DCAT® GLOBAL SUMMIT

BUILDING A RESILIENT PHARMA SUPPLY CHAIN: STRATEGY, RISK & INNOVATION FOR THE FUTURE

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Building a Resilient Pharma Supply Chain: A CDMO perspective

Building a Resilient Pharma Supply Chain:

How strategic CDMO partnerships help organizations stay agile and protect supply continuity in a rapidly shifting global landscape

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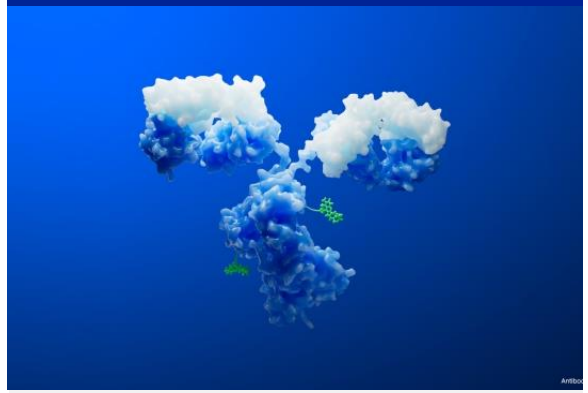
What is Driving Supply Chain Risk Today

A convergence of global and industry specific trends

Three drivers of pharma supply chain risk

Rising Complexity

Molecule and industry complexity increases



- Rising molecular and process complexity
- ADCs need multiple supply chains & processes linked

Global Uncertainty

More demands for on- and near-shoring supply

- Geopolitical fragmentation and regulatory divergence
- Talent and infrastructure constrains

Tightening Capacity

Bioreactor availability tightening across biologics

- Share of reactor utilization increase over time
- CDMO and hybrid companies to hold over 50% by 2028

Supply chain resilience is now a strategic imperative

Building Resilience Through Strategic Outsourcing

From vendor to strategic partner

Grow with strategic partners, not just manufacturers

Alignment

- Planning your supply across scales and regions for unforeseen demand changes
- Co-investments in capacity or capacity models providing molecule flexibility

Network strategy

- Simplification through integrated and end-to-end Services
- Dual sourcing capabilities, safeguarding supply

Operational agility

- Rapid development and tech transfer timelines
- Scalable technology and shared QMS
- Global expertise and regulatory support

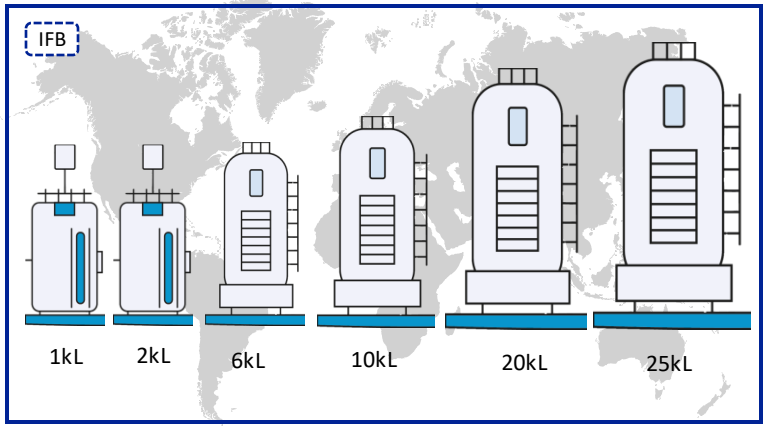
Innovation

- Process intensification to lower COGs
- Increased visibility with real-time data
- Predictive modeling, AI to improve speed & first-time-right

Network Strategy: Simplification through E2E Services

Aligned manufacturing strategy across scales and region

The Right Scale at the Right Time



Qualified scale down models allowing for comparable scale up to any scale

Simplification through drug substance and drug product integration

We coordinate **batch scheduling** and **shipping across sites** for a peace of mind experience

DS Site

Eng Batch | PPQ Batches | PAI Batch | Comm Batches

Tech transfer to scale → Process Characterization → PPQ and Filing → Commercial Production

