

Helping to manufacture and ensure the safety of life enhancing drugs

2012 Life Science Information Day

Andrew Bulpin

Head of Process Solutions Business Unit

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Merck KGaA
Darmstadt · Germany





Disclaimer

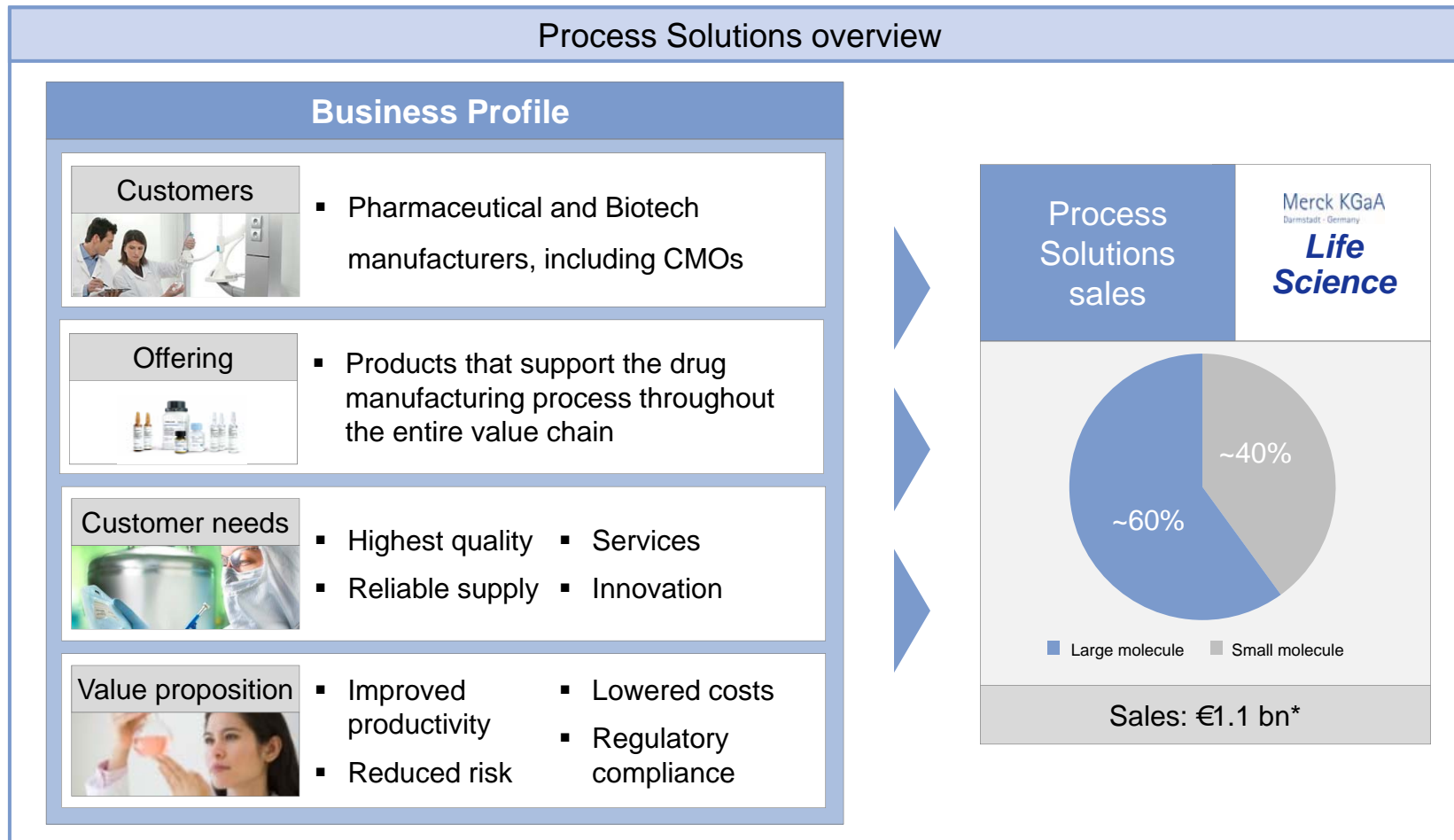
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Process Solutions serves manufacturers of small and large molecule drugs

