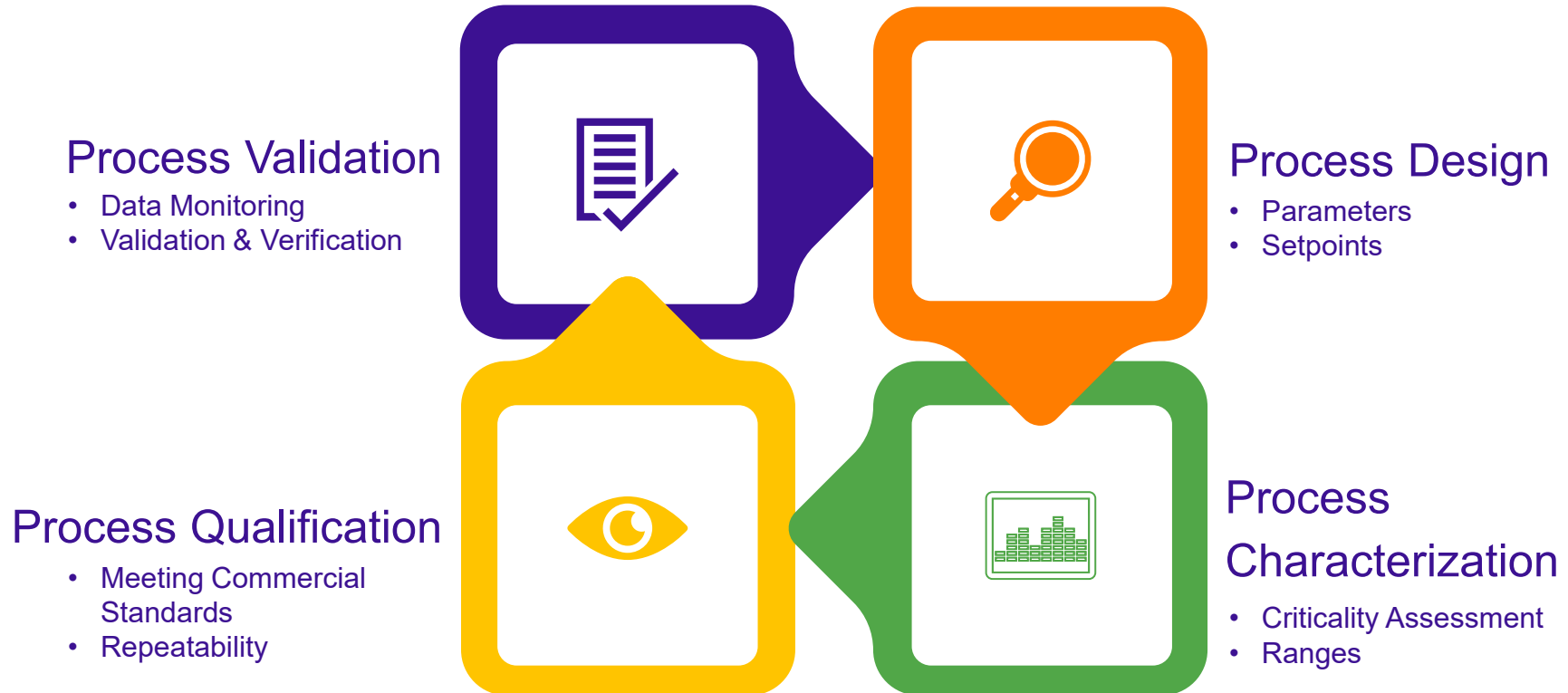


Development, Characterization, and Commercialization of Platform Processes

Stephen Madaras
BioProcess Engineering in Process Development



Process Validation Lifecycle



Platform Process Design Elements

I. Standard Production and Purification Process Framework

- Fixed unit operations with tunable parameters

II. Robust Analytical Strategy

- Core analytics for titer and impurity profiling standardized across products for comparability

III. Regulatory-Ready Documentation

- Clear statistical strategy and platform data leveraged to reduce burden for IND/BLA submissions



