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Simplifying Progress

How Data Analytics can Boost the Bottom Line at a CDMO

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November 12th, 2020 4:00 PM - 5:00 PM CET



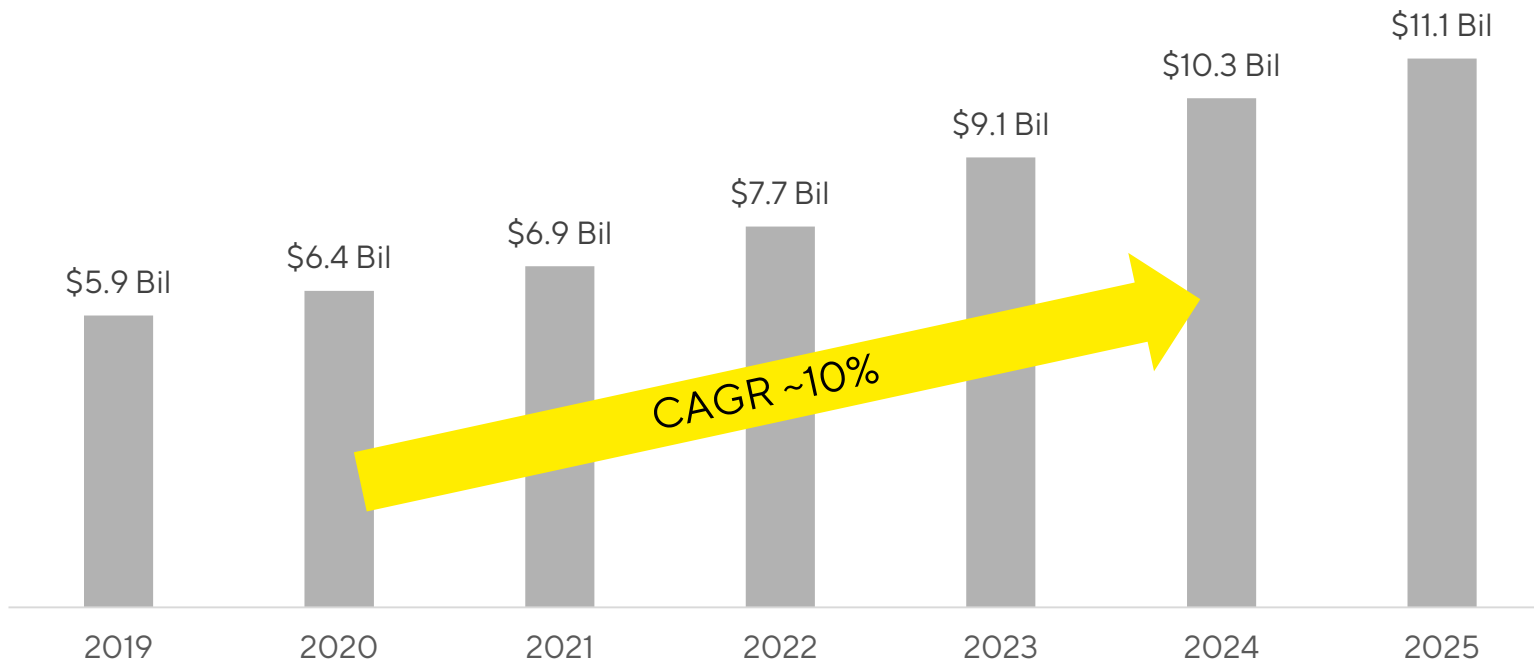
Agenda

- **Contract Manufacturing and Development Market Overview**
 - Market Size and Growth Drivers
 - CDMO Selection and Outsourcing Risks
 - Top Customer Needs and CDMO Innovation Trends
- **Addressing CDMO Innovation Trends with Data Analytics**
- **Smart Services Concept for CDMOs**
 - Partner Access Options
 - ROI Calculation



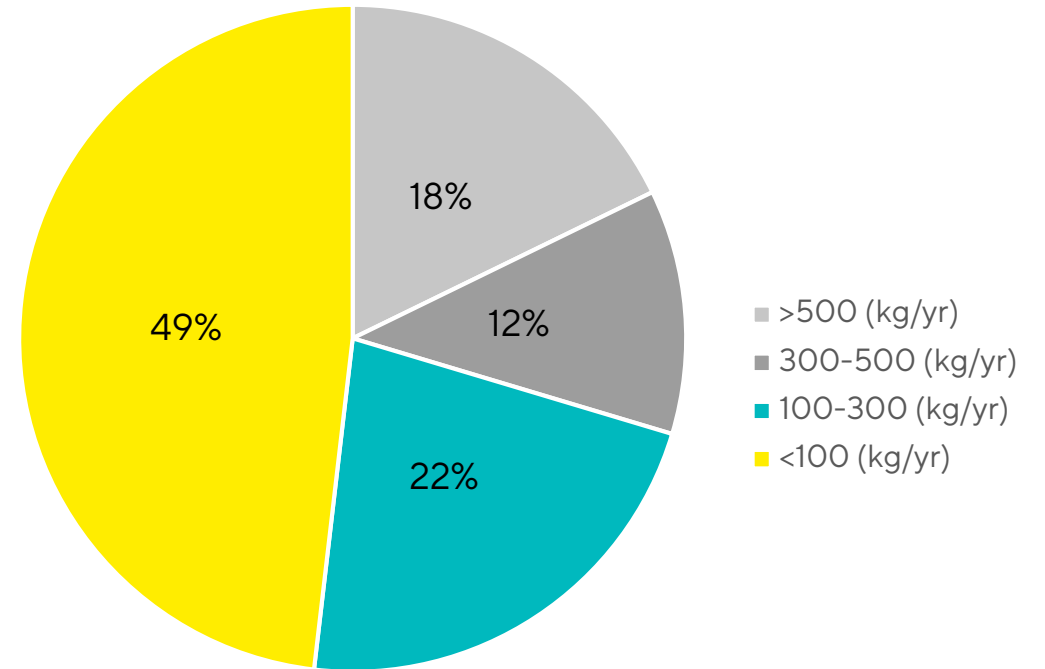
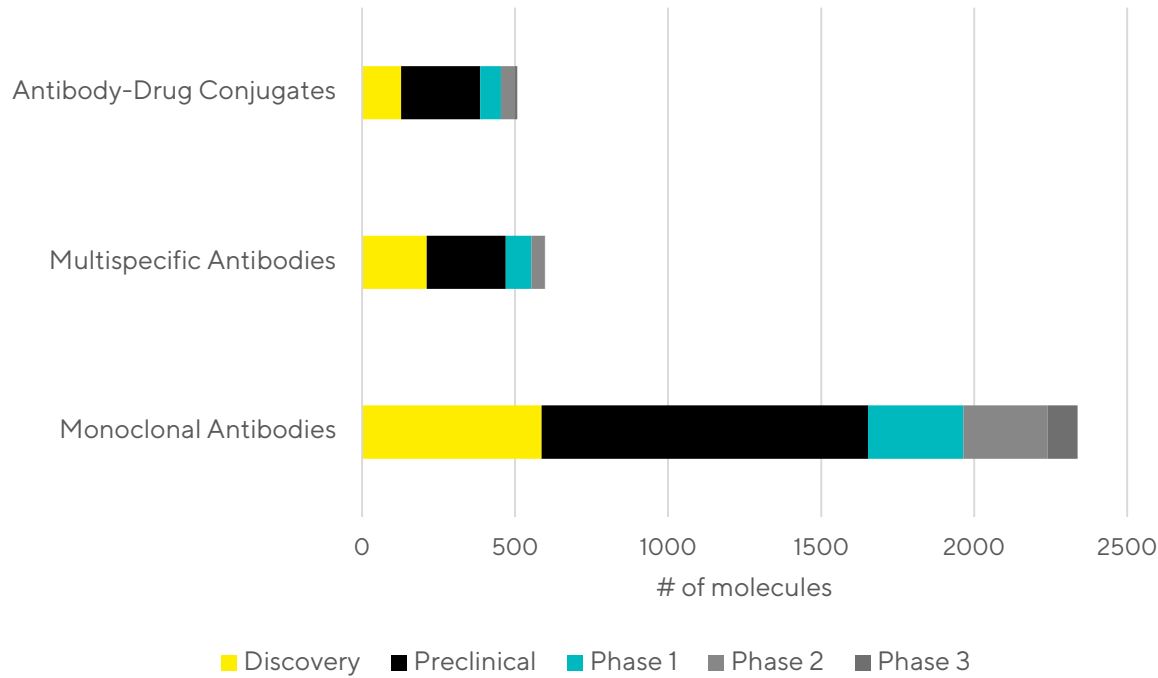
Contract Manufacturing Market Growth

