Just – Evotec Biologics

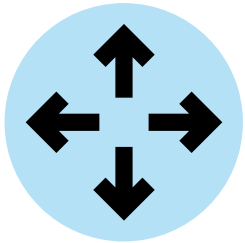
Considerations for the Design and Construction of Next Generation Biologics Manufacturing Facilities

Superior biologics with next generation technologies

Just – Evotec Biologics is providing solutions to fundamental industry challenges

Highest Quality

Higher Speed



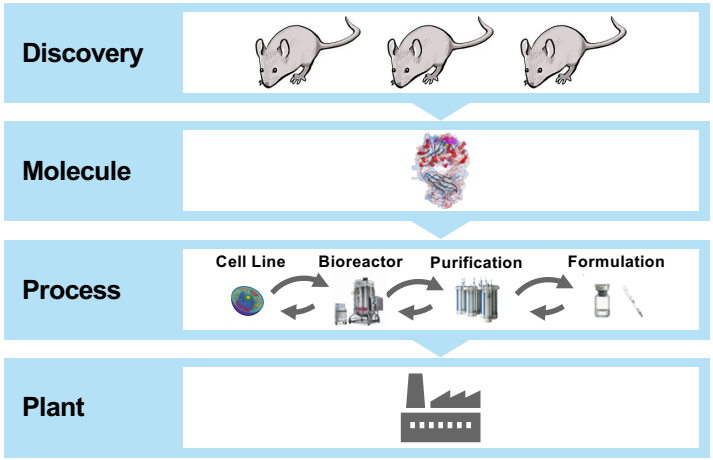
Flexible Capacity

Cost Efficiency

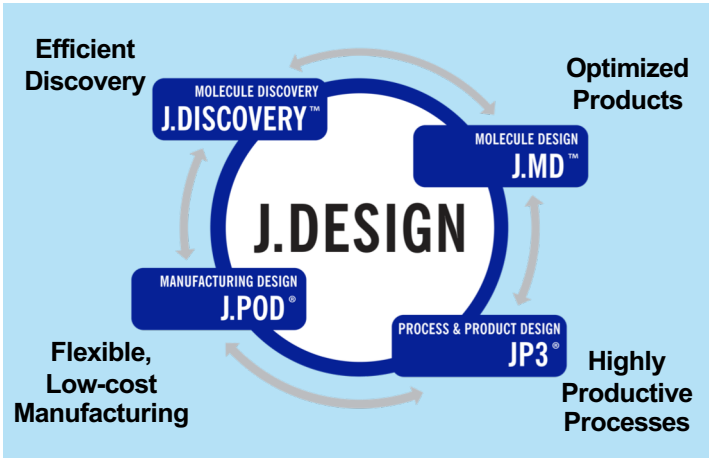
Just–Evotec Biologic's approach to integrated design breaks down functional silos to save time and cost

Traditional "Silo" vs. Integrated Design approach

Traditional "Silo" Approach



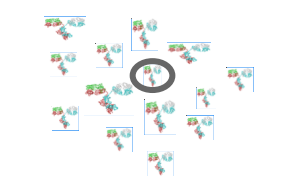
Integrated Design Approach



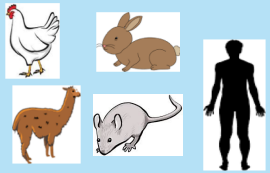
Lead antibody candidates can come from *in vivo* sources or from *in vitro* display libraries

Multiple points of entry for clients and partners

Large Full length “Humanoid” antibody display libraries for screening



J.DISCOVERY™



Internal or External Lead Antibodies

Abacus is a suite of ML tools that optimize molecular design of existing lead antibodies

To improve developability and manufacturability for intensified processing

Large Full length “Humanoid” antibody display libraries for screening

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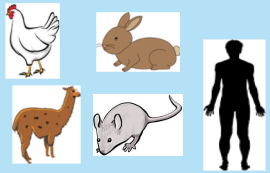
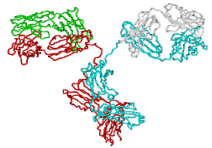


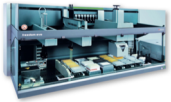
Internal or External Lead Antibodies

Abacus, a collection of *in silico tools,* is used to improve manufacturability and developability



J.MD™

ML and high throughput methods are used to quickly design highly productive processes



…that can be run in relatively small unit operations

JP3®

AI generated Humanoid libraries build quality into the molecule from the point of discovery

Pre-optimized for developability and manufacturability for intensified processing

