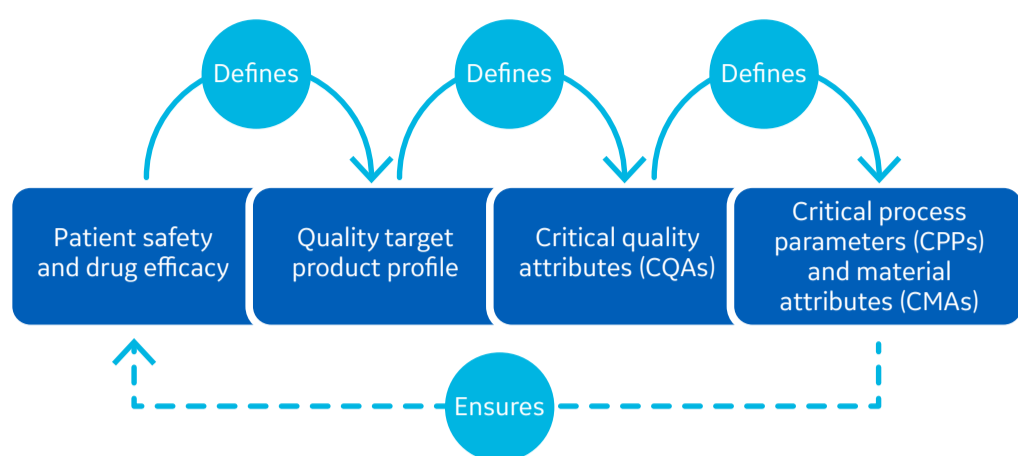




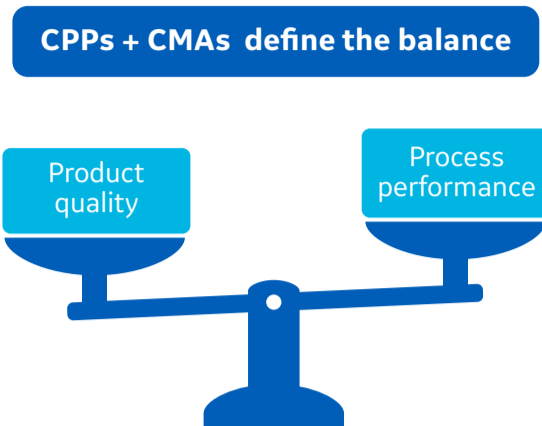
How to ensure process robustness in chromatography

Understand the interplay between process parameters and resin variability

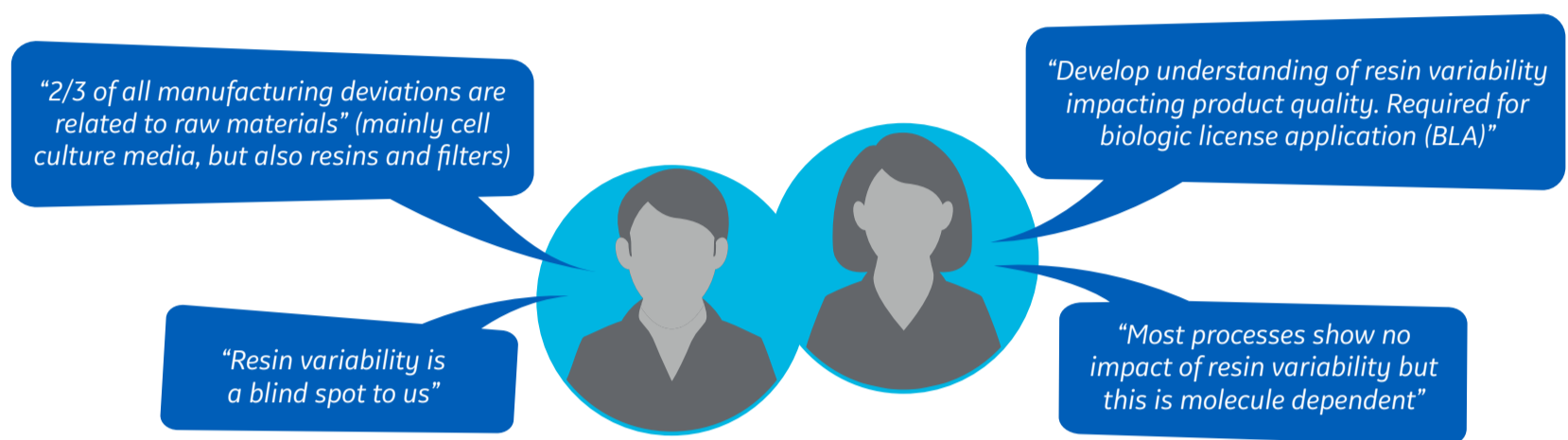
A QbD-approach to biopharma process development