Overall Biopharmaceutical CDMO Market, 2019-2025 (in USD)¹



- CDMOs hold 20% of manufacturing capacity (~5Mil liters), projected to reach 30% by 2025
- 30% are actively expanding capacity
- Highly fragmented market by size (small 30%, mid-sized 45%, large 15% and very large 10%)
- Over 40% operate at all scales /drug lifecycle stages

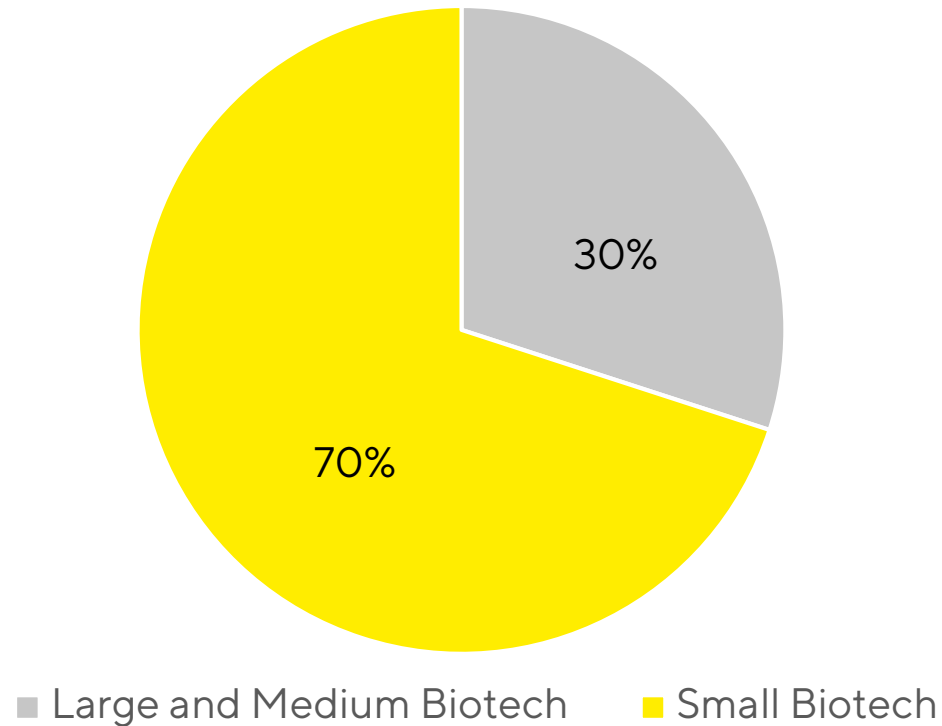
Growing Molecule Pipeline and Future Throughput Needs



Demand for new niche biologic modalities requires rapid capacity expansion and new expertise from contract manufacturers

New protein biologics will require less drug per year, allowing CDMOs to compete for a larger market share

~70% of the Innovator Mab pipeline is held by Small Biotech



- Smaller players entering market have limited manufacturing capacity and are much more likely to outsource.
- Companies can avoid \$50-\$100+ million or more costs for facility construction.