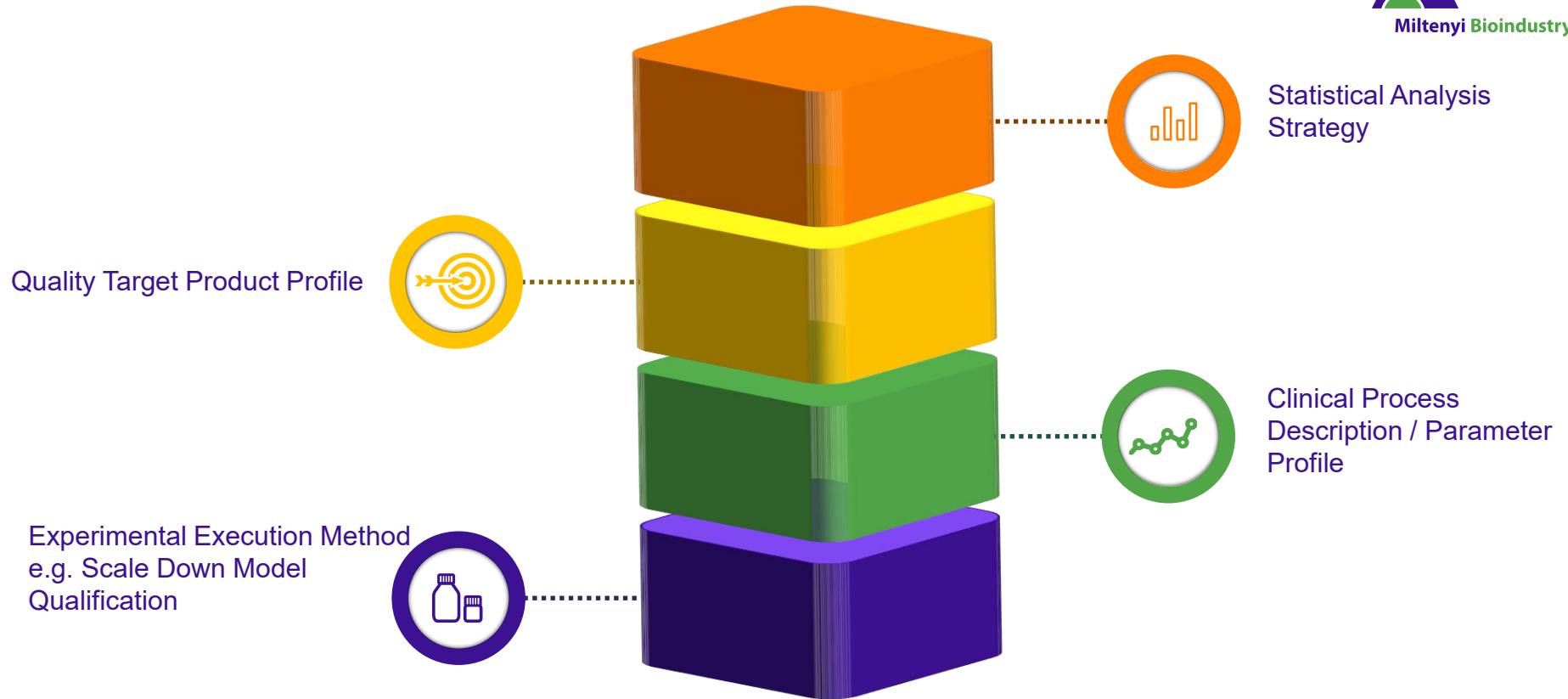


Miltanyi Bioindustry

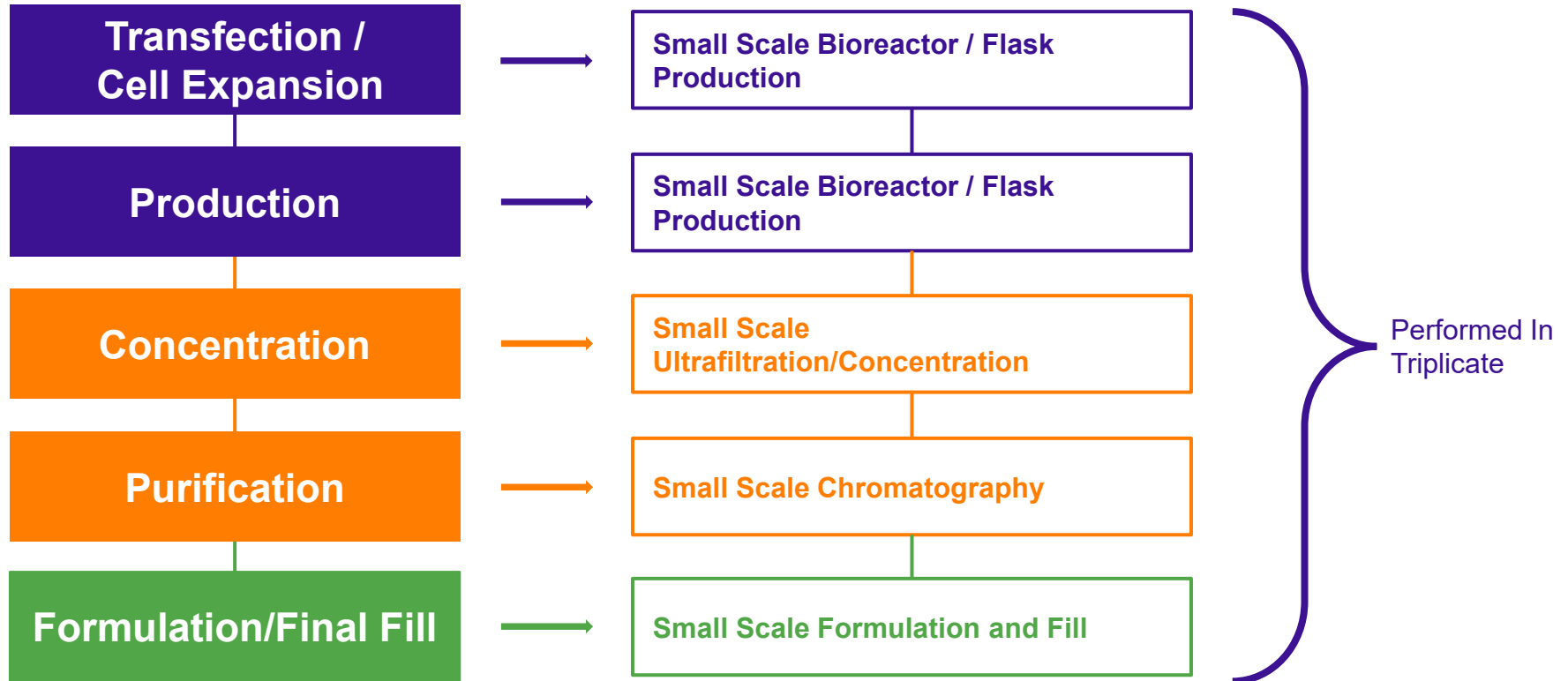
Process Development & Quality by Design

Quality driven Development, Characterization, & Commercialization ensure robust process controls and a consistent product