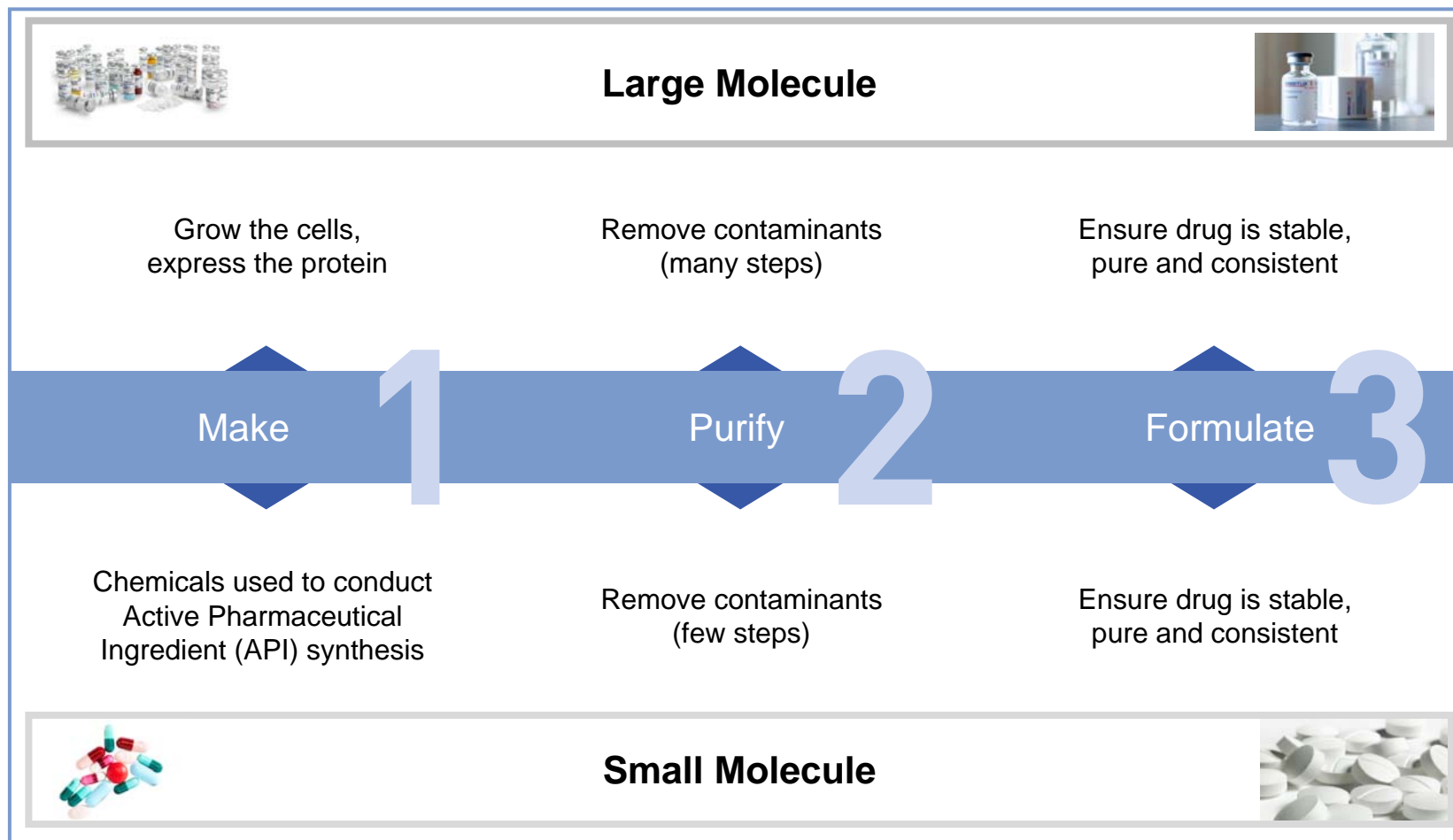
Difference between small and large molecule drugs			
Small Molecule			
Production	Made or derived from chemical synthesis		
Costs	Inexpensive to manufacture		
Classification	Easy to characterize, predictable		
Application	Primarily taken orally		
Example	Antibiotics		
Large Molecule (Biologics)			
Production	Made or derived from living cells		
Costs	Expensive and complex to manufacture		
Classification	Difficult to characterize, unpredictable		
Application	Primarily taken by injection		
Example	Monoclonal antibodies (Erbitux)		
Sales potential for Life Science in large molecules is 5x bigger than in small molecules			