CDMO Selection Criteria



Speed



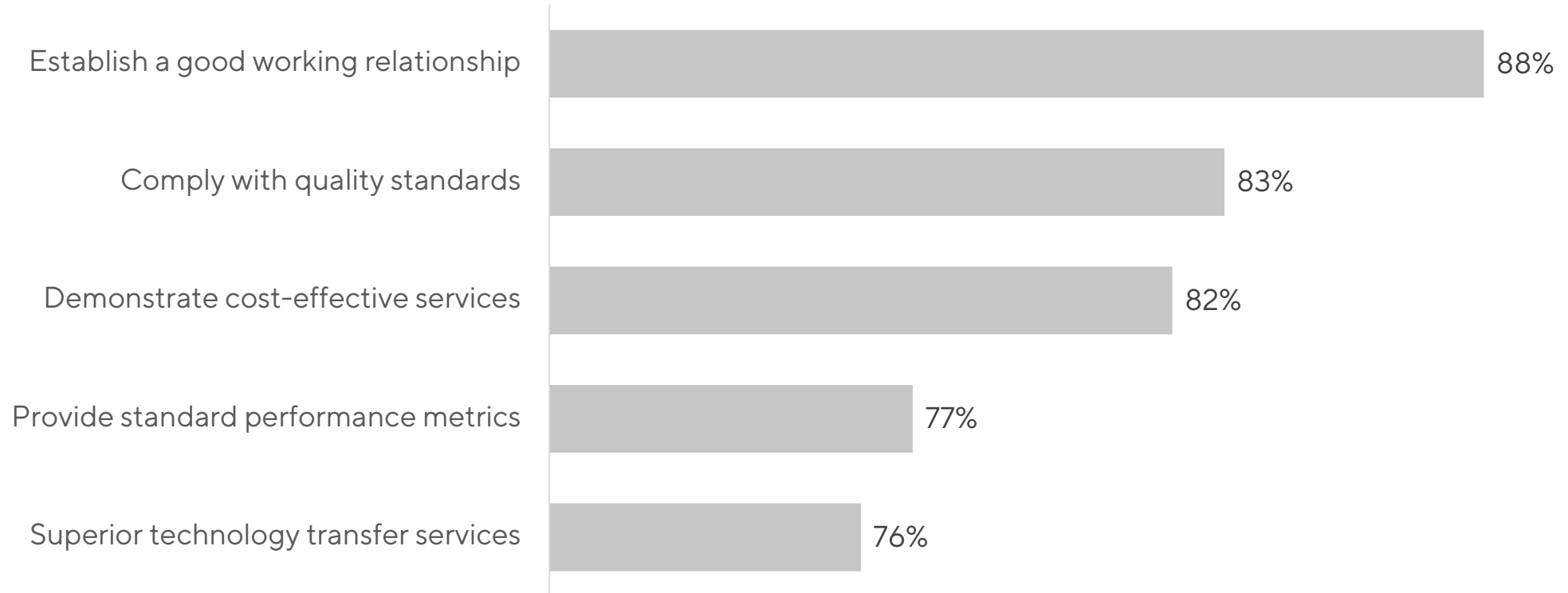
Quality



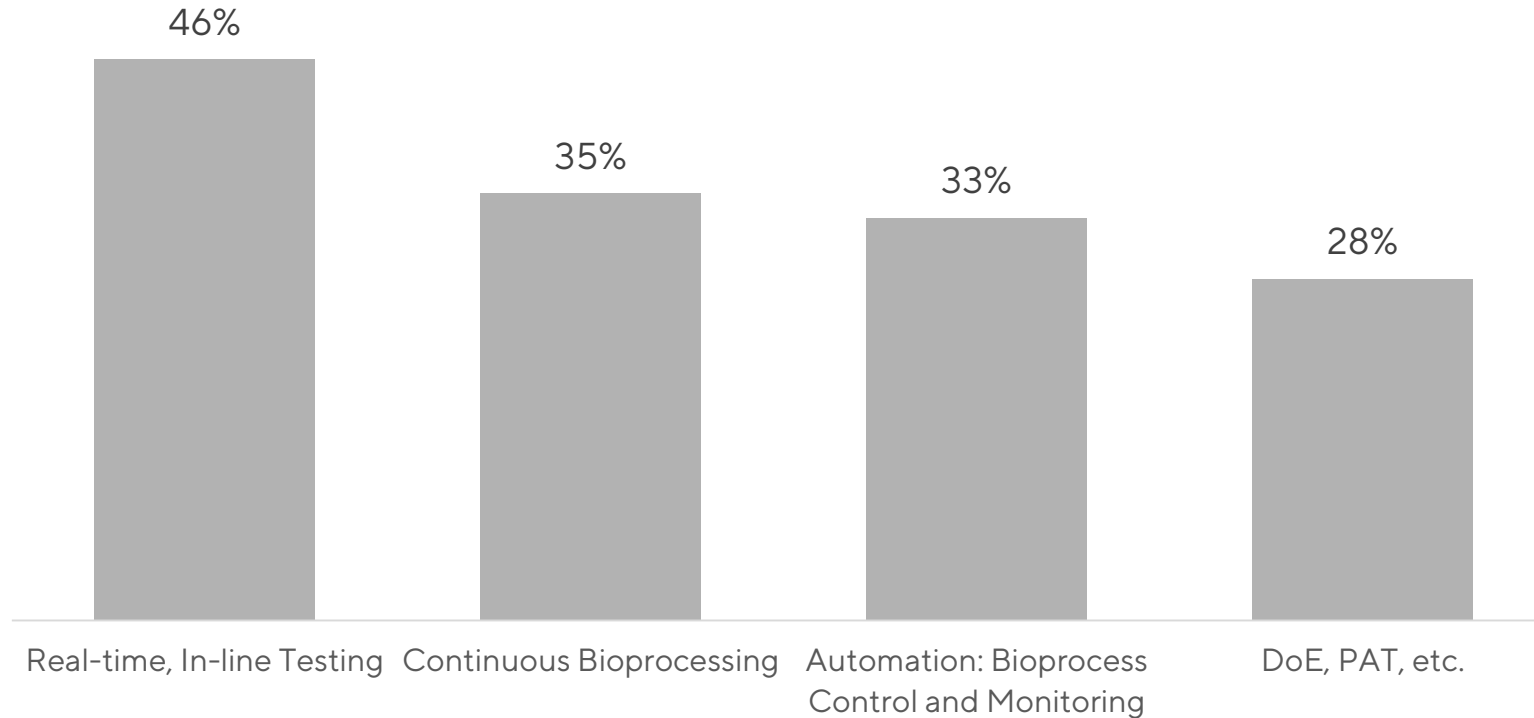
Cost

CDMO clients are driven by the need to get their product manufactured with the right quality as fast as possible

