

The future of biologics: reverse engineering for successful product supply

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DEVELOPMENT



DELIVERY

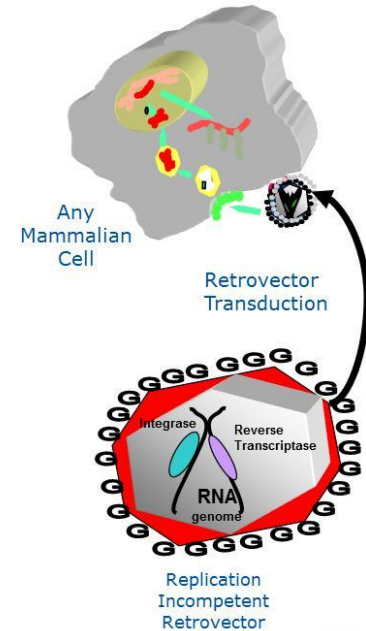



SUPPLY

more products. better treatments. reliably supplied.™

Catalent's biologics presence

- Advanced GPEX[®] cell line engineering technology and IP
- Cell line development, optimization and banking
- Cell culture process development
- Non-clinical and cGMP clinical scale bulk biologics manufacturing (currently up to 200L)
- Clinical scale vial filling , lyophilization
- Clinical/commercial prefilled syringes
- SECURE-VIAL[™] plastic stoppered vial, ASI[™] Autoinjector
- Bioassay development and validation
- Viral clearance studies
- Proven expertise in Oral, Respiratory, Injectable biologics delivery
- Substantial vaccine fill/finish/pack expertise



A top-down view of a disassembled computer system on a light-colored wooden surface. The central component is a white computer case with its front panel removed, revealing the internal hardware including a motherboard, RAM, a power supply, and a cooling fan. Surrounding the case are various components: a hard drive, a CD-ROM drive, a DVD-ROM drive, a graphics card, a network card, a sound card, a power button, and several cables. The components are arranged in a circular pattern around the central case.

**Reverse engineering
as I learned it...**

Commercial success drivers and trends



What drives commercial success in biologics?



Proven
Safe & Effective



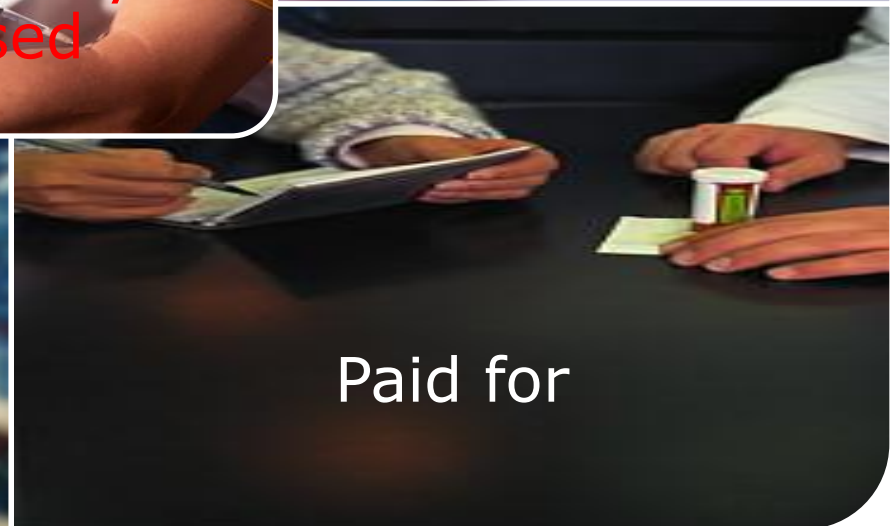
Prescribed



Properly
used



Produced & dispensed



Paid for

Step 1 – Approval as Safe and Effective



Key trends

- 20% of R&D spend
- NBEs more likely to be approved than NCEs
- NBE tox-to-launch delays
- Late-stage licensing growing substantially
- Multi-indication strategies
- Biosimilar path evolving

Commercial Success

Step 2 – Driving prescription volumes



Key trends

- Primary care use growing substantially
- “Buy and bill” economic incentives for docs
- Special handling complicates office-administered drugs
- EU/US Docs very open to biosimilars
- Concerns about infections, off-label use

Step 3 – Reimbursement a gating factor to growth



Key trends

- Substantial cost spikes
- Access controls – step therapy, prior auth, limit off-label
- More oversight of “high cost” conditions, specialty pharmacy
- New “tier IV” for biologics, greater cost sharing by patient
- Likely aggressive on biosimilar adoption

Commercial Success

Step 4 – Distribution complexities



Key trends

- Cascade special handling to ultimate administration point
- New models needed due to high inventory carrying cost
- Avoiding waste and loss from breakage, expiration
- Advanced IT support (serialization?)
- Developing markets bring unique challenges

□ More to come from later presenters!

