



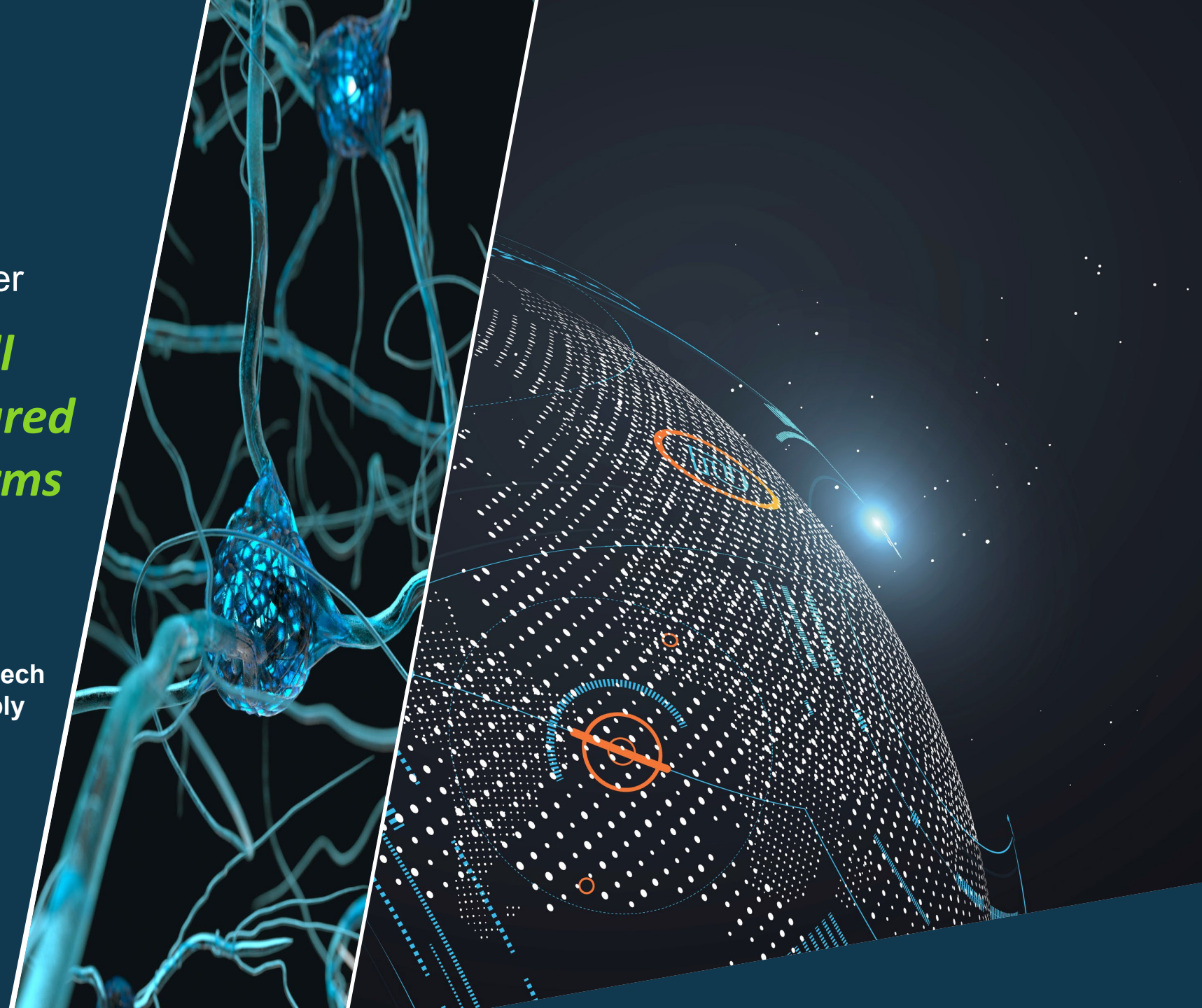
Transforming Biotech @ Bayer

Industrialization of Cell Therapies through Shared Manufacturing Platforms to bring Health for All



Jens H. Vogel, PhD
SVP & Global Head, Bayer Biotech
Pharmaceuticals Product Supply

November 2023





Bayer's Global Biotech Network Covers the Entire BT Continuum

End-to-End Large Molecule Development & Supply, as well as CGT Industrialization

Research + Early Dev

IND Enabling CMC
Development &
Early Phase Clinic Supply

BLA Enabling CMC
Development &
Pivotal Clinical Supply

Launch & Market Supply

Biotech Continuum

PS-Biotech Covers Diverse Portfolio

We Deliver Through a
Diverse Global Footprint



Cell
Therapies



Gene
Therapies

Industrialization of
Revolutionary New
Therapeutics



mAbs



Conjugates

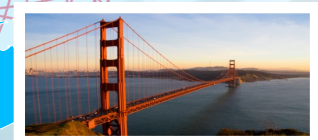
Highly Efficient & Rapid
CMC Development