Critical outsourcing challenges ranked by level of importance

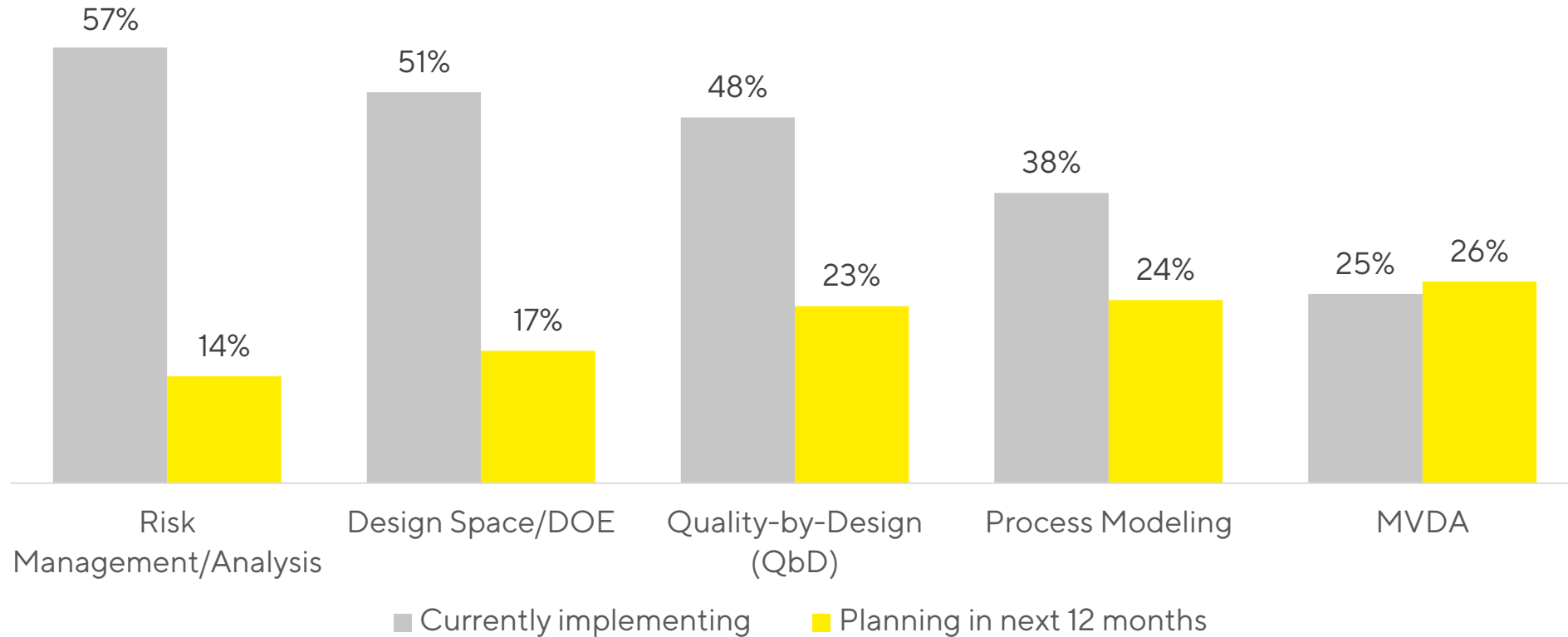


Top new product development areas needed at CDMOs



Process analytical technology (PAT) and other types of advanced process models for process control are pivotal to support the industry trend toward continuous manufacturing

Quality initiatives are already being implemented in the industry

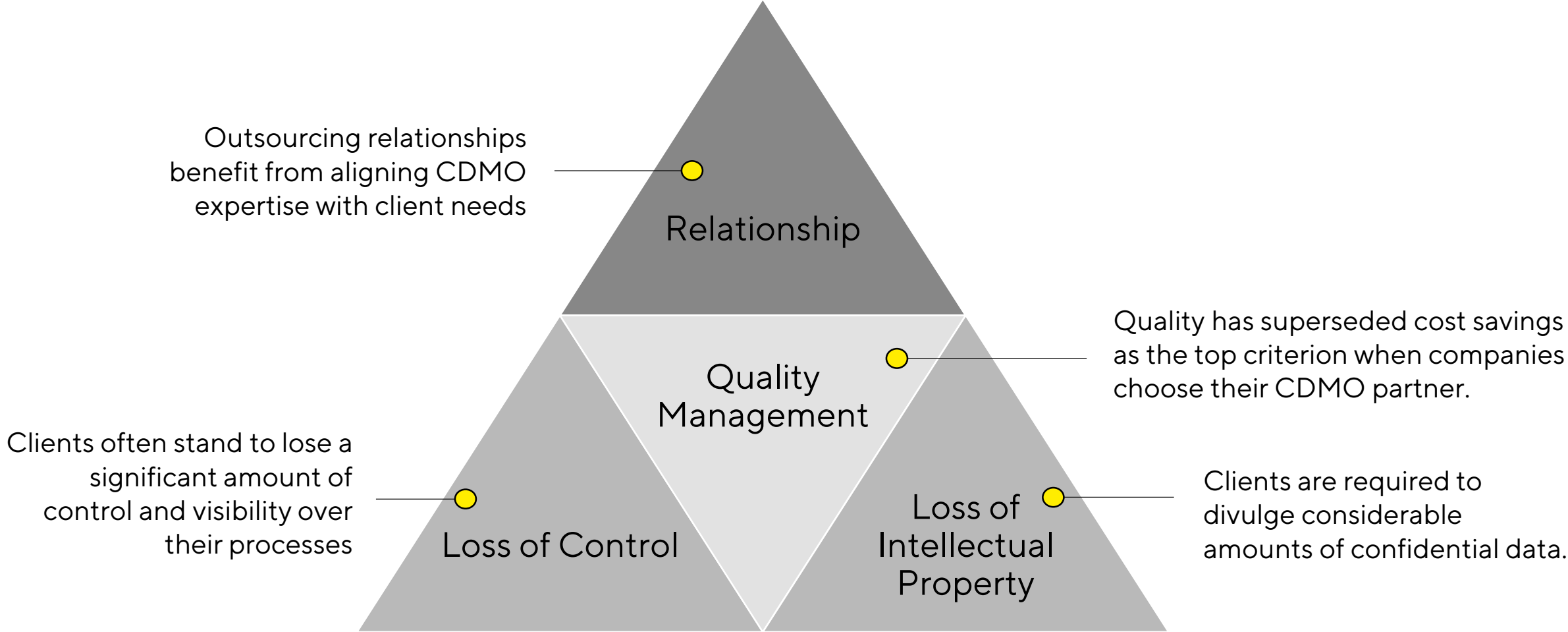


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Challenges Related to Outsourcing



Reacting to those Challenges with Data Driven Solutions

Loss of Control

Supply your partners with **real-time accessibility** to their processes

Loss of Intellectual Property

Allow for more **transparent data transfer** to and from your partner

Quality Management

Go the extra mile to ensure **process traceability** and **product quality**

Relationship

Tap into the **value of data** and use it as a **strategic differentiator** to **provide market leadership** and **long term partnerships**.

