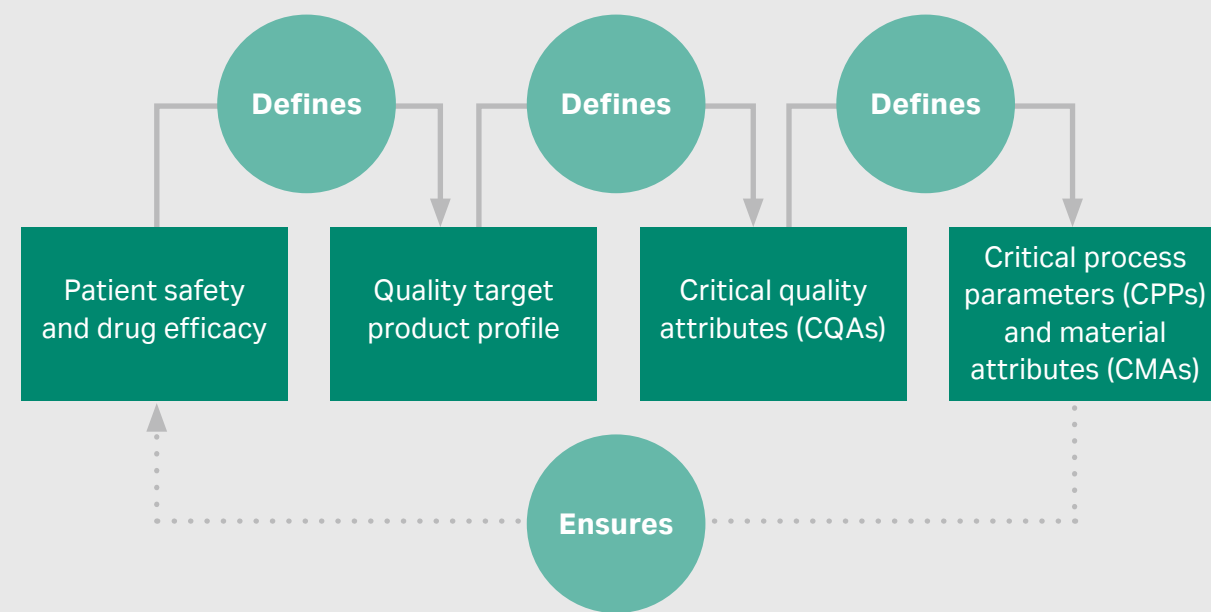


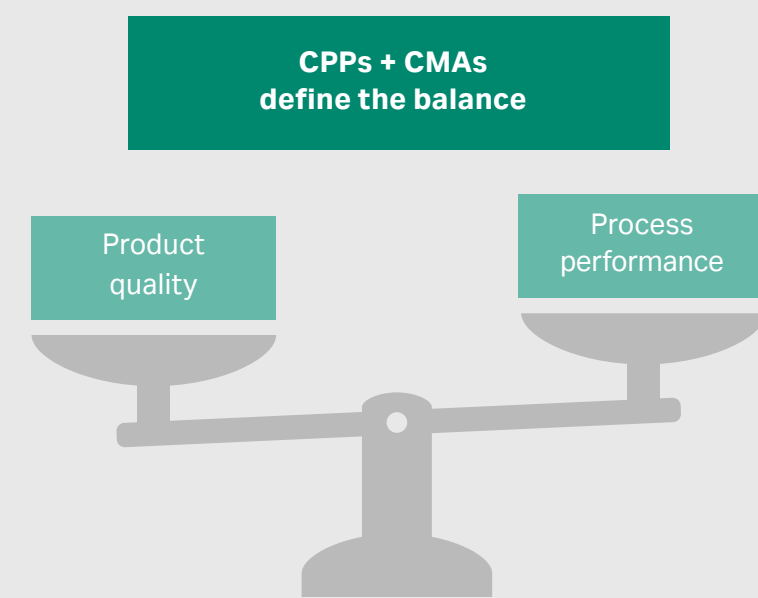
How to ensure process robustness in chromatography

Understand the interplay between process parameters and resin variability

A QbD-approach to biopharma process development



Balancing process outcome



The need to understand the interplay between CPPs and CMAs on process outcome grows with the increased molecular diversity

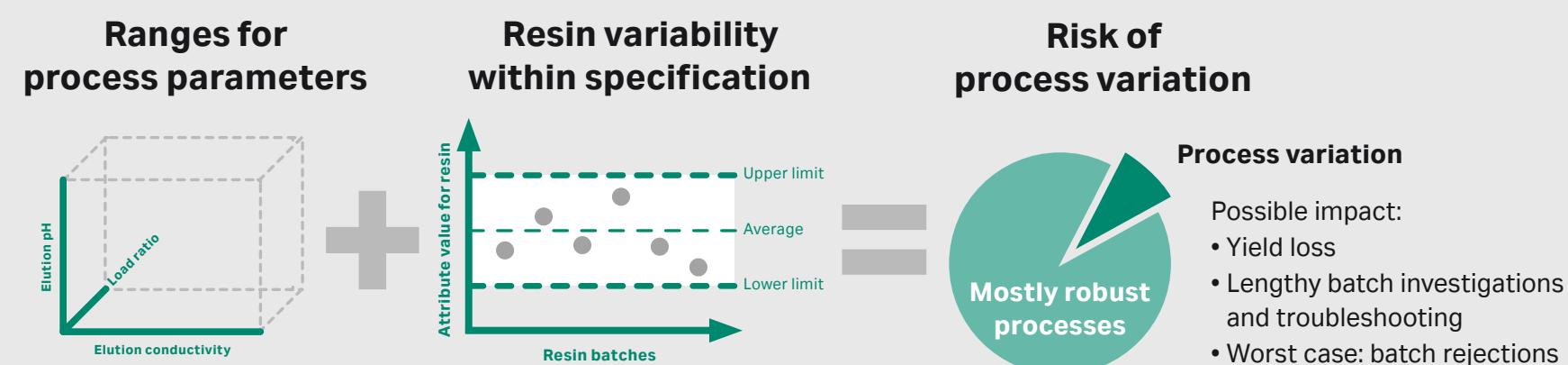
"2/3 of all manufacturing deviations are related to raw materials" (mainly cell culture media, but also resins and filters)

