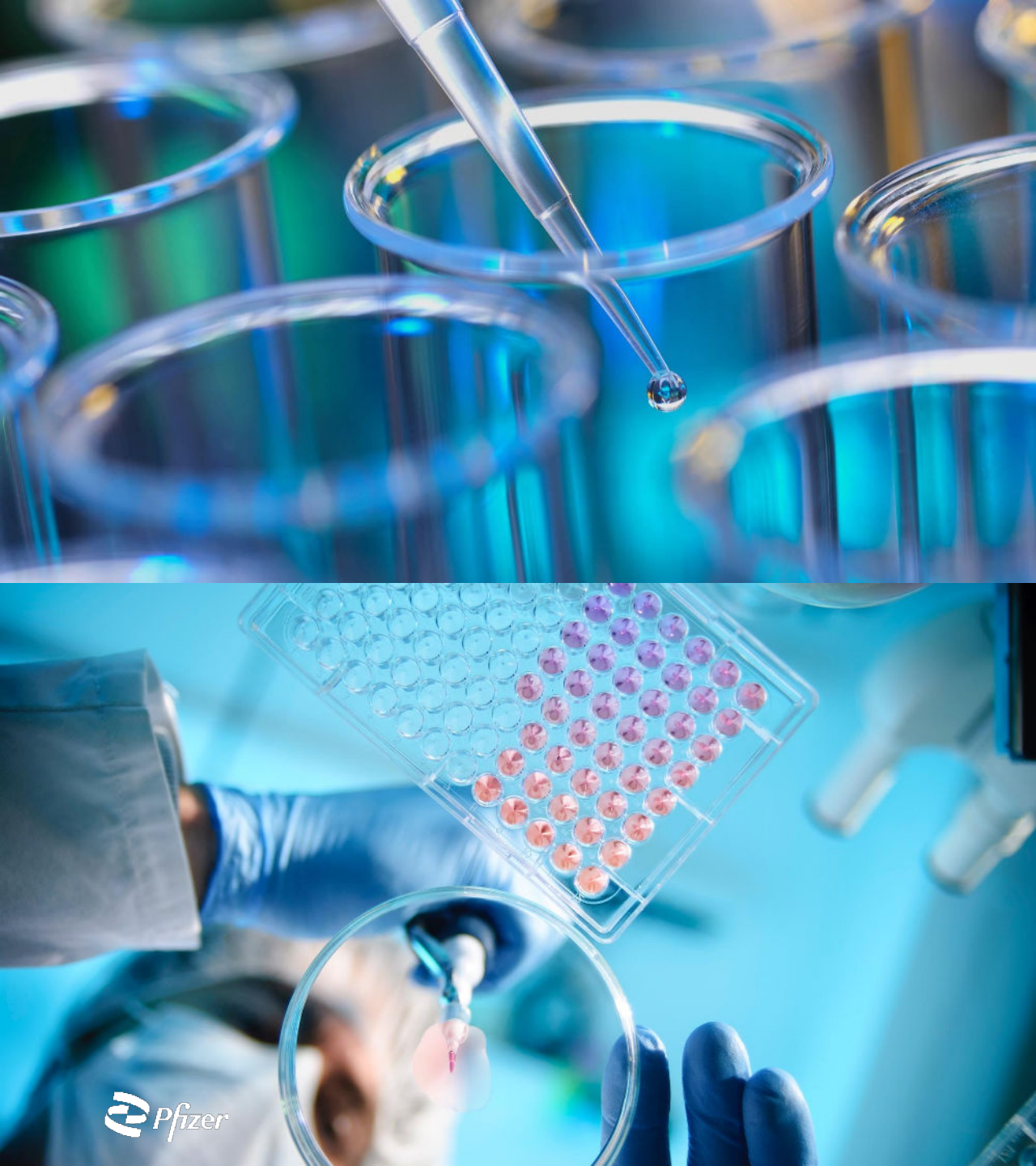


Strategic Production Dynamics: Balancing In-house Capabilities and Outsourcing for Competitive Advantage