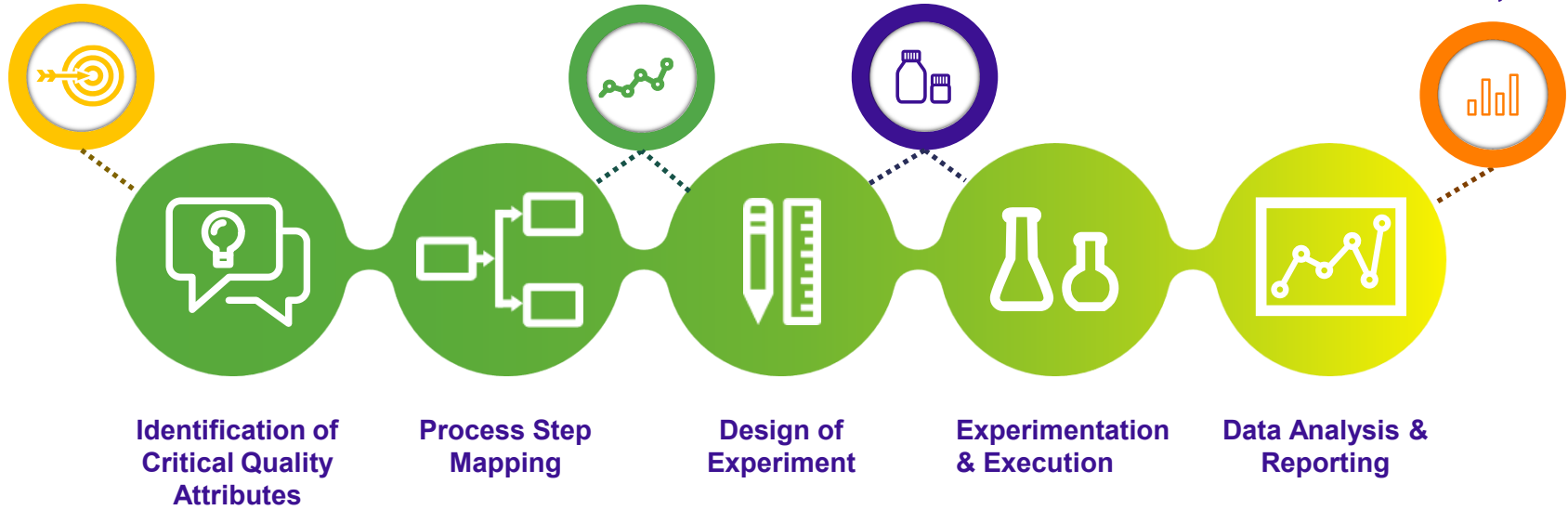
Building Blocks of Characterization



Platform Scale Down Model Qualification Strategy



Miltenyi Characterization Procedure Elements

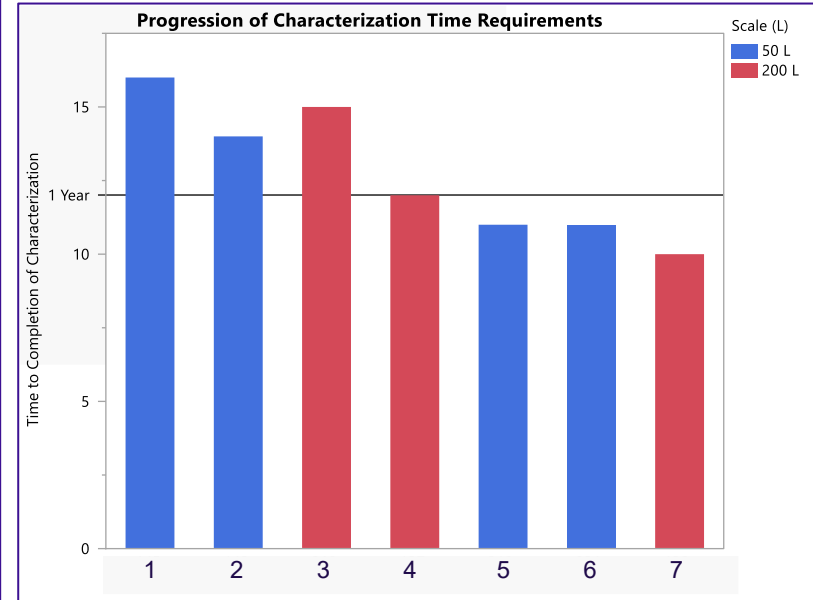


Outputs

Critical Process Parameters
Normal Operating Ranges and Proven Acceptable Ranges
Control Strategy