Put your Partners back in the Driving Seat



What your Partners Can See

The dashboard displays a production overview with the following key metrics:

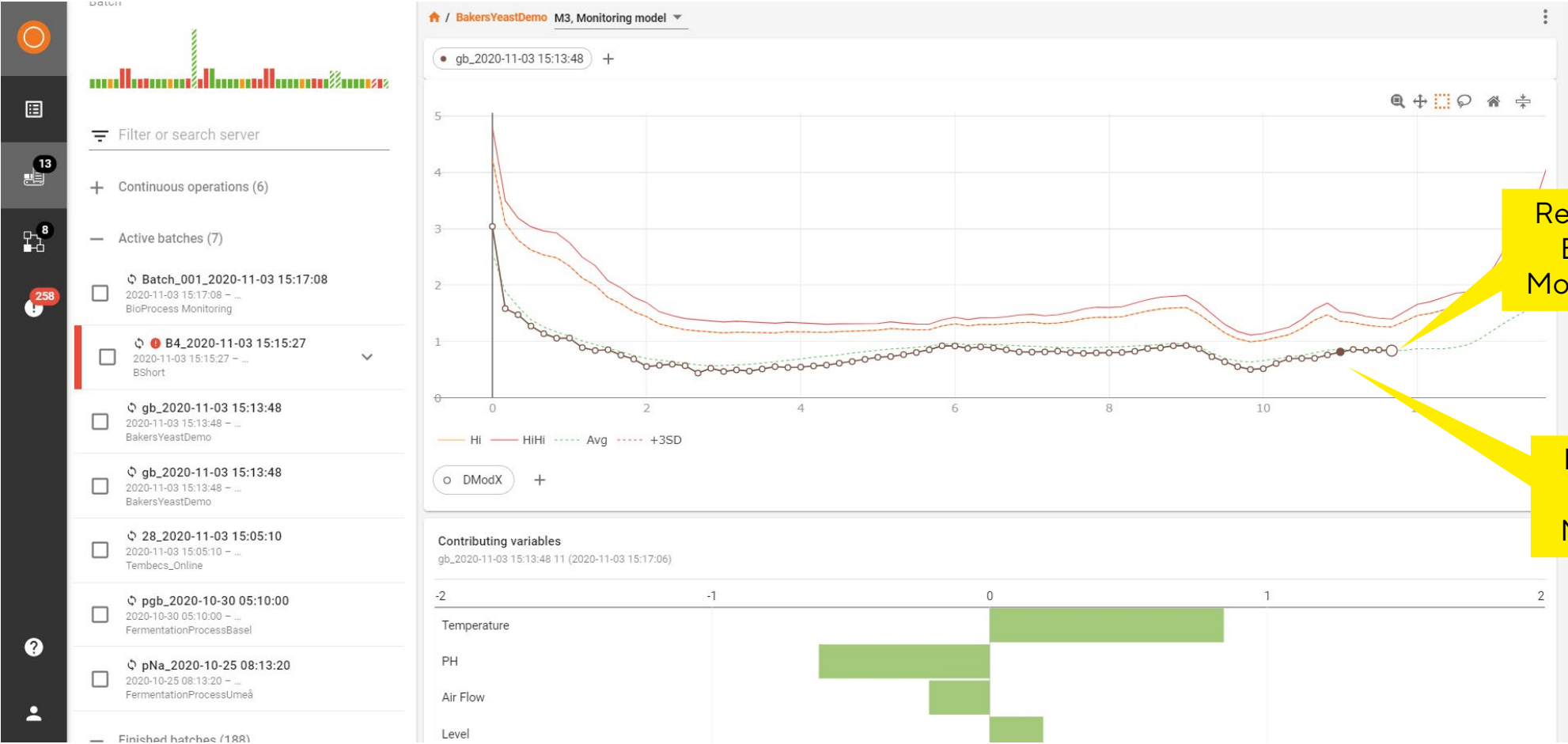
- Production:** 15 units. Status: In Control (12), Warning (1), Critical (2).
- Units:** 9 total, 5 offline. Status: In Control (7), Warning (1), Critical (1).
- Alarms:** 240 total, 0 reset. Status: Warning (141), Critical (99).

The interface includes a sidebar for batch management and a main area for production timelines and unit status. Callouts highlight specific features:

- Active Batches:** Points to the 'Active batches (9)' section in the sidebar.
- Completed Batches:** Points to the 'Continuous operations (6)' section in the sidebar.
- Individual Production Units:** Points to the unit status bar charts.
- Alarms:** Points to the alarm status bar charts.
- Batch Production Timelines:** Points to the production timeline bar chart.

Footer information: SARTORIUS, SIMCA®-online Solutions, Umetrics® Suite of Data Analytics Solutions, Copyright © Sartorius Stedim Data Analytics AB.