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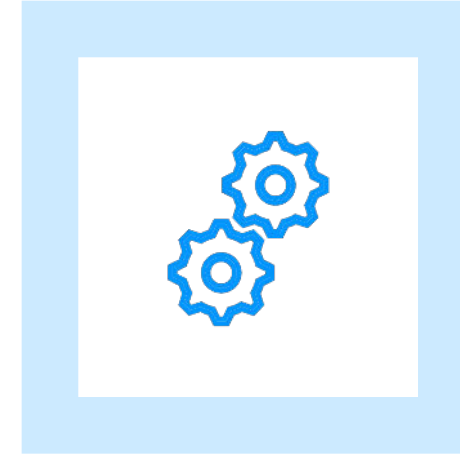
Today's Agenda

- Introduction to Strategic Production Dynamics
- Overview and Theory
- Case Studies

Network Strategy



Network Strategy creation, refinement and updating must be done keeping in view the needs of the customers, the drivers of the pipeline, the risks seen by the stakeholders and the overall philosophy that the organization has set from the top down



Nobody will get everything met, but the best strategy is one that achieves the key organizational requirements, and as many of the other inputs as necessary, but keeps within the guardrails set out by the company

Key Starting Questions



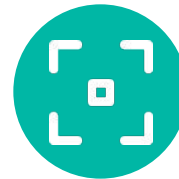
Technology
Do I have it in house already or not?



Can I utilize this capacity elsewhere if it becomes excess?



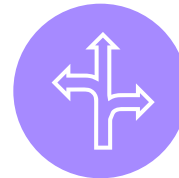
How much does new capacity cost versus product returns?



How cost competitive does this product need to be and for how long?



Flexibility
How dynamic is the space and how responsive do I need the supply node to be?



What does the landscape look like in 5 – 15 years?

Considerations

- Is the technology novel / giving competitive advantage
- Do I have operational capability to manufacture this technology
- Can I acquire technology asset and / or operational capability
- Can I secure external capability / capacity
- Do I have a partner / partners that I can work with to achieve the supply requirements
- Am I the best fit to own this product

Outsourcing Considerations

- Does geography of CMO have impact
- Does history with CMO have impact
 - Quality history, Operational success history, PM history and innovation history all play a key role
- What about strategic partnerships?
 - Significantly impactful if they can represent the sharing of the risk as well as the sharing of the benefit – if it is only structured to be one way, then it is not a partnership

Case Studies

Case Study 1 – Large Molecule Drug Substance – Large volume New Product



- 1 New biological entity in late Ph3 requiring very significant commercial volumes
- 2 As innovative biologics are less susceptible to LOE impact, longer term strategy running past patent coverage required
- 3 High value DS so unit cost improvements amount to very significant savings
- 4 Should be available at best value strategy for the company
- 5 Investment in capacity will deliver payback and favorable NPV over lifetime of the product

Case Study 2 – Large Molecule Drug Substance bundle - Biosims



- 1** Biosimilars product bundle established on the market requiring significant commercial volumes

- 2** As Biosims are more susceptible to competition from other Biosims, longer term strategy will be at higher risk to volume erosion

- 3** High value DS so unit cost improvements amount to very significant savings

- 4** Should be available at best value strategy for the company

- 5** Investment in capacity unlikely to achieve payback and favorable NPV over lifetime of the product and so External Sources with higher unit cost but no capital outlay is best choice

Case Study 3 – API bundle – new and old molecules



- 1 New and lifecycle chemical API volumes outgrowing current capacity
- 2 Significant volatility in these products through launch, market growth and then LOE and subsequent varying impact on volumes
- 3 Chemical API transfer are usually lower cost and risk with very significant global capacity and expertise
- 4 Should be available at best value strategy for the company
- 5 Only invest if there is high probability of payback but safer option is to use external sources at higher unit cost but without the capital investment

Summary

- Overall supply strategy principles set from top
- Assessment of need, capacity and capabilities with risk-based weighting
- Constant revision to consider macro events



Thank You