"Develop understanding of resin variability impacting product quality. Required for biologic license application (BLA)"

"Resin variability is a blind spot to us"

"Most processes show no impact of resin variability but this is molecule dependent"

The interplay between process parameters and resin attributes might lead to process variation



Risk assessment: our recommendations for when to study impact of resin variability

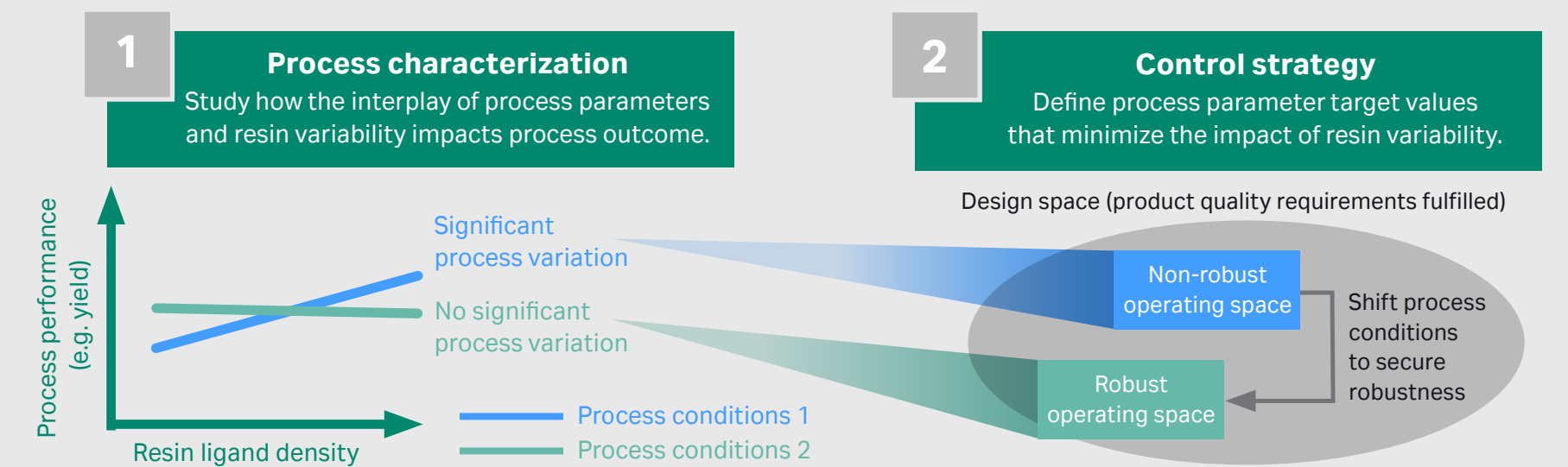
Chromatography technique	Mode	Process parameters	Resin ligand density	Resin base matrix properties
AIEX	B/E	●	●	●
	FT	●	●	●
CIEX	B/E	●	●	●
	FT		Not applicable/not assessed	●
HIC	B/E	●	●	●
	FT	●	●	●
Multimodal CIEX	B/E	●	●	●
	FT		Not applicable/not assessed	●
Multimodal AIEX	B/E	●	●	●
	FT	●	●	●
Protein A affinity	B/E	●	●	●
	FT		Not applicable/not assessed	●

Ligand density is the resin attribute most likely to impact process outcome...

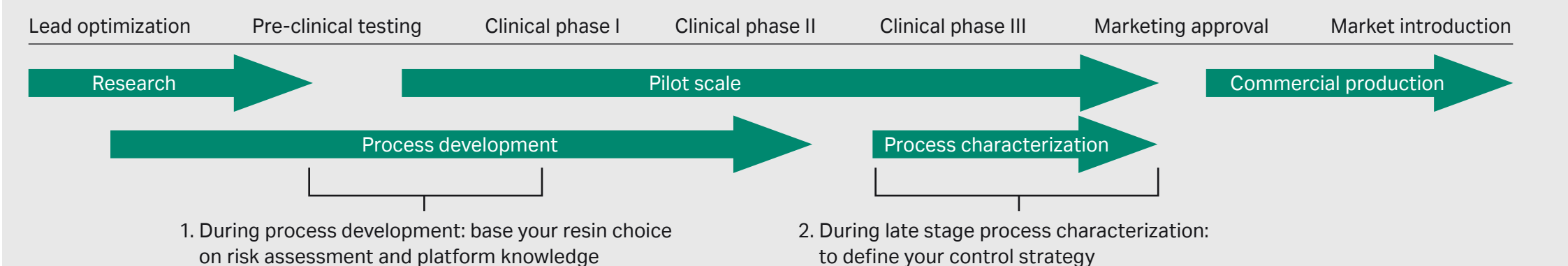
...especially for challenging chromatography separations.

- Characterization recommended
- Characterization to be considered
- Considered robust

How can you ensure a robust process performance?



When should you consider the possible impact of resin variability?



Learn more about process characterization

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AIEX = anion exchange chromatography
CIEX = cation exchange chromatography
HIC = hydrophobic interaction chromatography
B/E = Bind/elute mode
FT = Flow-through mode
QbD = Quality by design



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