Evolution of Process Characterization Timelines

Process Characterization Program (Chronologically)	Scale (L)	Number of Executed Experiments	Time from Kick-off to Report Package Finalization
1	50 L	11	16 Months
2	50 L	10	14 Months
3	200 L	12	15 Months
4	200 L	12	12 Months
5	50 L	9	11 Months
6	50 L	8	11 Months (Expected)
7	200 L	8	11 Months (Expected)



LVV Pre-Commercialization Accomplishments



8

Process
Characterization
Programs
Initiated



71

Process
Characterization
Experiments
Executed



75

Process
Characterization
Reports



5

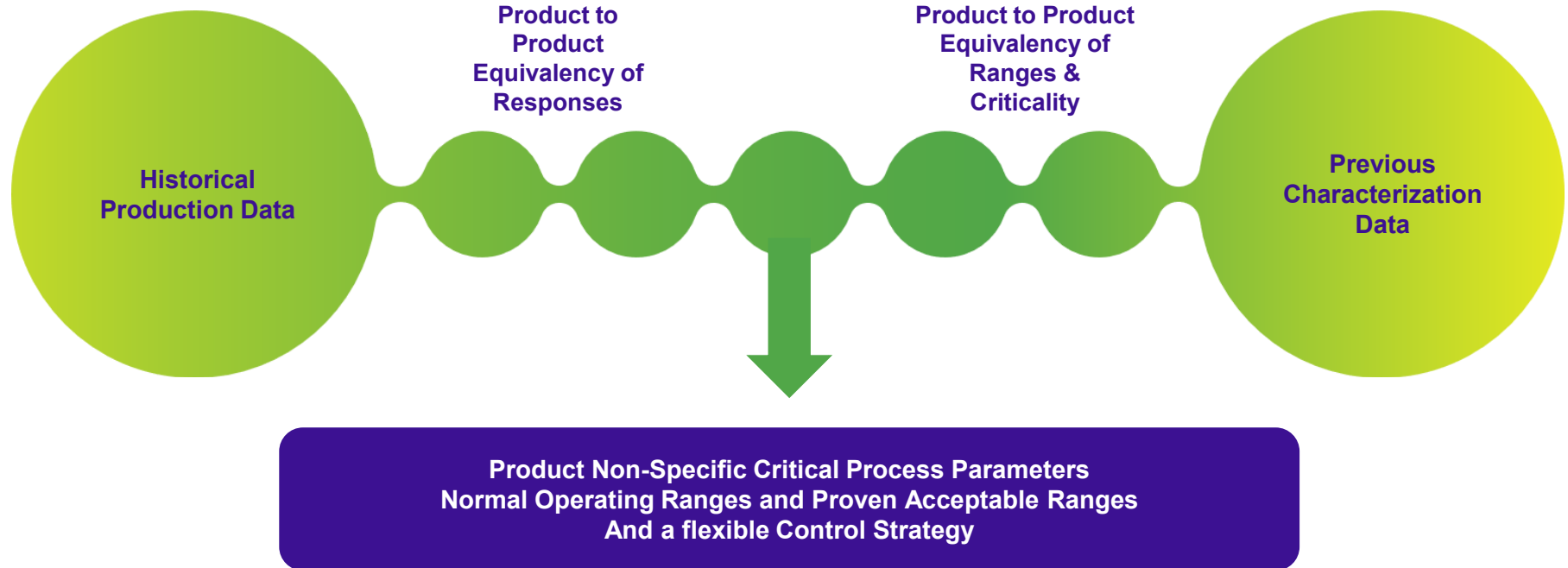
Completed
Process
Characterization
Programs



1

Commercially
Approved
Product

Streamlined Path to Commercialization





Process Qualification & Validation

Our data leveraging efforts do not end with characterization and the establishment of the control strategy! The process ownership is passed off to the Manufacturing Sciences and Technology team for Qualification and Continued Process Verification, utilizing similar platform statistical approaches for analysis and reporting.

**Thank you
for your attention!**