We are the industry leader and a trusted partner to drug manufacturers

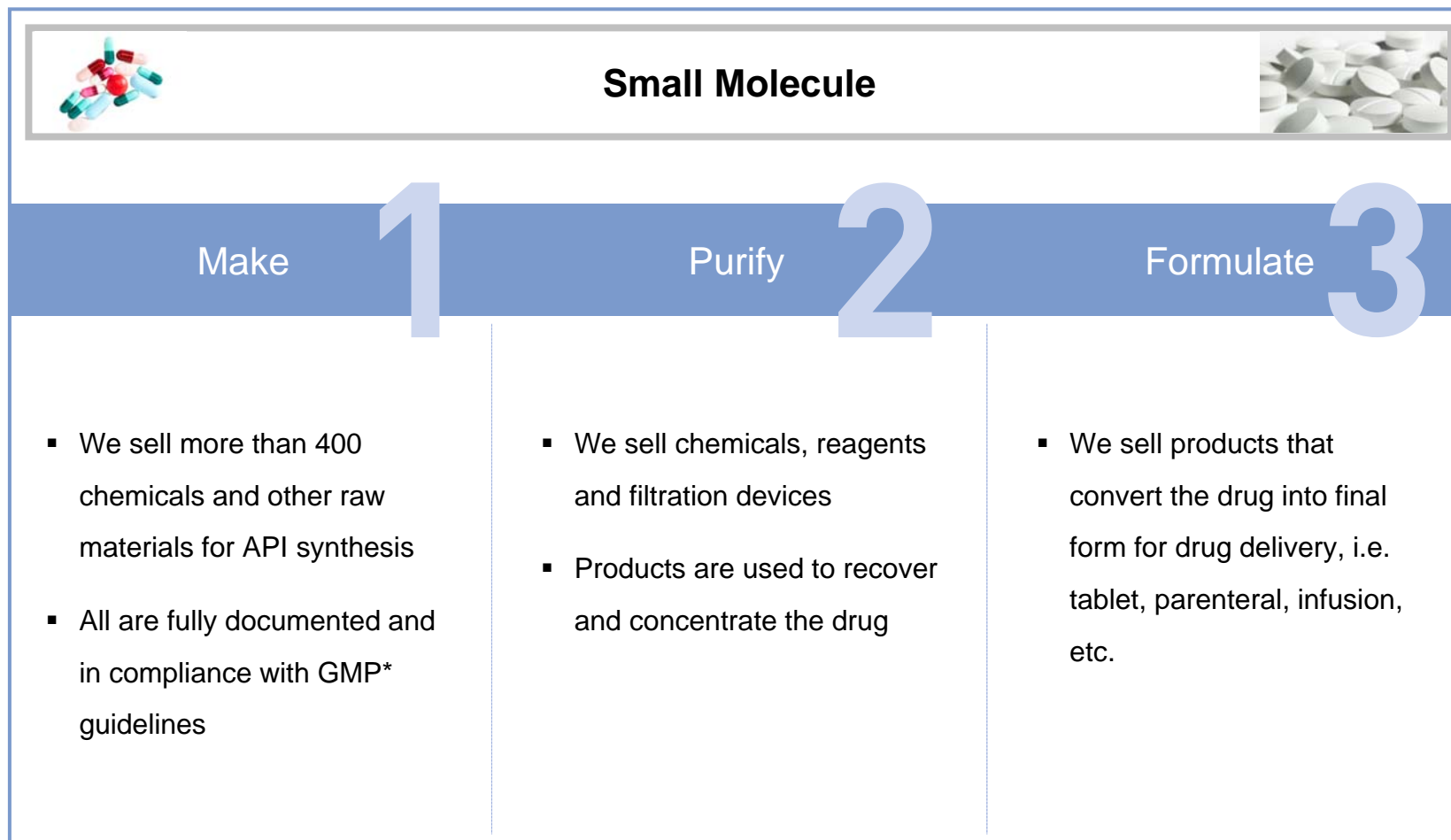


* 2012E

We are critical to the production processes of both small and large molecule drugs



Detailed product offering: small molecule drug production



* Good Manufacturing Practice

Bioavailability: helping customers to optimize drug delivery and release

Case study: Small Molecule Drugs

Customer challenge



Patients are demanding rapidly orally dissolving tablets rather than swallowing oral pills

Life Science solution



Parteck ODT, an excipient for orally dissolving tablets that provide fast-acting medication with a taste patients enjoy