Supporting Sales Growth
through Operational Excellence



Basel, CH
Berkeley, US
Berlin, DE
Leverkusen, DE
Wuppertal, DE
Shiga, JP



Berkeley Fully Integrated
Biotech HQ Site



Making it Real Requires Close Partnership Between Innovation & Industrialization Engines

PS BT Continuum to Provide Shared CMC Service for CGT Industrialization

Research + Early Dev

Development & Early Phase Clinic Supply

Pivotal Clinical Supply & Launch

Market Supply

Bayer Platform Companies & Partners
Early Phase, **Research Driven** Companies & Assets

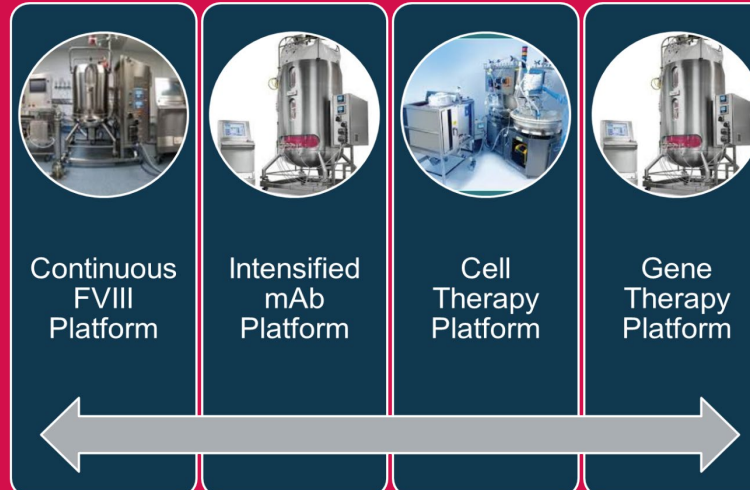
IND Enabling CMC Dev



Arm's Length
Innovation Engines

BLA Enabling CMC Development & Mfg for **Smooth Commercialization**
Leverage PS BT Strengths, Synergies & Flexible Modular Platforms

PS Biotech Industrialization Engine

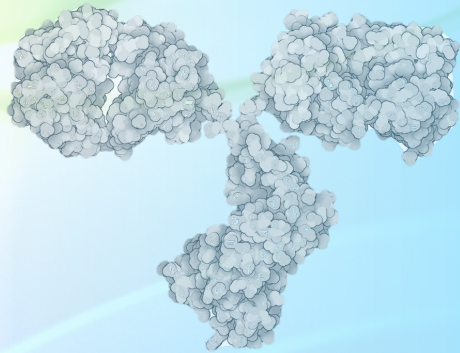


Berkeley Late Stage / Launch



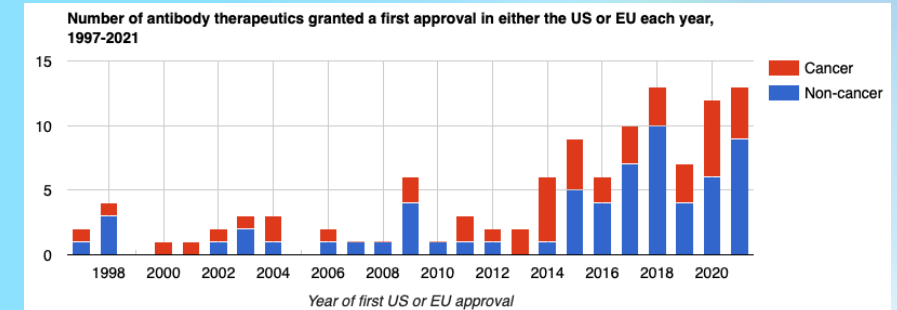
How Do You Industrialize Complex Biopharmaceutical Products?

Some Lessons Learned from Industrialization of Large Molecules



Industry Convergence on “Consensus Manufacturing Platform”

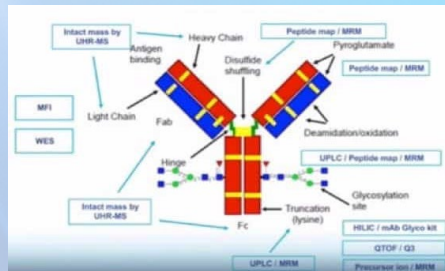
- **Fed-batch bioreactors (2,000-20,000L)** followed by Protein A based purification scheme
- **CHO** as standard workhorse; Culture Media & Feed-strategy



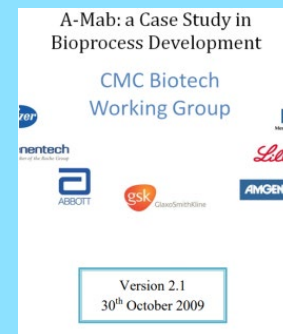
<https://www.antibodysociety.org/resources/approved-antibodies/>

Quality-by-design based CMC approach

- **Fundamental Product understanding**
 - What are the CQAs determining Safety & Efficacy?
- **In-depth Process understanding**
 - What are the CPPs?
 - What are the KPPs?
- **Control strategy**