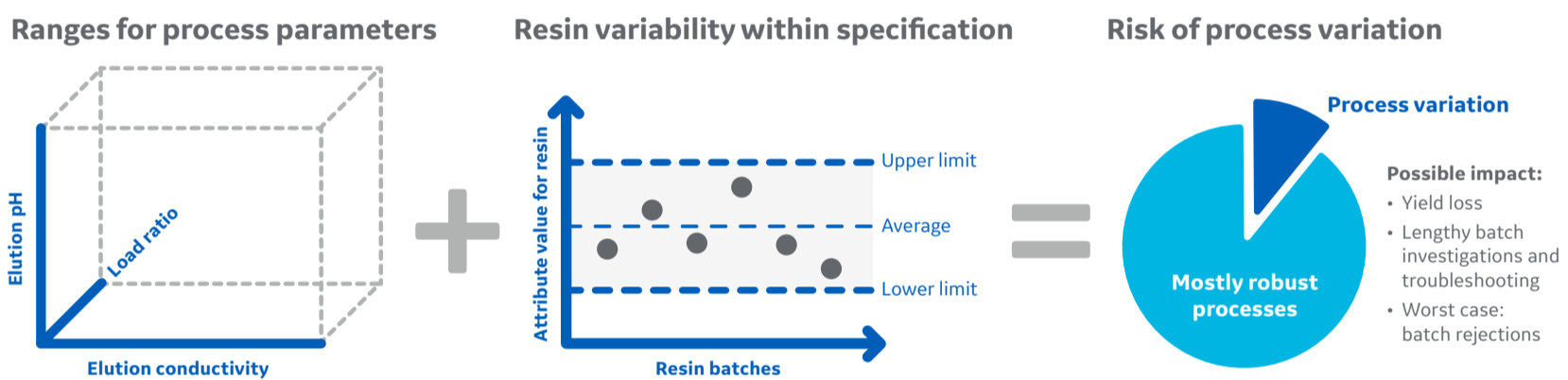
Balancing process outcome



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



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



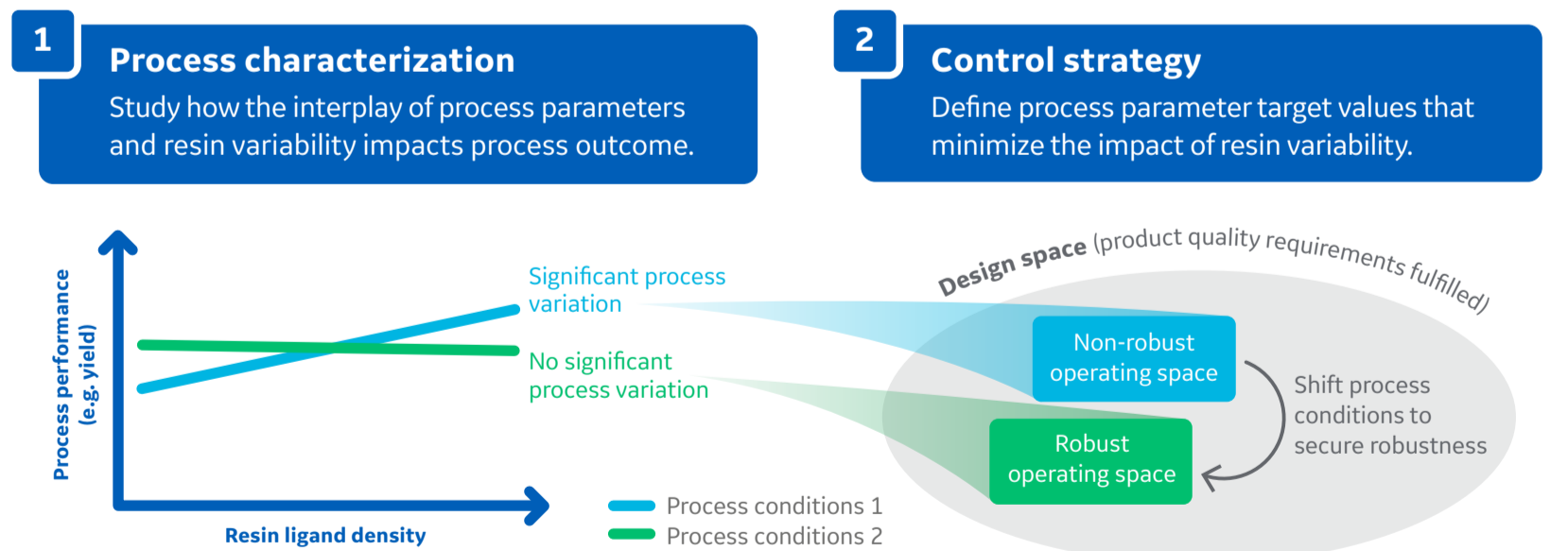
Risk assessment: our recommendations for when to study impact of resin variability

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		

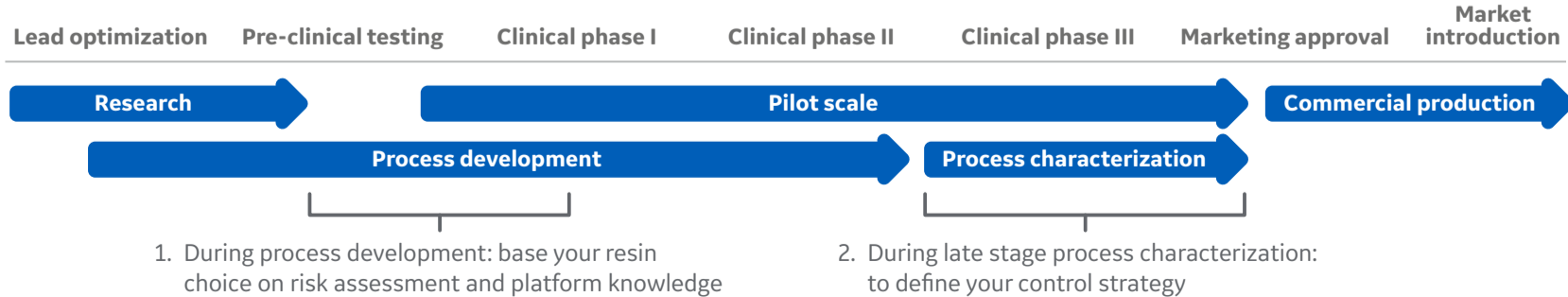
● Characterization recommended
● Characterization to be considered
● Considered robust

Ligand density is the resin attribute most likely to impact process outcome...
...especially for challenging chromatography separations.

How can you ensure a robust process performance?



When should you consider the possible impact of resin variability?



Learn more about process characterization

gelifesciences.com/QbD

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GE Healthcare Bio-Sciences AB, Björkgatan 30, SE-751 84 Uppsala, Sweden
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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