DP Stein

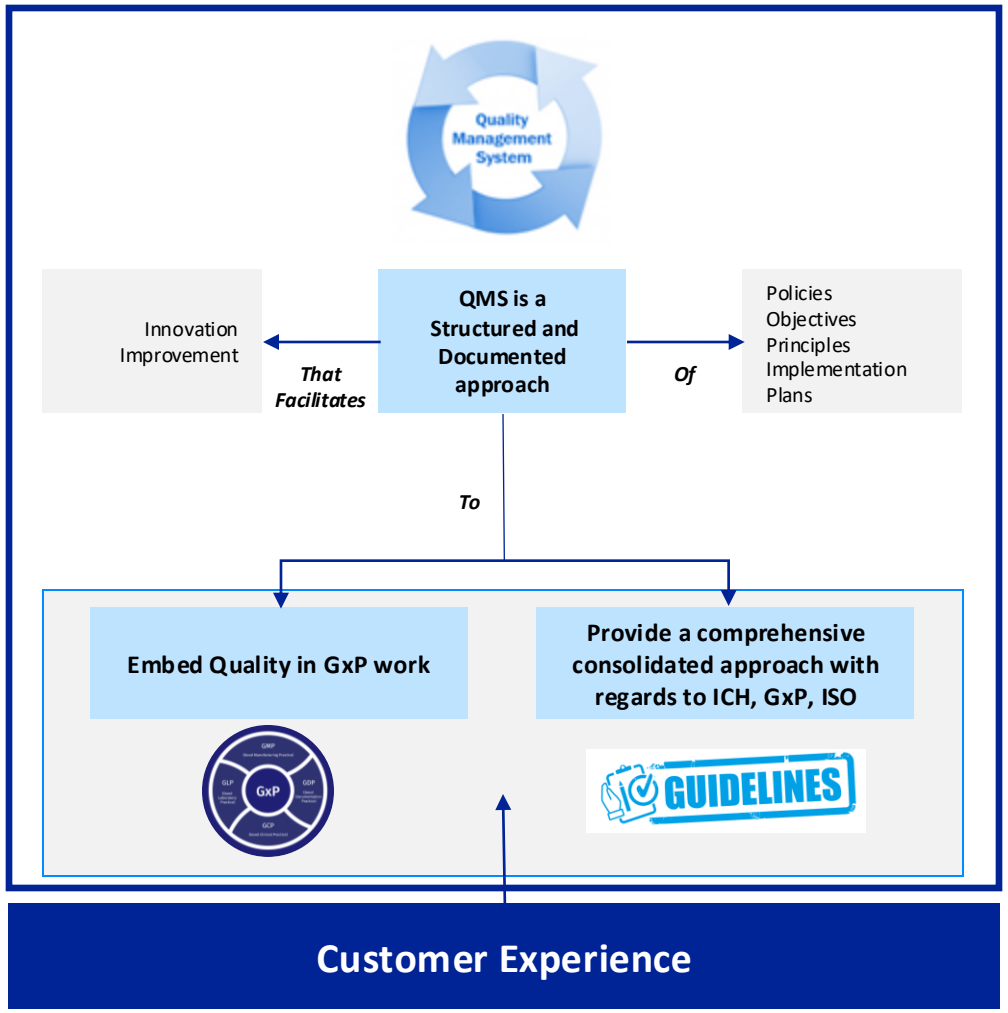
Tech transfer Stein Site → Process Characterization → PPQ and Filing → Commercial Production

Eng Batch | PPQ Batches | PAI Batch | Comm Batches

1. Process characterization for BLA programs, for sBLA assume 6 months Eng run OOF to PPQ 1 OOF. Matching DP Timeline.
2. DS PPQ batches 3+1 approach, DP 3 PPQ batches
3. PAI timing subject to Customer filing date.

Operational Agility: Shared Quality Management System Across Sites

Streamlined quality processes to reduce complexity & improve transfer agility



REQUIREMENTS are defined in:

QMS DOCUMENTATION

- Quality Manual
- CORP-GROUP
- SOPs
- Records

CONTROLS are ensured by:

QMS CONTROLS

- **Quality Risk Management**
- **Auditing and Self – Inspection**
- **Information Management Control (KQIs, Trending…)**

PROCESSES are owned by:

QMS PROCESSES

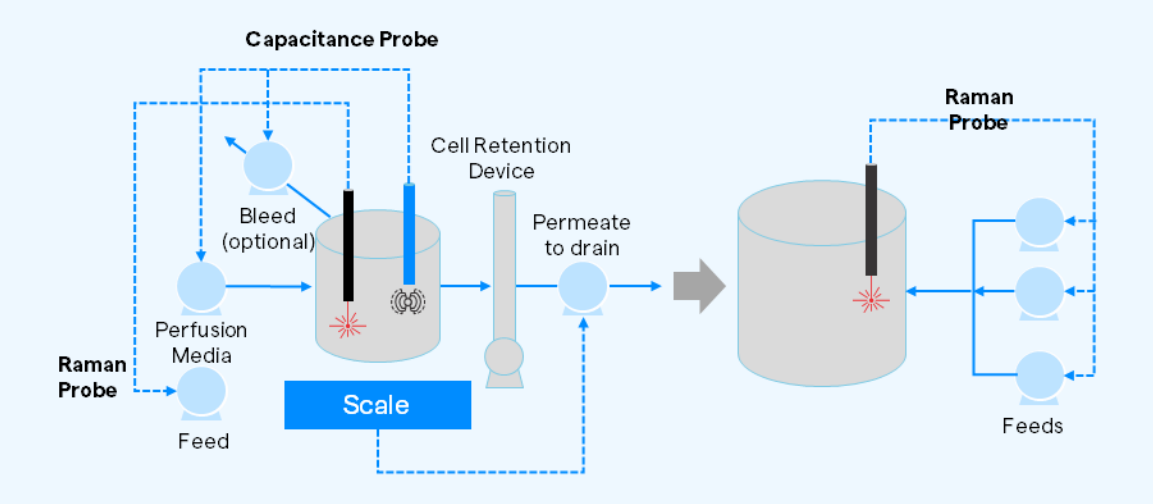
QUALITY SYSTEM OWNERS

Ensure "**Design" + "Maintenance"** of a ***FIT FOR PURPOSE QMS Process that is: Efficient, Agile and Flexible to Support the Business***

- **Training:** Design and management of Training material
- **Document & Record Management**
- **Exception Handling:** Deviations, Complaints, Inv. certifications
- **Change Controls**
- **3rd Party Operations**

Innovation: Process Intensification, A Smart Way to Reducing COGs

Increased cell concentration and titre uplift of 70% on average



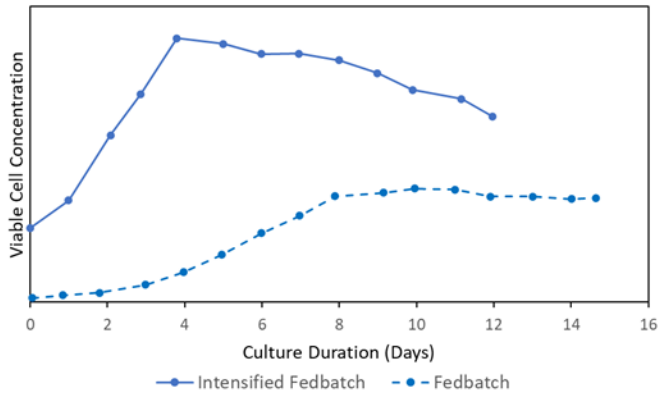
N-1
Perfusion Bioreactor

Purpose: expand cells to VCC of > 50 x 10^6 cells/mL

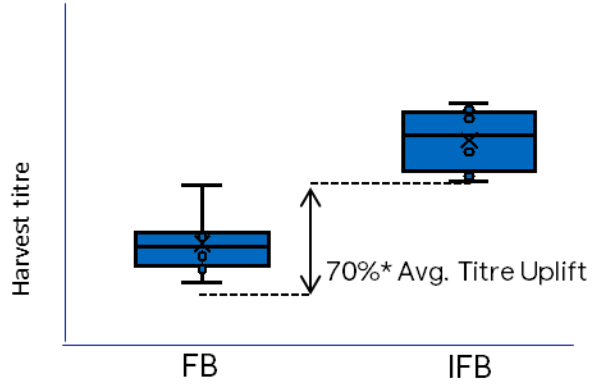
N
IFB Bioreactor

Purpose: increase in productivity compared to FB

Increased Viable Cell Concentration while maintaining cell-specific productivity



Average titre uplift of 70%.



VCC = Viable Cell Concentration

FB = Fed-batch
IFB = Intensified Fed-batch

*Lonza mAb producing cell lines.
Data represent 16 clones expressing different IgG products

Digital Innovations and Artificial Intelligence

Some use cases in the CDMO industry & potential impact for customers

Promising use case pipeline for ML / AI*

Automation of repetitive digital tasks and laying data foundation
- Configuring Master Data in SAP & MES
- Software objects development
- Extraction of instrument data to automation specifications
- Consumption report verification

Machine Learning (ML) Models to learn from process data to make predictions (CQA) or process decisions
- Predictive/Usage Based Maintenance
- Raman for Cell Culture Monitoring and CQA Predictions

Natural Language Processing (NLP)
- migrate like-for-like code from one vendor software to another vendor software

Retrieval-Augmented Generation (RAG) combines document retrieval with AI generated responses
- Accelerating facility fit assessment