Analytical Tool-Box



Biotech Clusters

- Critical mass of talent & expertise crucial in early phase of technology development
- Maturing of technology platforms enables “commoditizing”



Bayer Biotech's CT Platform Vision to Enable Industrialization of Cell Therapies

A Comprehensive Global CT Industrialization Program Containing 5 Elements

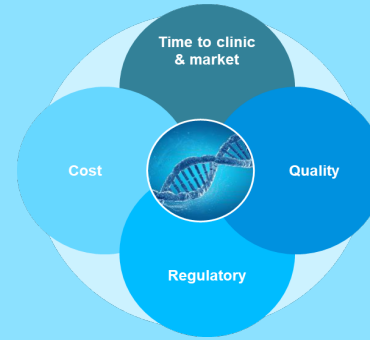
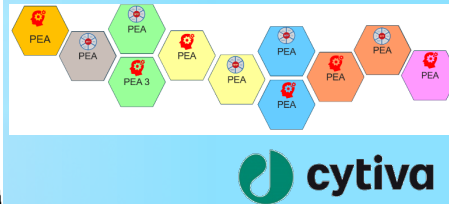
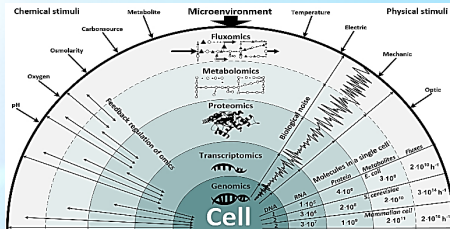
**"Software" =
CT Process Platform**

**"Hardware" = CT
EQT Platform**

**"Operating System"
= CMC Ecosystem**

People & Culture

Flexible Facilities



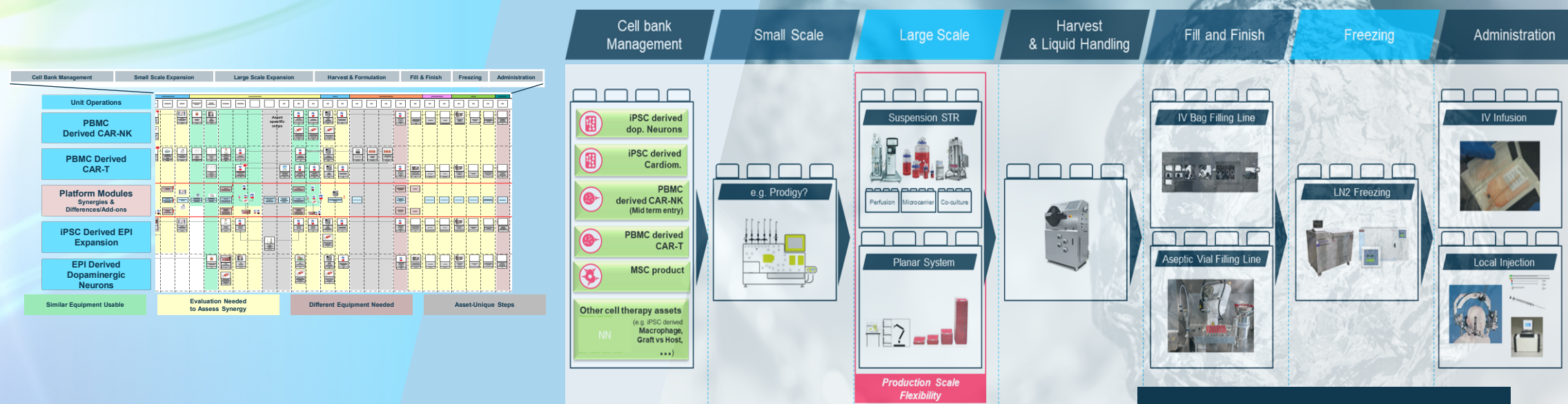
Target

- Fundamental** understanding of cells as products and their biology
- In-depth **process understanding**
- Culture media platform
- Small-scale **models**
- Scale-up** strategies
- Well- characterized, automated, robust EQT **modules tailored** to process needs
- Engineering and automation **specifications**
- Plug and play systems
- Development Plan & CMC Strategy** for CT products
- QbD based workflows** supported by **efficient, data-driven** decision making
- Control strategy**
- Phase-appropriate **filing templates**
- Building diverse high-performance **team, strong CT competencies** and **capabilities**
- Collaborative, "No Silo"** culture
- Driven by one common goal**
- Strong internal and **external partner network**
- Flexible facilities to enable efficient late-stage development & launch
- Modular, flexible & rapid deployment** of "capacity on demand"



Our Vision: A Modular, Flexible Hardware Platform Covering Diverse Allogeneic Cell Therapies

How to Build an End-to-End “Consensus Platform” Able to Industrialize Diverse Assets



Modular & Flexible



Highly Integrated
& Automated



End-to-End Single
Use Flow Path



Intensified
Small Footprint



Process Analytical
Technology



Reliability Engineering
& Industrial Design

Strong partnership with
Cytiva





We can only do it together!

Expanding partnerships with academic and industrial leaders for industrialization platforms



Thank You!

