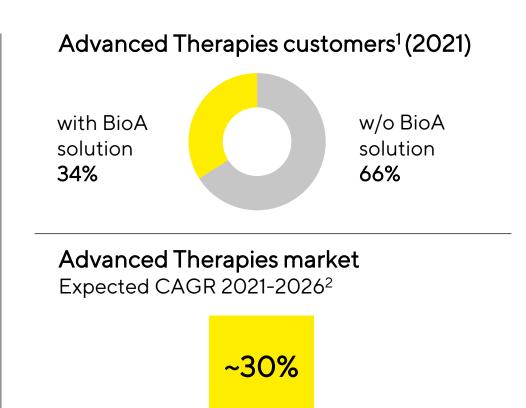


- Technology for automated analysis, selection and isolation of cells
- Monoclonality verification and single cell productivity measurement on a single platform
- Workflow is saving time and costs; superior performance compared to competing methods



Also in Advanced Therapies workflow, Bioanalytics instruments are increasingly used

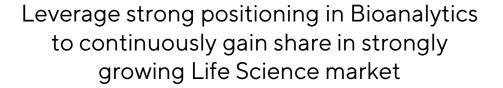




1 Bio A solution: Products by top \sim 100 Advanced Therapies customers; 2 Global data, analyst reports









Continue expansion in North America and establish strong footprint in China



Provide workflow solutions for advanced cell models & new drug modalities (e.g. CGT)



Capitalize on strong software competence



Expand share of recurring revenue





Simplifying Progress

Capital Markets Tutorial:
Cell Culture Media & Chromatography

René Fáber, Hugo de Wit, Michaela Pischke



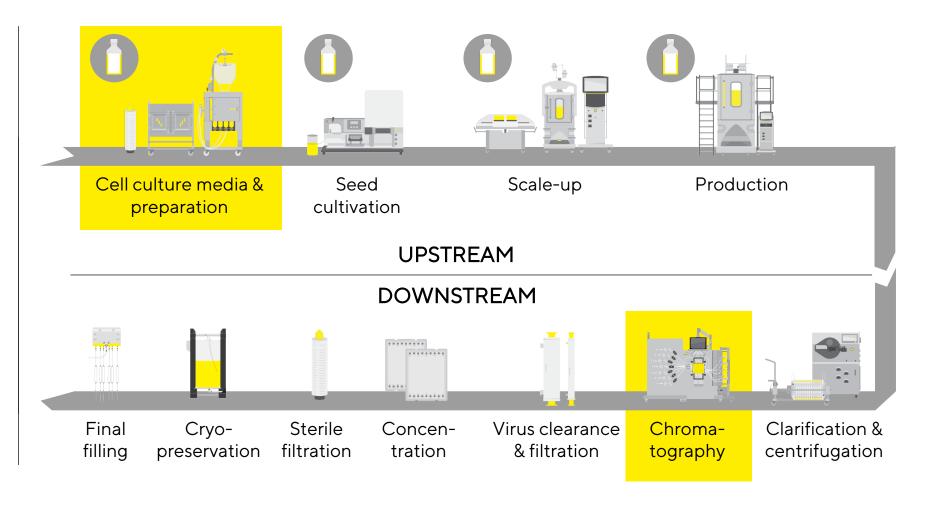
Bioprocess Solutions (BPS): solution provider for biomanufacturing



36.2% EBITDA margin¹2021

~75%
Recurring revenues

~90%
Sales share biopharma

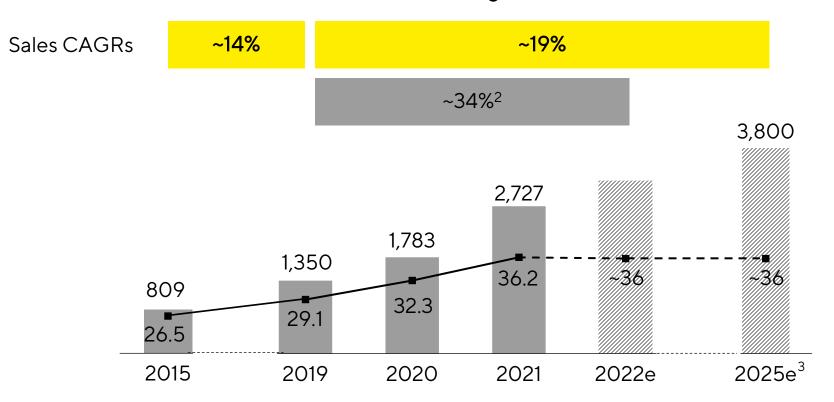


1 Excluding extraordinary items



Running ahead of initial mid-term plan in terms of sales growth and margin expansion