Large Full length “Humanoid” antibody display libraries for screening

J.DISCOVERY™

Fast from Discovery to Development- No need for Abacus optimization

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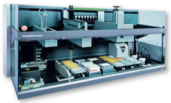

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JP3®

Abacus, a collection of *in silico tools,* is used to improve manufacturability and developability

J.MD™

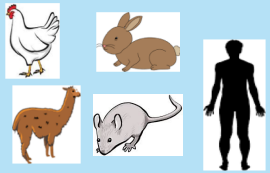
Internal or External Lead Antibodies

Optimized molecules designed to be therapeutics can be manufactured more efficiently and robustly

Quality begins with the molecule

Large Full length “Humanoid” antibody display libraries for screening

J.DISCOVERY™



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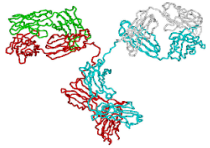

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Fast from Discovery to Development- No need for Abacus Optimization

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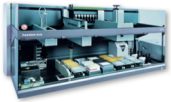

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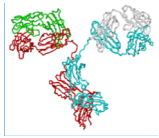
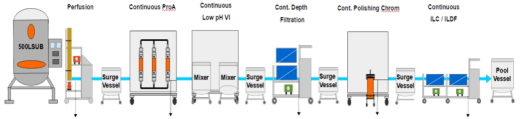


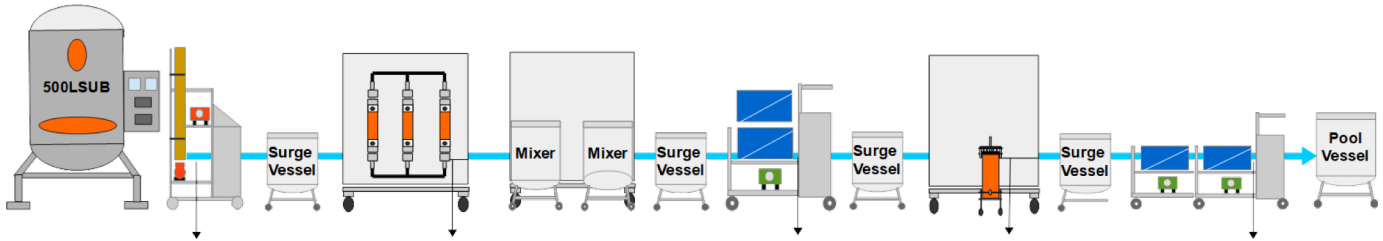
High Quality Molecules

High Quality Processes



Continuous processing requires intense focus on a few critical areas for success

Focusing on the fundamentals



Critical areas of focus

- **Aseptic Envelope** - across the entire drug substance process
- **Process Control** - maximizing productivity while delivering consistent product quality
- **Supply Chain** - rapid supply of high quality disposables and consumables at a reasonable price

Bioburden is undetectable

Bioburden (CFU/ 10mL)							
		Production Day					
Location	Sample Type	8	10	12	15/16	19	22/23
Bioreactor	Whole broth	0		0	0	0	0
SUSV1	ProA Load	0	0	0	0	0	0
ProA Outlet	ProA Flowthru	0	0	0	0	0	0
VI Mixer	ProA Elution			0	0	0	0
SUSV2	Neut. VI		0	0	0	0	0
SUSV3	AEX Load		0	0	0	0	0
SUSV4	AEX Flowthru		0	0	0	0	0
Final Pool	ILDF Ret			0	0	0	0

Clinical and commercial processes operate at the same scale to facilitate seamless transfer