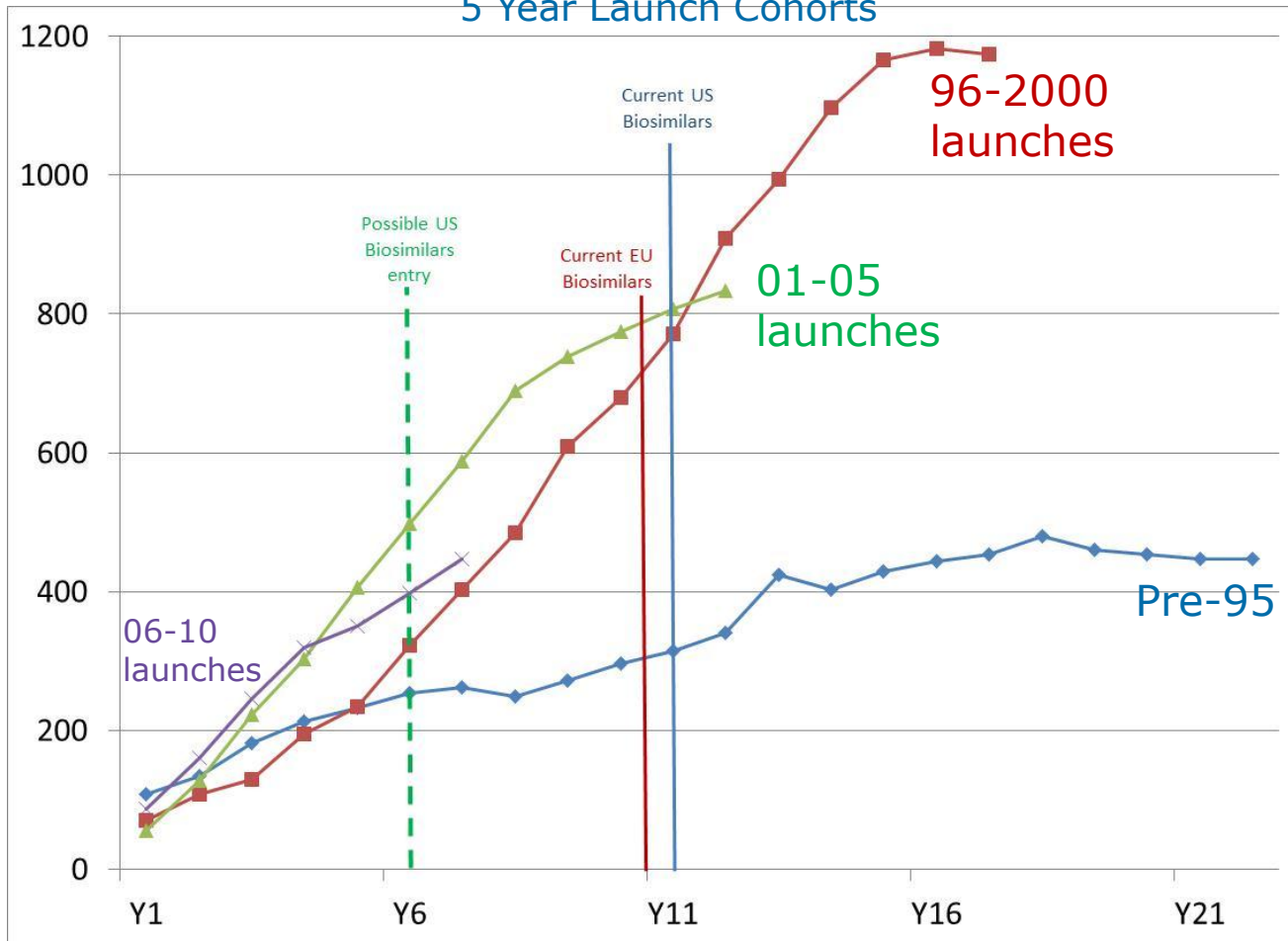


Key trends

- Avoiding high medical cost administration points
- Non-injectable routes: oral, respiratory, transdermal
- Adherence issues persist
- E-enabled future solutions

Biologic lifetime commercial value declining?