BPS sales revenue, € in millions; EBITDA margin in %¹

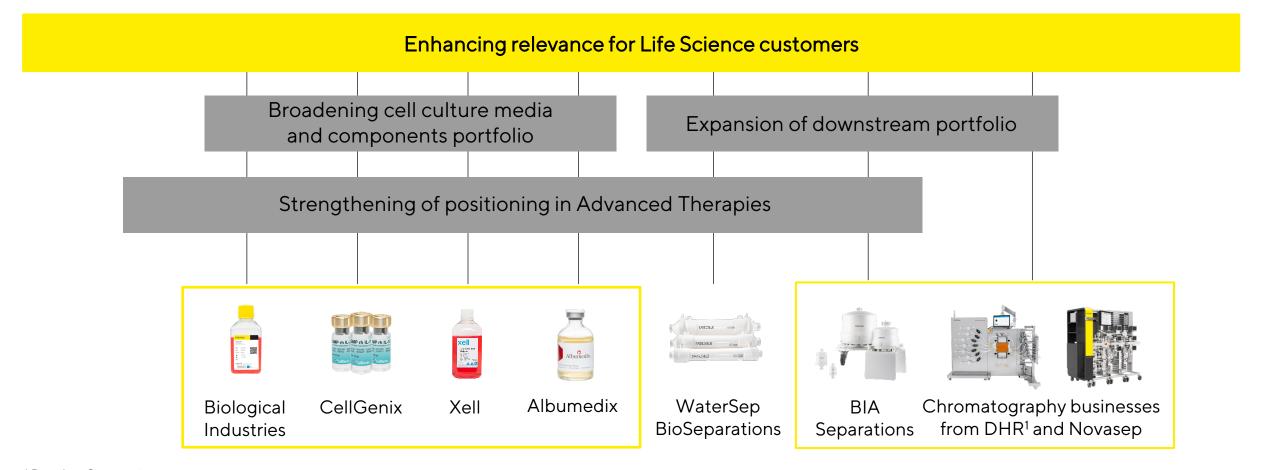


- Mid-term targets were increased in 01/2021 (sales) and 01/2022 (margin)
- 2019-2022 extraordinary growth driven by Corona vaccines and some customers' changed ordering pattern
- Normalization ongoing since mid of 2022
- Strong fundamental market dynamics unchanged

1 Excluding extraordinary items 2 Based on mid-point guidance 2022 3 Based on mid-term targets up to 2025: published in 2018, updated in 01/2021 (sales) and 01/2022 (margin)



M&A strategy: adding innovation, increasing share of wallet



1 Danaher Corporation

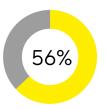


Addressing customer needs with a strong, differentiated portfolio

Protein-based therapies

- mAbs
- Bi-/Multi-specifics
- Bioconjugates | ADCs
- Recombinant proteins and peptides
- Protein-based vaccines.





Viral-based therapies

- Viral vectors for gene therapy
- Virus and viral vector vaccines
- Oncolytic viruses
- Novel modalities (e.g., mRNA, DNA, Exosomes)



Advanced therapies

- Cell therapy (e.g., iPSC, MSC)
- Gene-modified cell therapy (CAR-T)













27%



Unmet needs

Process intensification

Yields

Robust manufacturing



Share of molecules in R&D pipeline; source: GlobalData, November 2022

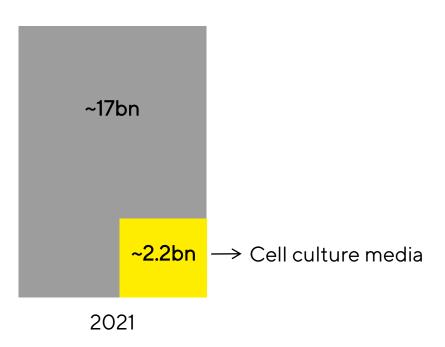


Expected market CAGR 2021-2026, Sartorius estimates



Cell culture media (CCM) business: well positioned in an attractive market

Total addressable BPS market¹, in €



Strategic considerations

- Leverage the leading position in upstream processes
- Media are specified into the process and part of the approval and therefore difficult to replace
- Recurring revenue with attractive gross margins