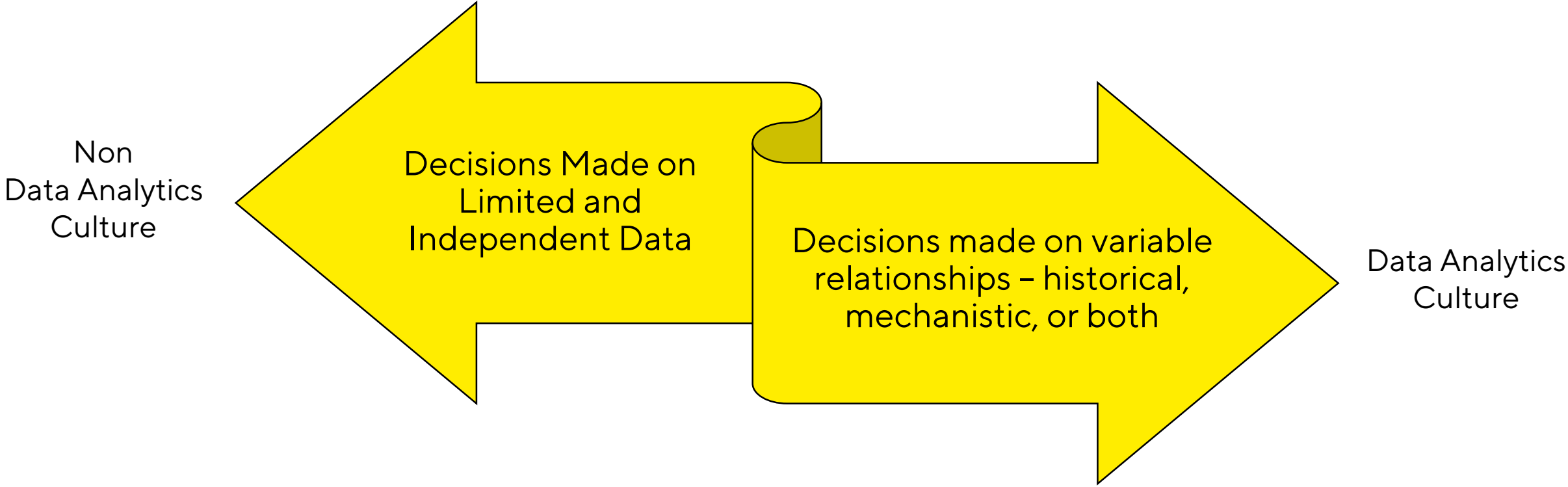
What your Partners Can See



Real-time Batch Monitoring

Real-time Risk Mitigation

A Changing Culture at CDMOs

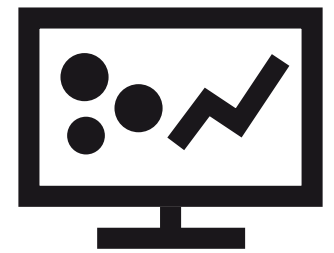
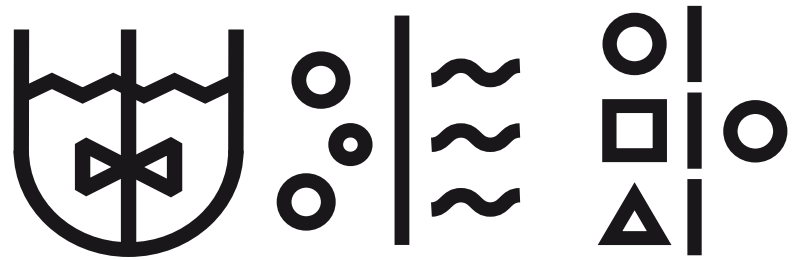




Data Analytics Driving Quality Assurance at CDMOs

Process

Data Analytics

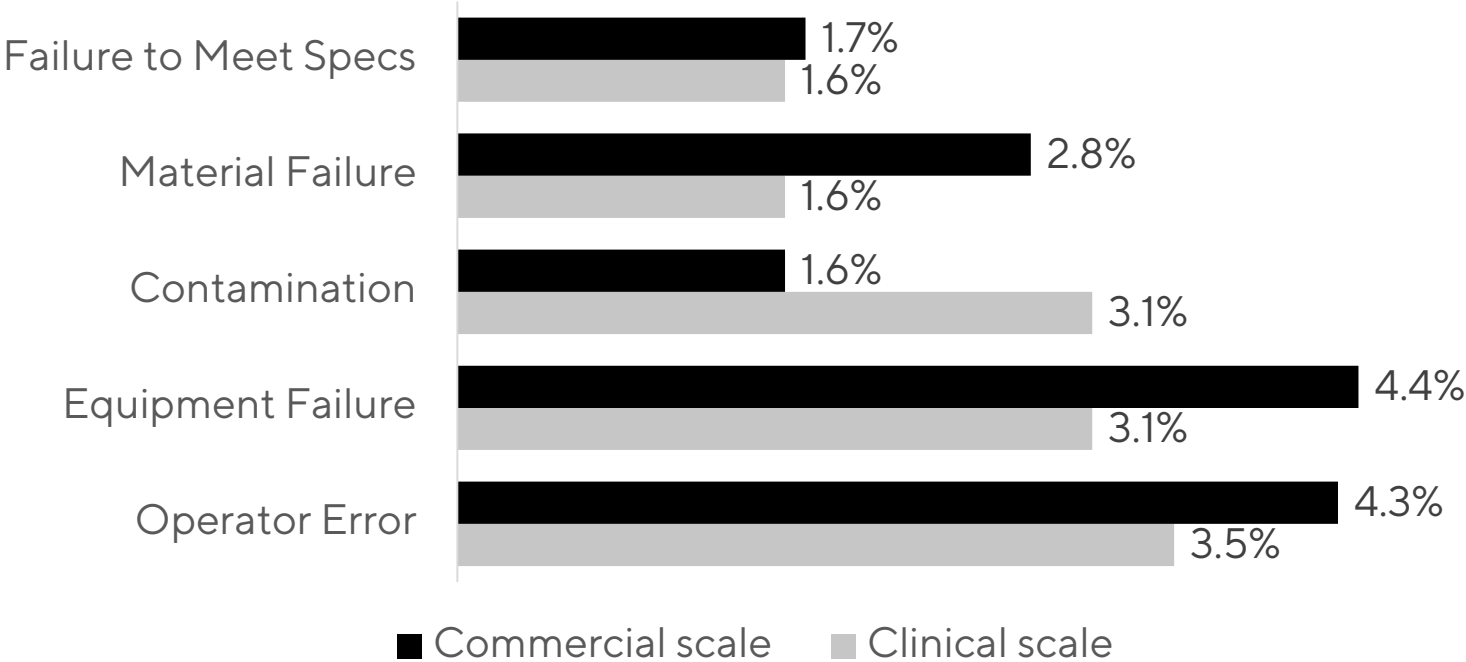


- Raw material properties
- In-process measurements
- Equipment parameters
- Analytical measurements

- Remote Monitoring
- Immediate Fault Detection
- Root Cause Analysis
- Automatic Corrective Recommendation
- Process Forecasting