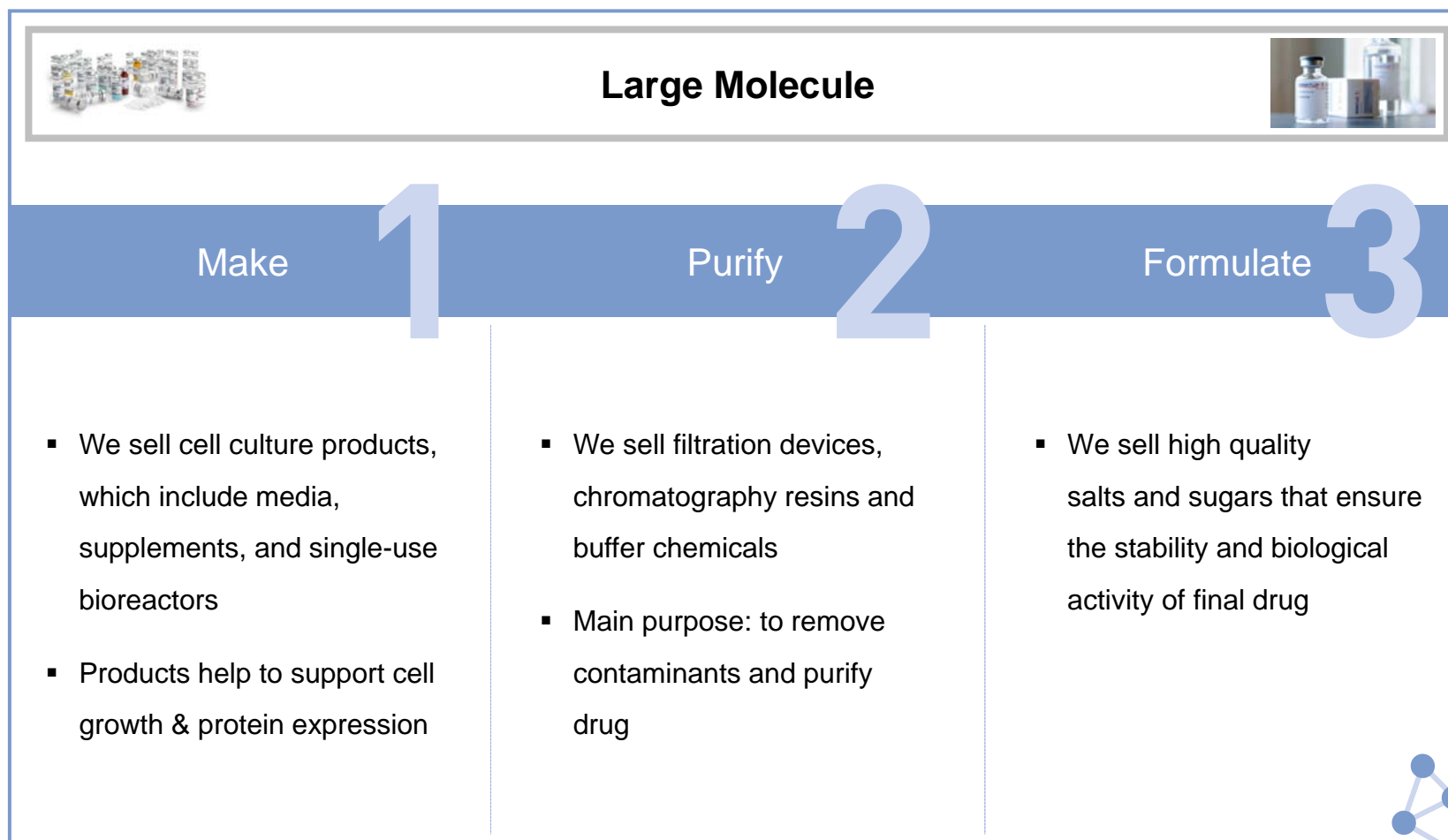
Value to customer



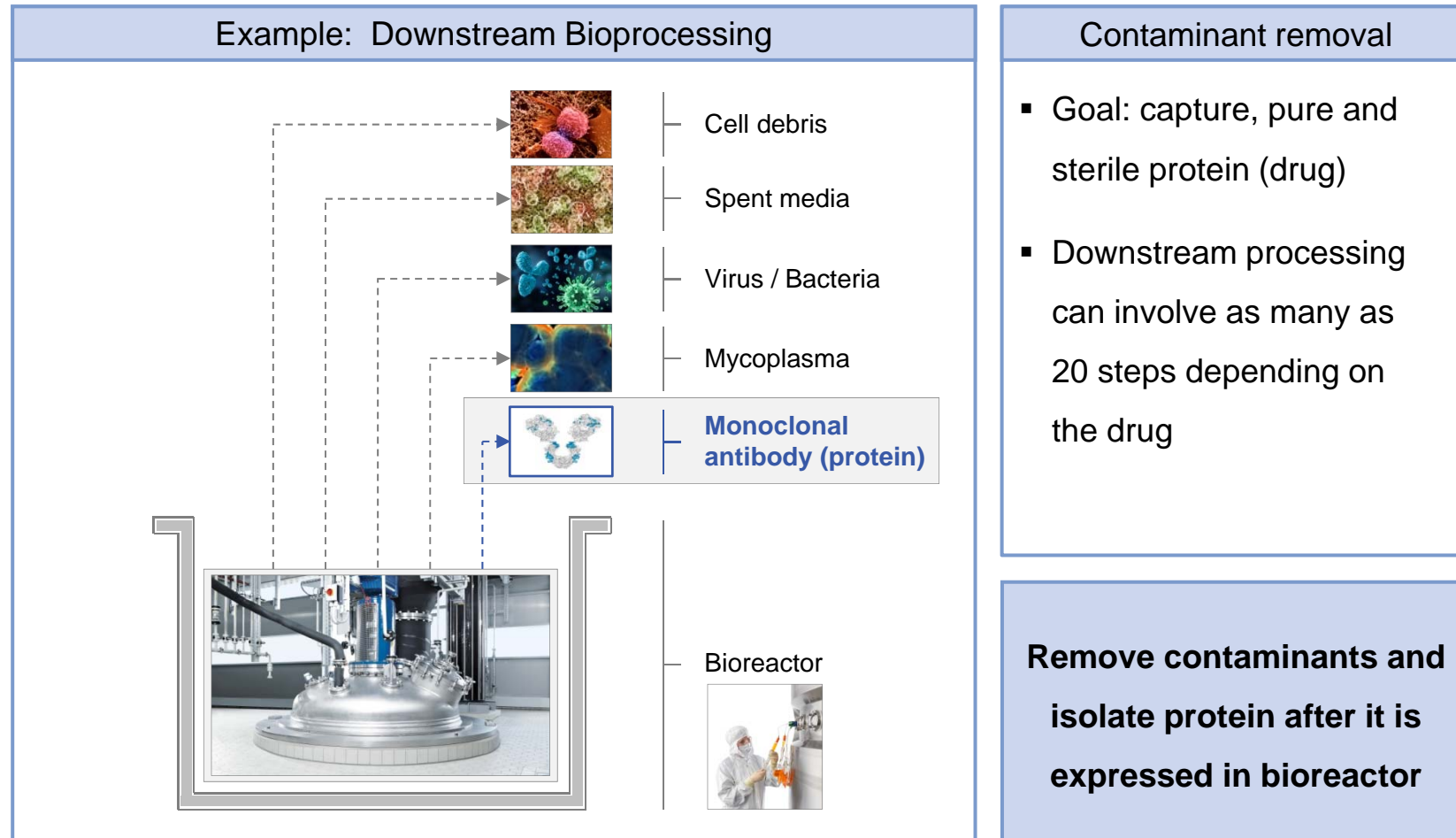
Differentiation in a generic market, optimal drug delivery and release, simplified process steps