Growth drivers

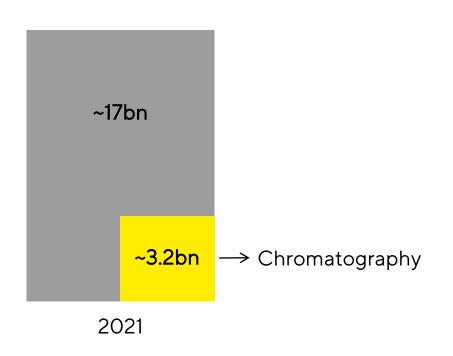
- Media market expected to grow in line with the modalities of the biopharma market
- Focus on faster growing Advanced Therapies
- Demand increases as drug candidates move through clinical phases, continuous demand after approval

1 Sources: Global Data, Citeline, Alliance for Regenerative Medicine and BCC Research; Sartorius estimates



Chromatography business: recent acquisitions significantly strengthened BPS' positioning

Total addressable BPS market¹, in €



Strategic considerations

- Chromatography an essential step in purification of biopharmaceuticals
- Sartorius' purification offering broadened through "classical" plus innovative assets
- Focus on intensified chromatography and cell & gene therapies

Growth drivers

- Healthy and strong pipelines of novel modalities
- Growing need for process intensification in mAbs and biosimilars
- Strong positioning of monolith and membrane technologies & strategic portfolio fit for intensified market

1 Sources: Global Data, Citeline, Alliance for Regenerative Medicine and BCC Research; Sartorius estimates



Extensive synergies in CCM's sales and manufacturing network

Cross-selling synergies within existing portfolio

Synergies within cell culture media operations

- CHO cell line
- Cell line development
- Bioreactors
- Fluid Management
- BIA monoliths











portfolio of

CellGenix

Biological



CellGenix



supplies growth factors and cytokines as raw material for Bl¹ media production





Albumedix



supplies and produces critical components for Bl¹ and CellGenix media



Xell



produces HEK and CHO portfolio



1 Biological Industries



CCM trend #1: regulatory requirements for GMP grade critical raw materials

When new modalities start to enter the clinic phases, there is a need for regulated quality products and regulatory support to obtain approval



Research / discovery / development phase

- Use RUO¹ media and additives
- No need for regulatory advice/support
- Focus on efficacy getting the treatment to work



Clinical trials / market supply phase

- Need for FFM²/cGMP³ media and additives, DMF⁴
- Need for regulatory understanding to file and obtain approval for trials and market
- Beside efficacy focus on safety and quality

1 Research Use Only 2 Fit for Manufacturing use 3 current Good Manufacturing Practice 4 Drug Master File



Case study CellGenix: regulatory know-how and state-of-the-art products support accelerated approval



Sartorius "Off-the-shelf" portfolio to satisfy customers' needs and help them overcome their challenges



Customer situation

- Customer develop new therapies in their laboratories for many years
- Regulatory requirements ask for safety and quality assurance beside efficacy before allowing clinical trials
- This means switching materials, repeating pre-clinical studies or delayed start of trials to comply with regulations

Sartorius solutions

- Enable safe, efficient and consistent manufacturing of cell & gene therapies and accelerated market approval
- Regulatory support for specific customer requests and/or respective regulatory agency (EMA¹, FDA², PMDA³)

1 European Medicines Agency 2 Food and Drug Administration (U.S.) 3 Pharmaceuticals and Medical Devices Agency (Japan)



CCM trend #2: new platforms for safe and reliable raw materials

Innovative technology platforms enable the replacement of animal and human sources for critical raw materials, increasing safety, quality and affordability



Customers' challenges using animal / human serum

- Contaminates from human/animal source
- Batch to batch variability
- Limited supply



Sartorius solution

- Safe recombinant source
- Defined quality, proven batch-to-batch consistency and controlled manufacturing
- Scalable supply



Case study Albumedix: enabling safer, scalable access to high quality and affordable critical raw material



Sartorius enables regulatory trend towards recombinant critical raw materials



Customer situation

- Current commercial manufacturing for a vaccine developed decades ago
- Design and use of suboptimal manufacturing processes, using animal and human sourced material with risks of process carry-overs, batch to batch variability and high cost

Sartorius solutions

- Next-generation, serum-free, highly purified vaccine manufactured using serum-free media and recombinant rather than serum-derived excipients
- Result: vaccines stay therapeutically effective, safer, more affordable and stable, enabling distribution in more than 100 countries, including most of Asia and Africa