Primary Causes of Batch Failures at CDMOs

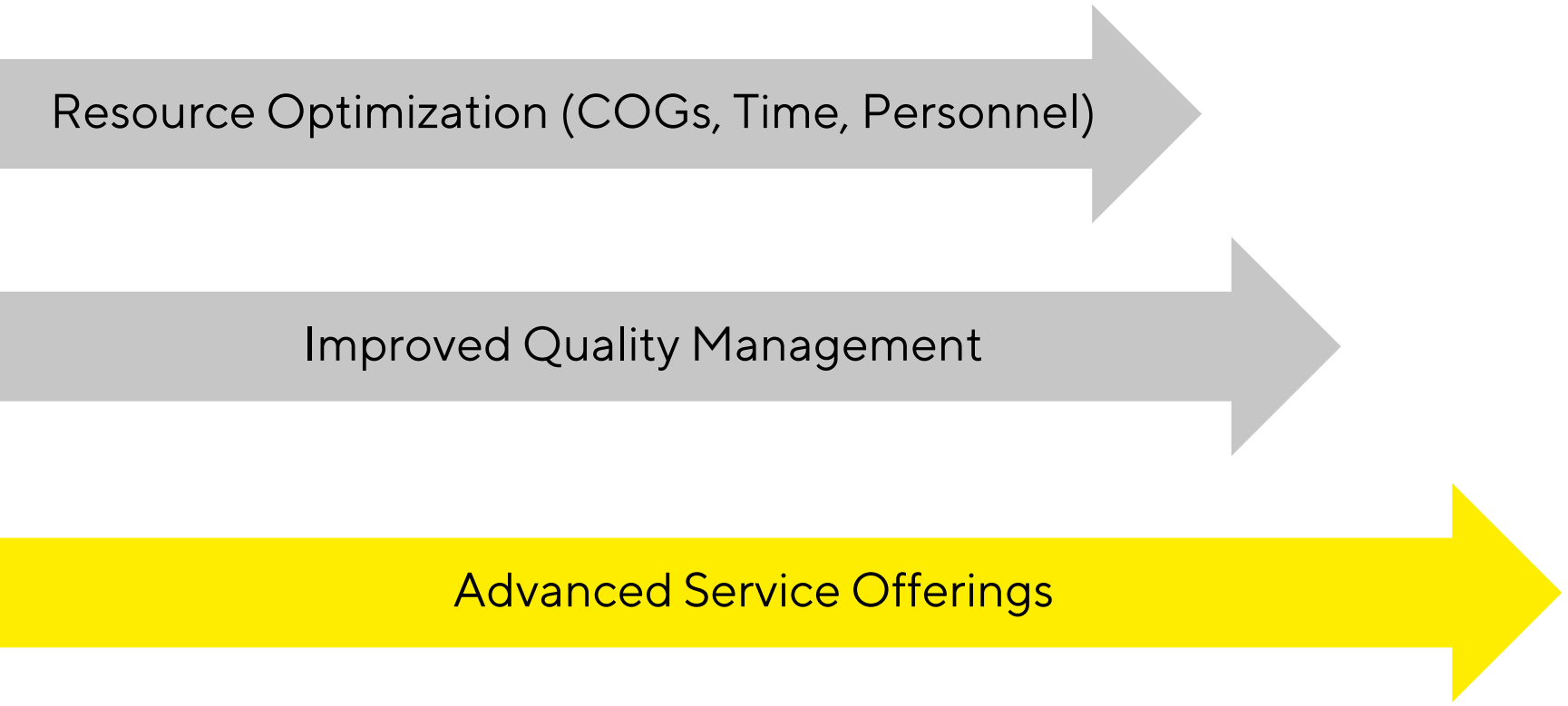


The average batch failure rate/year is 1.12

- Facilities can better manage their manufacturing and avoid failures by:
 - Using increased process monitoring and PAT.
 - Improving failure analysis.
 - Adopting better inspection of equipment and other supplies upon receipt.
 - Providing more and better operator training and expertise.
 - Practicing suitably sophisticated data security, putting defenses against hackers in place, etc.



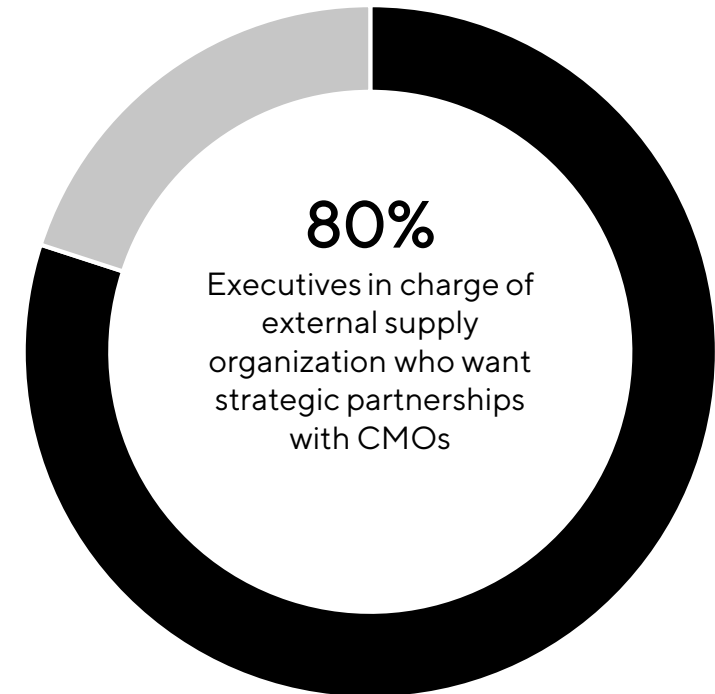
How can CDMOs Leverage Data Analytics to Boost their Bottom Line?



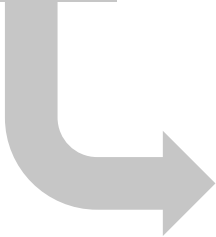
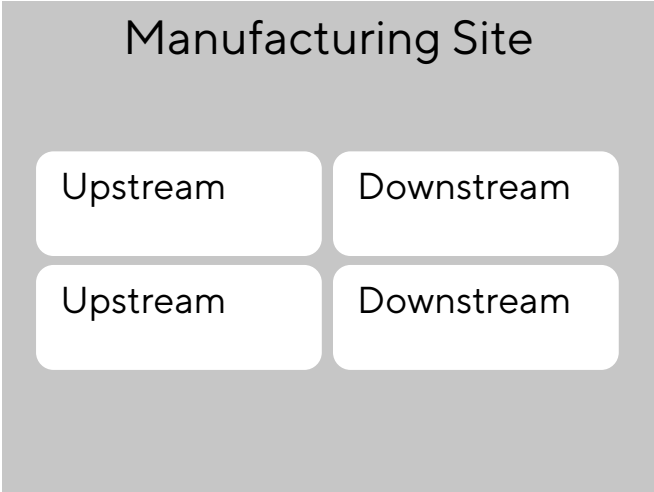


CDMO Pricing Trends

- In pricing services, most CDMOs generally price the production of large molecule API on a **per-batch basis**
- However, with the changing market dynamics more biopharma companies **seek out strategic partnership models**
- Examples of strategic partnership models include:
 - Reserved capacity: contractual guarantee of access to specific capacity for agreed-upon time
 - Join Venture: Co-investment with CDMO partner to expand an existing facility, payment varying from upfront costs or fixed annual suite fee
 - Global Enterprise: Co-investment in new assets with a CMO partner to gain access to its global network



How to calculate your ROI for a data analytics advanced service offering?