J.POD® facility design reduces scale-up risk

Clinical and Commercial processes operate at the same scale

Small operations fit Inside PODs

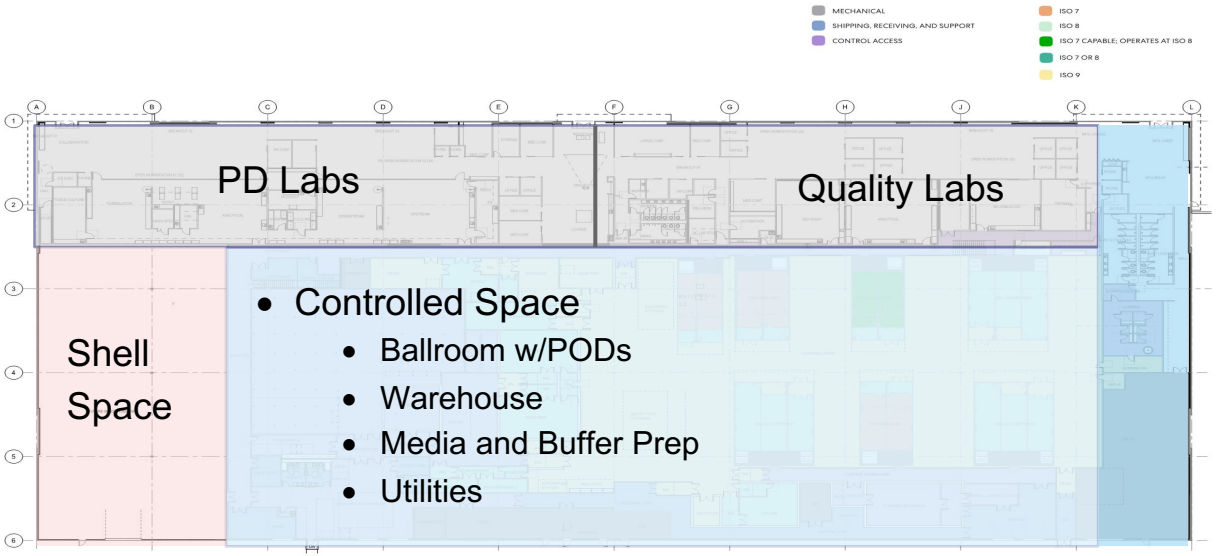
Seamless transfer

PODs can be moved and reconfigured in the facility

Production from a few kilograms to metric tons in the same facility

J.POD® manufacturing has shifted complexity and cost from the facility to the process

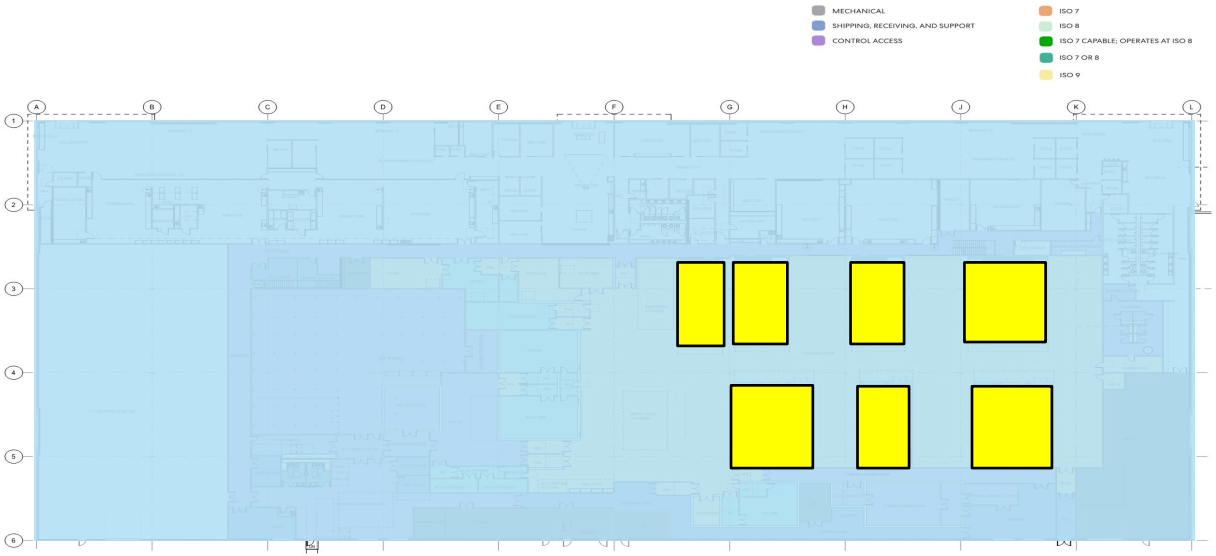
No central CIP and SIP systems with associated piping are required



Processing space is expensive to build and operate, but will only be a small fraction of the facility footprint

Total ISO 7 and 8 space represents <10% of the total J.POD® plant

POD Manufacturing Space



PODs can be added, subtracted or reconfigured to adjust capacity for maximum flexibility

Facility shell is a new warehouse, but an appropriately designed old warehouse could also be used

Minimizing the cost of the facility envelope

…when completed, it will look something like this

Focusing investment on the manufacturing core

Conclusions

- The quality of manufacturing begins with the molecule
- Successful continuous processing requires intense focus on the fundamentals
  - Aseptic Envelope
  - Process Control
  - Supply Chain
- Continuous processing in well designed, relatively inexpensive manufacturing facilities can deliver flexible capacity for manufacturing the highest quality biologics at a reasonable cost

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Questions?

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