CCM trend #3: scaling-up solutions for new modalities

Especially for new modalities there is limited process know-how and scalability available, which is required for an efficient and economic market entry



New modalities process development

- Focus on getting the process to work in the lab
- Limited experience and manufacturing expertise available



New modalities manufacturing

- Focus moves to Cost of Goods
- Need for access to scalable process solutions
- Need for access to production know-how



Case study Biological Industries: combination of innovative products with scalable manufacturing solutions enables fast access to market



Sartorius combines media know-how and supply with proven solutions to freeze and thaw liquids in bags





Customer situation

- Started to use stem cell media selected on performance
- Supply of frozen media in bottles
- Larger quantity of media to be supplied in bags, once scale-up starts and moves to manufacturing scale
- Challenge to freeze/thaw bags in a consistent manner
- Solving the problems can be time-consuming and delay clinical trials

Sartorius solutions

- Celsius system, specifically designed for the controlled thawing and freezing of the bags containing liquid media
- Result: fast, scalable, robust solution, that supports short timelines towards clinical production at high and stable quality



Chromatography trend #1: from batch production to intensified processing



Batch

- Limited productivity
- Larger production footprint
- Higher resin consumption

Intensified processing

- 10x higher productivity
- 3x less footprint and CAPEX
- Higher product quality, less batch-tobatch variability



Levels of intensification in downstream processing









Level 0

Standard batch standalone unit operation



Intensified, standalone unit operation:

increases the individual step productivity; less resin usage; improved buffer management

Level 2

Connected process:
at least two process
steps; subsequent steps

start before first step is finished; software orchestration is beneficial

Level 3

Continuous process: highly integrated connected process; steady-state flow; software orchestration is a must; long running times; closed processing



Sartorius' solutions for intensified processing



Process intensification leads to >10-fold higher productivity & saves up to 30% cost in clinical process







Process 80/250

Resolute BioSMB

- Continuous chromatography systems
- Single-use flowpath
- Scalable



Pilot

Resolute BioSC

- One system combines up to 3 process steps
- Low footprint

Case study large pharma: BioSMB improves footprint, productivity and flexibility at reduced costs

Before: single-column batch Protein A chromatography

- Column diameter: 40 cm larger footprint and requires a lot of storage space
- Resin volume: 20L Protein A one of the most expensive steps in downstream
- Specific productivity: 16g/L/h

Conversion to single-use multi-column Protein A step

- Resin volume: 3.85L, 80% reduction of protein A resin
- Reduction in overall cost
- Specific productivity: 56g/L/H





Chromatography trend #2: from multi-use, resin-packed columns to single-use chromatography devices







Resins

- Column packing & cleaning validation
- Large equipment footprint
- Less applicable to large biomolecules like viral vectors or plasmids

Membranes Monoliths

- 14101101111115
- High processing speed, high productivity
- High purification performance for new drug modalities
- Plug & play: ready-to-use formats, single use

Sartorius' solutions for high performance chromatography in novel and demanding applications

Sartobind Rapid A



- Single-use alternative to Protein A resins
- 20x higher productivity
- >30% cost reduction in clinical manufacturing

CIMmultus



- Unique high performance technology
- Specifically optimized for purification of new modalities, e.g. viral vectors, mRNA, plasmids
- Single-use and reusable options

Case study monoliths: scalability and robustness, high purity and yield

Molecule type

Adeno-associated virus AAV

Challenge

Achieving a scalable and robust separation of full from empty viral capsids with high purity and yield for multiple AAV serotypes

Sartorius BIA Separations products

- CIMmultus SO3
- CIMmultus QA
- PATfix



Key benefits

- Higher capacities than resin-based columns, due to large size channels, high flow rates with low pressure drops and high surface accessibility of binding sites for AAVs
- Downstream processing time reduced by 60%
- Significantly improves the recovery of AAV
- Plug & play cGMP formats, scalable from 0.05mL to 40L

Business result

- Integration of Sartorius BIA Separations' technologies into customer's cGMP facility (50L to 500L)
- Customer added a monolith-based process to its purification toolbox
- Included in customer's advanced analytical toolkit for process & product characterisation





Leverage global customer base by seeding new innovative products



Building relevance and significant share in new modalities



Continuously combining existing and acquired portfolios to create innovative solutions



Media and chromatography businesses contribute to differentiation and recurring revenue