Fee per Batch Model EUR USD

Insert number of process lines monitored (i.e 1 USP + 1 DSP = 2)

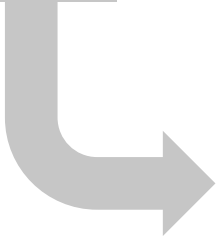
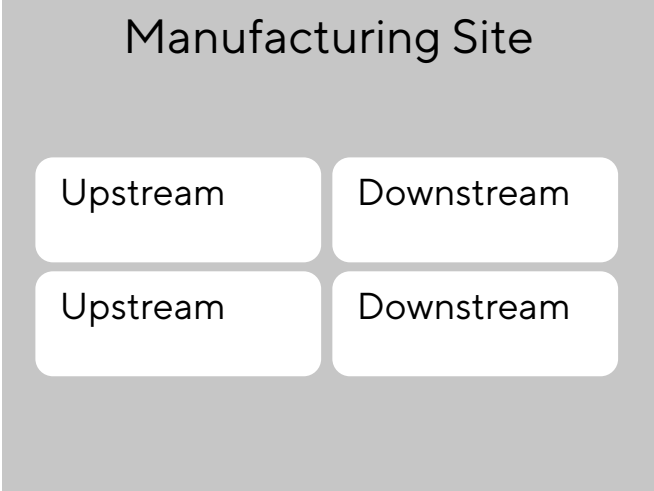
Insert number of batches you plan to run per/year

Insert estimated fee-for-service/per batch for data analytics offering

ROI: €350,000.00

Tip: If you're not sure how much you could charge your partners we can suggest a range between 5-20K/per batch

What about strategic partnership models?



Strategic Partnership Model EUR USD

Insert number of process lines monitored (i.e 1 USP + 1 DSP = 2)

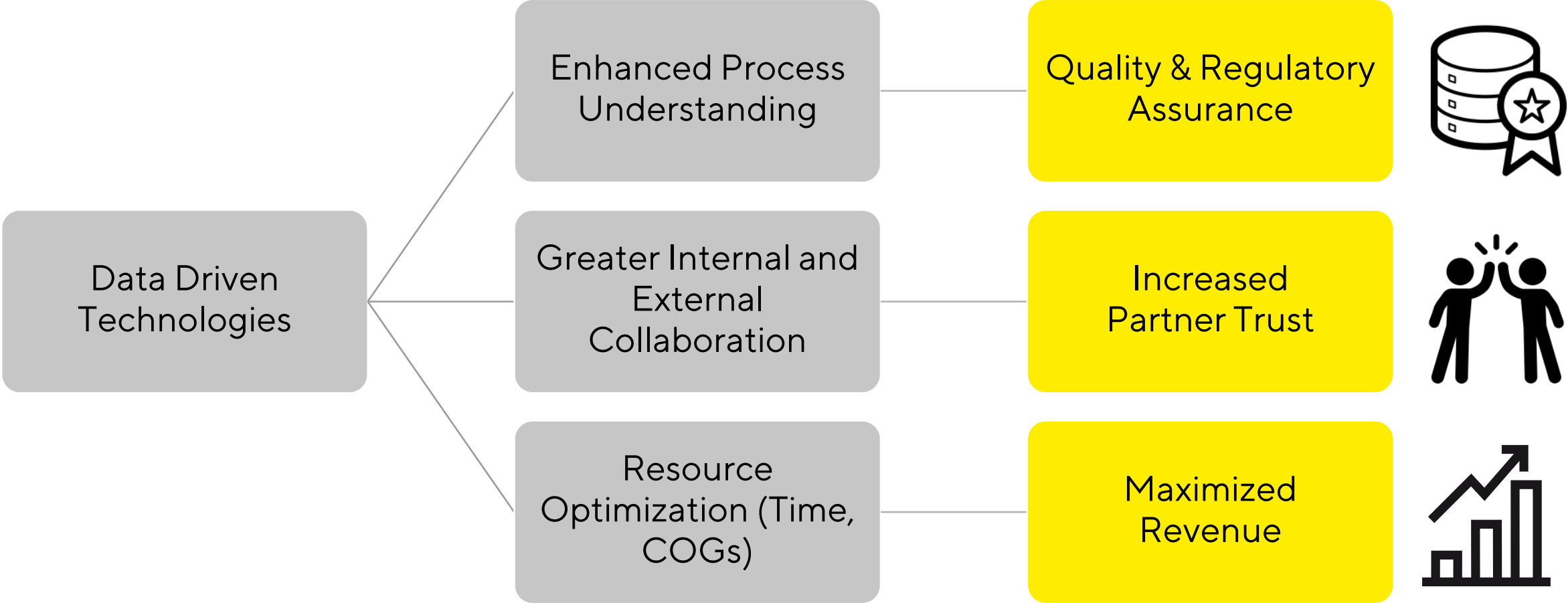
Insert number of partners you work with per/year

Insert estimated yearly fee-for-service/per partner for data-analytics offering

ROI: €560,000.00

Tip: If you're not sure how much you could charge your partners we can suggest a range between 100-200K/per year

Why adopt data driven technology at a CDMO?



Want to learn how you can implement Data Analytics at your CDMO?

Don't miss the upcoming webinar on Nov 24, 3pm -4pm CET/

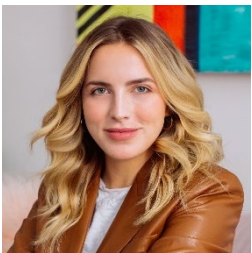
OSIsoft and Sartorius Partner to Help CDMOs Leverage their Data

Topics Include:

- Best practices for managing your data
- Synergies between Sartorius Data Analytics Tools and the OSIsoft PI system
- A FUJIFILM Diosynth Biotechnologies Success Story



SARTORIUS



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Thank you!

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The Sartorius logo is displayed in a bold, black, sans-serif font on a bright yellow rectangular background. The letters are closely spaced and have a clean, modern appearance.

Interested in Booking a 30-minute strategy session?



How to leverage your data to secure long-time strategic partnerships?



How data can be used to maximize profitability?



How your data can be used to speed up timelines and accelerate delivery

[Click here!](#)