Detailed product offering: large molecule drug production

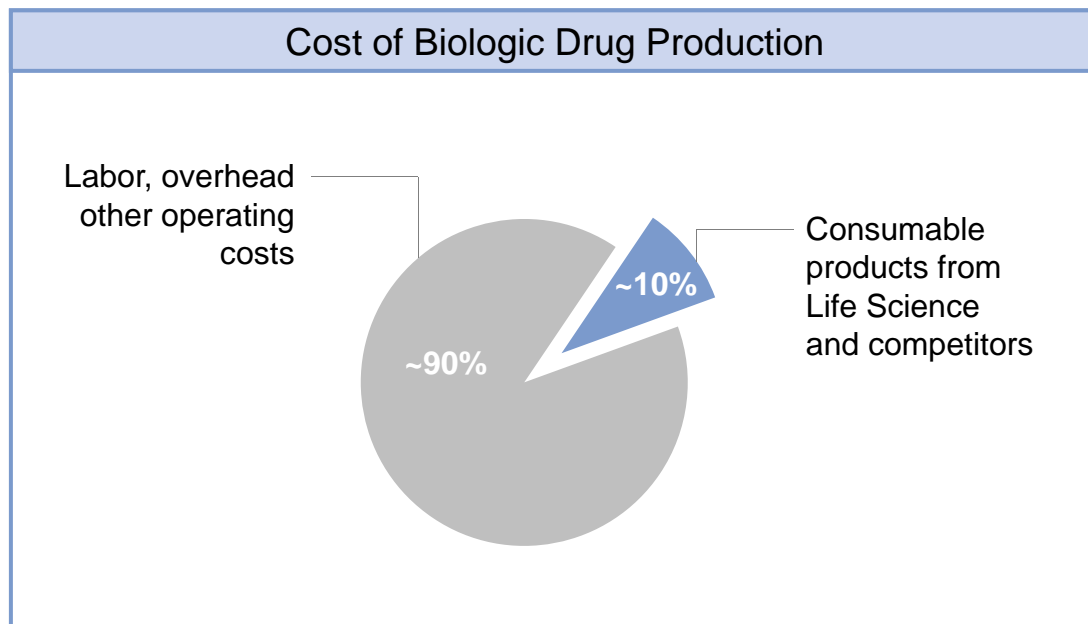


Most of our large molecule business is around purifying the protein



*Illustration

We are critical to the process, but represent a small percent of a customer's COGS



We represent a low percentage of the cost of a drug even though our products are critical to the drug's quality and safety