Average WW Biologic Sales
5 Year Launch Cohorts



As Waxman-Hatch and the US rise of reimbursement power impacted small molecule drugs, we will likely start to see faster, reduced value peaks, and shorter total lives of individual biologics

Implications for biologics product supply



Linking commercial drivers with supply chain



Supply Chain Implications

Development choices drive future success

Proving				
				
Supply Implications				

- Bulk speed from inception is critical to offset longer timelines
- Understand capacity needs for follow-on indications **early**
- Early capacity ID helps support later licensing (and more \$\$\$?)
- Don't forget route/dose form optimization at this stage

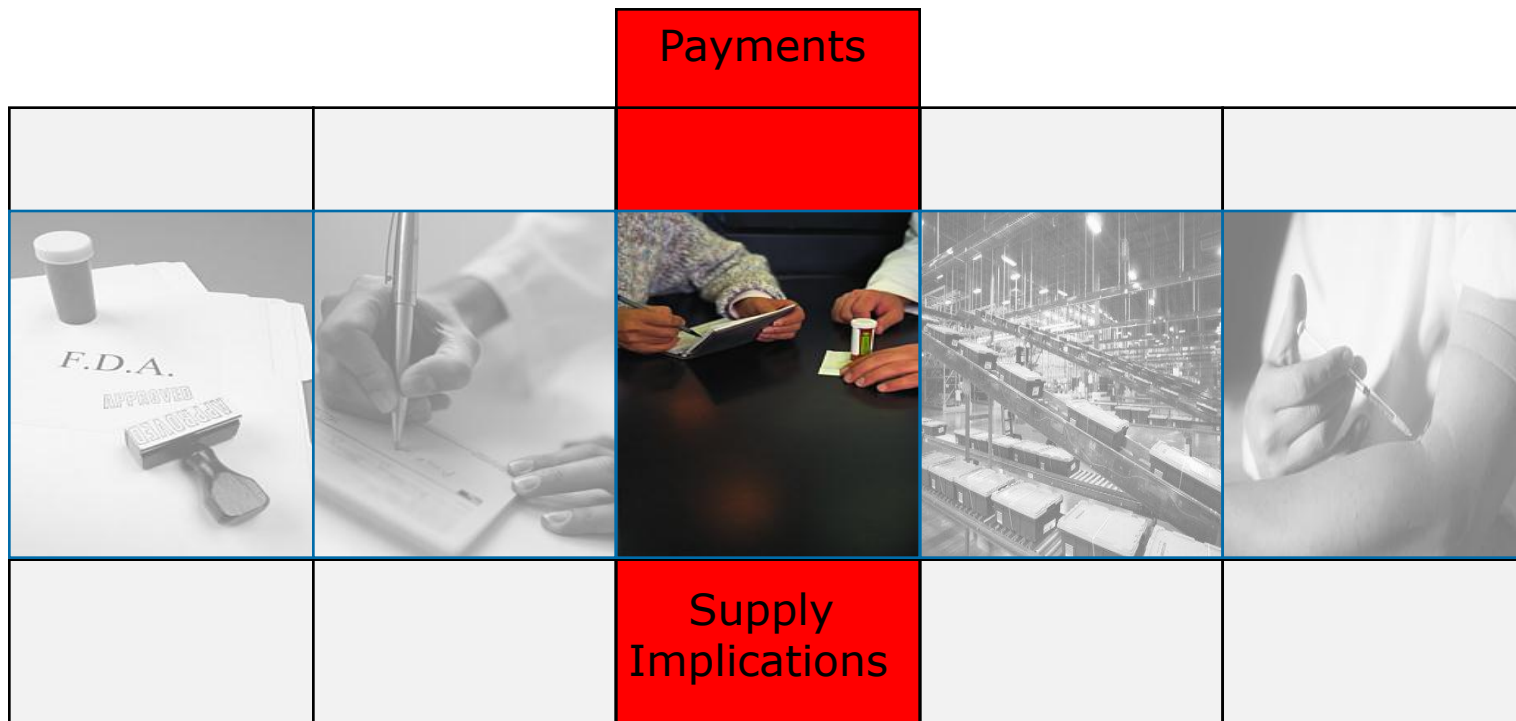
Supply chain implications Physicians & providers



- Minimize special handling needs – avoid cold chain if possible
- Choose “robust” dose forms/devices, and give extras to key docs
- Consider early experience kits for Docs, patients to educate
- Hospital pharmacists can provide unique in-patient perspectives

Supply chain implications

Payor pressure mitigation



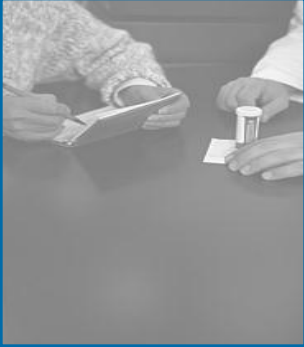




Maximize the cost efficiency of your process to allow pricing flex:

- Eliminate waste wherever possible (LSS: TIM WOOD)
- Consider expression-enhancement technology (more, faster)
- Improve purification levels (resins ~80% of variable costs)