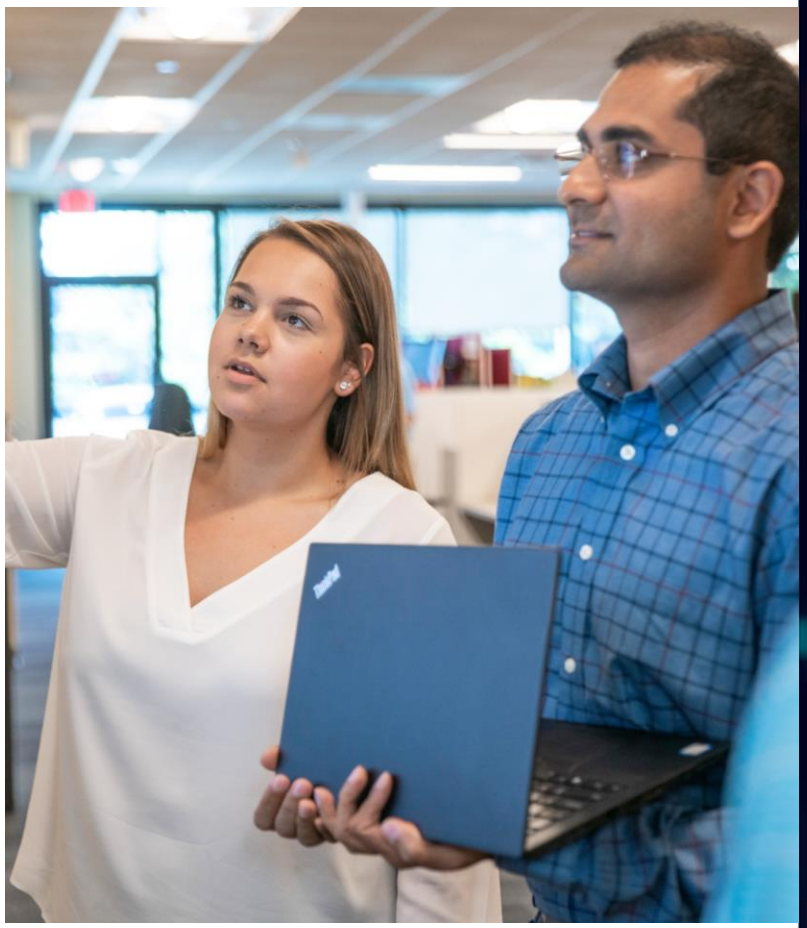
Digital Twins / Dynamic Simulations leveraging virtual replica of physical systems
- Supporting “first-time-right” deployment

Potential impact

Efficiency gains
(e.g. productivity and process improvements)

Timeline improvements (e.g. batch review and release)

Risk mitigation
(e.g. monitoring and proactive intervention)



*Disclaimer: This information represents exploratory and/or current use cases for illustrative purposes only and should not be interpreted as a guarantee, specification, commercial service or related offering

Strategic Focal Points for Commercial Launches

Then Vs Now.....

Meeting Global Demand

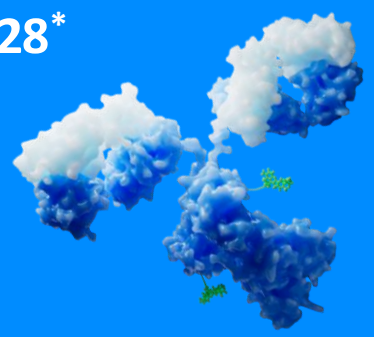
Increase complex / potent needs

by 30%*

*Bi-specific antibody development surged between 2014 and 2024, with significant increases in both FDA and CAGR approvals

ADC growth

40 ADCs by 2028*



*up from 17 in 2024. Based on Lonza's internal prediction modeling

What launch considerations Customers used to focus on...

- Design of Experiments
- Acceptable/ Proven ranges
- Quality
- Scientific advisory
- Access to patients