Our customers are demanding better cell culture media solutions

Case study: Large Molecule Drugs

Customer challenge



Drive higher yields in upstream bioprocessing, while reducing variability and improving consistency between manufacturing batches

Life Science solution



Cellvento, chemically defined cell culture media that is free of animal-derived products

Value to customer



Improved cell growth, lot-to-lot consistency, faster time-to-market



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**Life
Science**

The small size of viruses make them challenging to remove from biologic drugs

Case study: Large Molecule Drugs

Customer challenge



Viruses are challenging to identify and remove, especially during scale-up to large commercial volumes

Life Science solution



Viresolve viral clearance products

Value to customer



Safe and effective viral clearance solution which improves manufacturing productivity and ensures the safety and quality of drugs









Life Science Information Day

We are the only company to span the entire value chain of our customers

Market	Life Science	life technologies™	SIGMA-ALDRICH	GE Healthcare	PALL	sartorius
Pharmaceutical Chemicals						
Cell Culture						
Filtration						
Chromatography*						
Biomonitoring						
Single-Use Manufacturing						

*Process Chromatography for MAb & recombinant drugs

Current trends support process solutions business model

Implications of Industry Trends on Process Solutions		
 Higher protein yields	▶	Need for higher performing purification and single-use products
 Need for improved formulation & drug delivery	▶	Enhanced bioavailability to ensure best drug release
 Emergence of cell-culture based vaccines	▶	Develop products that help reduce time-to-market compared to egg-based manufacturing
 Entry of biosimilars	▶	Market expands, new customer base develops
 Single-use manufacturing	▶	Develop innovative solutions that change approach to small-scale manufacturing
 Higher quality / increasing regulation	▶	Need for high-quality products, improved analytics and regulatory support

Increased operational flexibility and versatility with single-use solutions

Single-Use (Disposable) manufacturing solutions

Mobius FlexReady	Key benefits
	<ul style="list-style-type: none">▪ Eliminates time and cost of cleaning and validating equipment▪ Reduced time to setup manufacturing processes, less downtime▪ Easily adaptable to different products▪ Lower capital investment▪ Reduced environmental impact
<p>Increased flexibility, while reducing the capital, time and costs for manufacturing drugs</p>	

Flexibility of single-use products driving adoption in clinical and small-scale manufacturing

Case Study: Smart Flexware single-use flowpath

Case study: Smart Flexware

Customer challenge



Manual, single-use assemblies are labor intensive, expensive and create lot-to-lot variability