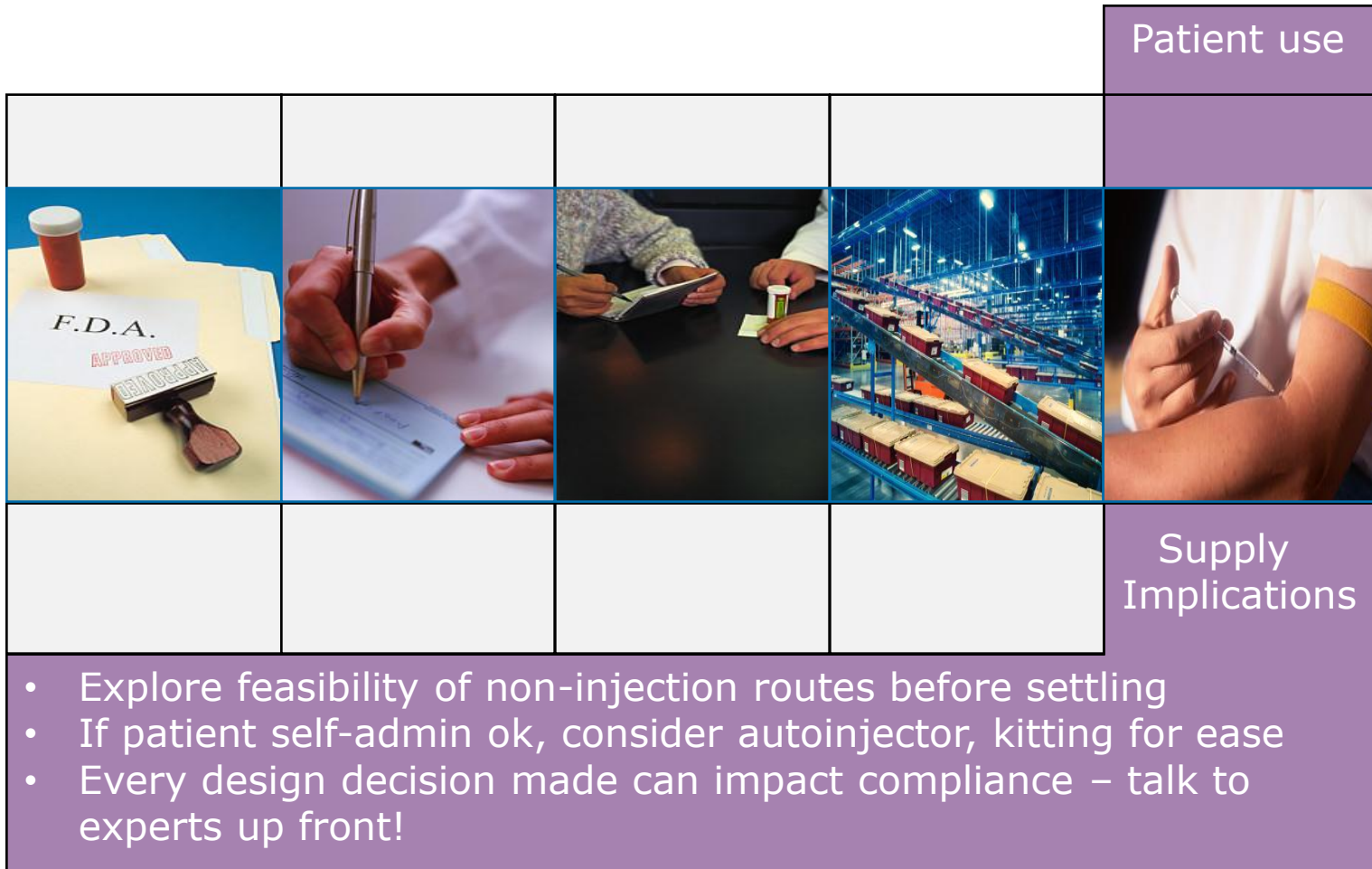
Supply chain implications

Distribution considerations

			Provision	
				
			Supply Implications	
<ul style="list-style-type: none">• Eliminate or mitigate special handling (frozen/refrig)• Breakage resistant dose forms (e.g. BFS vial technology)• Consider serialization and advanced IT to avoid expired waste• Disease-specific “in the wild” research may drive new approaches				

Supply chain implications

Driving better patient outcomes



Other considerations



- Optimizing **process stability** and implementing **Lean Six Sigma** can drive real economic value and measurable capacity improvement
- **Partnering for technologies and/or capacity** can substantially improve your ROIC vs large fixed capital and operating income investments
- Consider developing economies for siting **international greenfield capacity**, for financing, tax incentives and local market access
- Make the most of the substantial **New Jersey** talent and capacity base!



discover more.

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