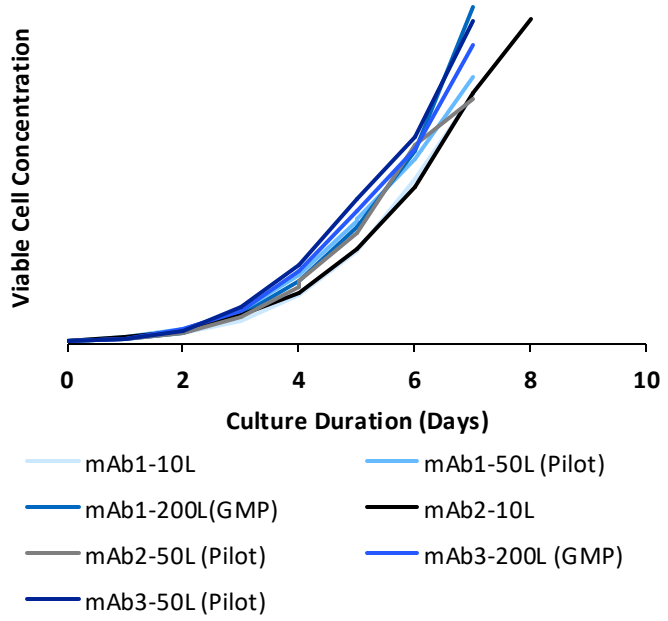
What launch considerations are increasingly in focus today...

- **Regional & dual sourcing**
  Across drug substance / drug product
- **Shipment agreements** supply logistics
- **Inventory Record Accuracy**
  Material handling, traceability, ownership
- **Most Favored Nation**
  Commercial strategy & long-term pricing flexibility
- **Supply agreements**
  Long-term manufacturing partnership
- **Invoices**
  Cash flow and financial operations
- **VAT**
  cross border transactions
- **Purchase orders**
  Procurement, execution and budget control

Intensified fed-batch at commercial scale

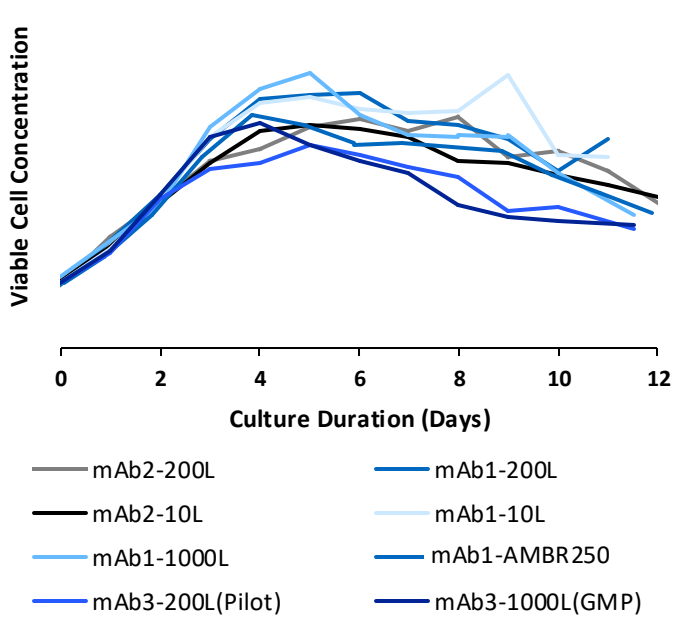
IFB is robust and scalable (development, pilot and GMP scales)

Consistent Cell Growth in Perfused N-1 Stage



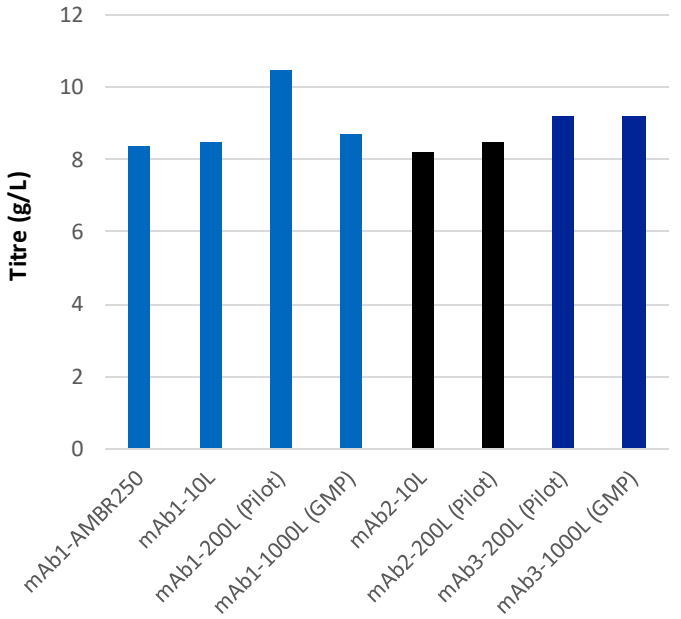
Consistent performance in perfused N-1 process stage

High Cell Growth in IFB Production Stage



High cell growth in all scales tested

Titre in IFB



Consistently high titre in all scales tested

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