Life Science solution



Smart Flexware fully integrated assemblies

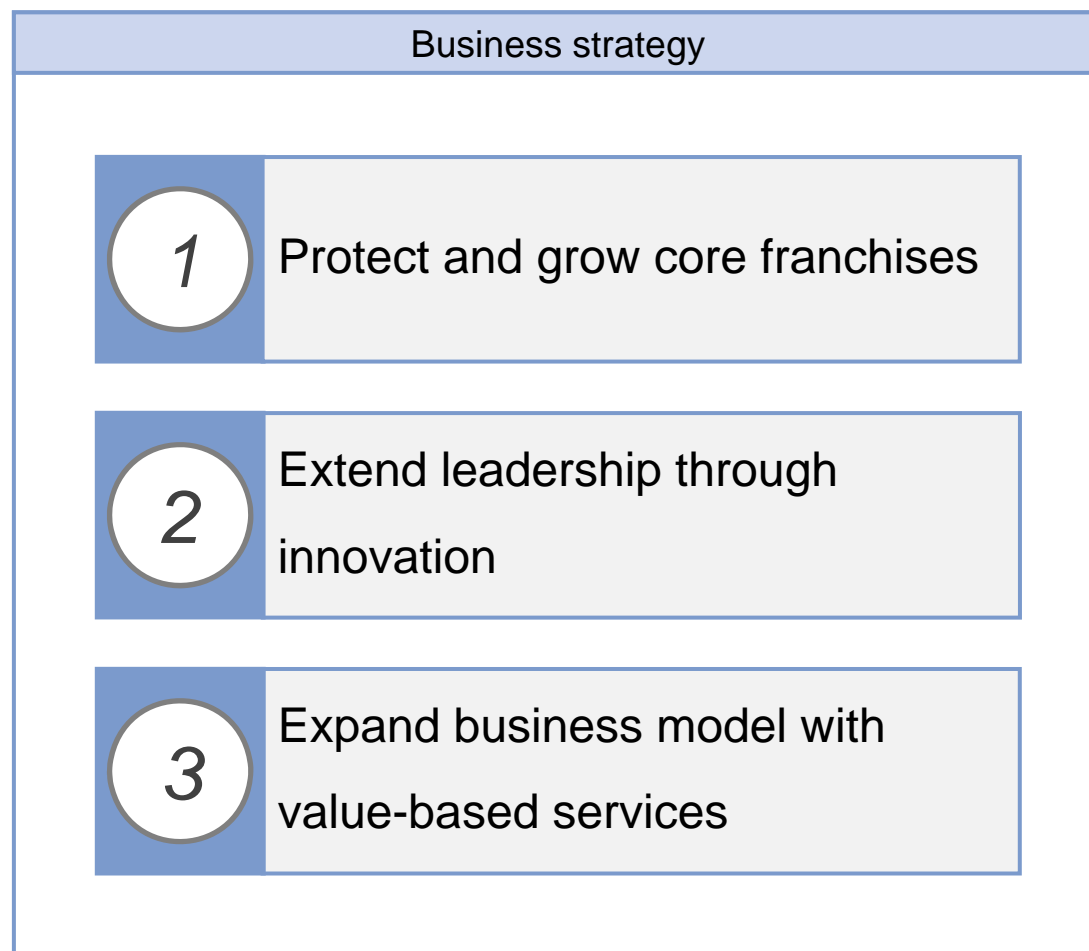
Value to customer



Simpler to operate, lower cost and fewer quality issues

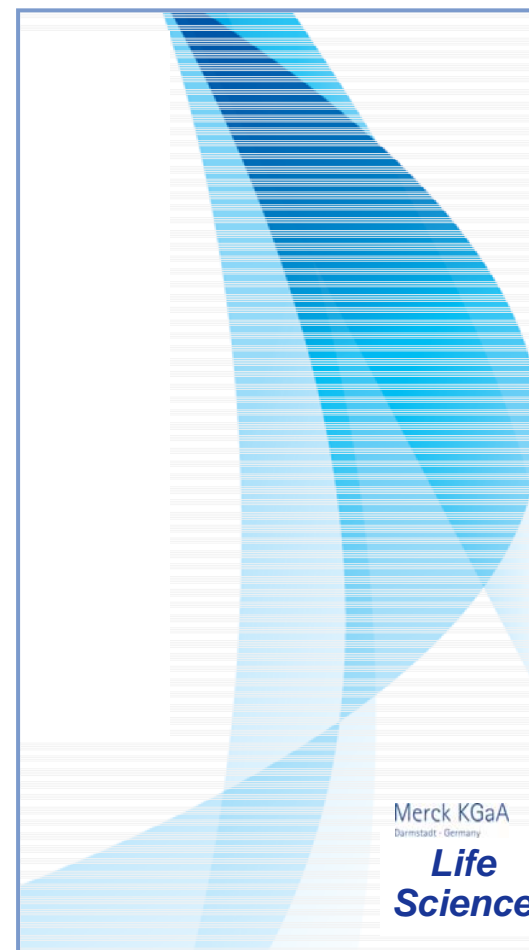


We have a clear strategy for future growth



Conclusion

<p>Market Leadership</p>	<p>We are the clear market leader serving the drug production market – over two times bigger than our next largest competitor</p>
<p>Quality Products</p>	<p>Our products are critical to improve customers' productivity, reduce their risk, & ensure regulatory compliance</p>
<p>Poised for Growth</p>	<p>Underlying trends should strengthen our market and create higher demand for our products</p>



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