

Process Improvements for Quality and Efficiency

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PHUSE US CONNECT 2021

Outline

Agenda:

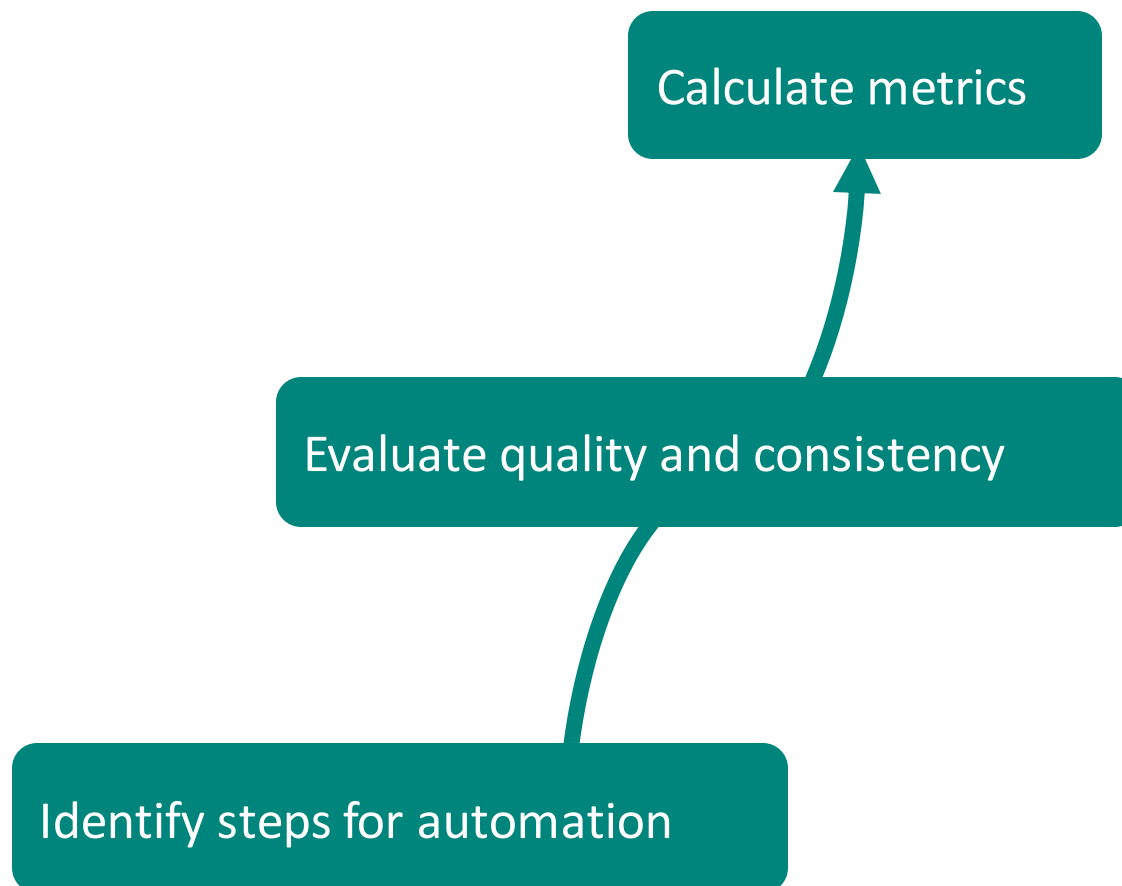
- Overview of Analysis and Reporting (A&R) process
- Automation

Rationale:

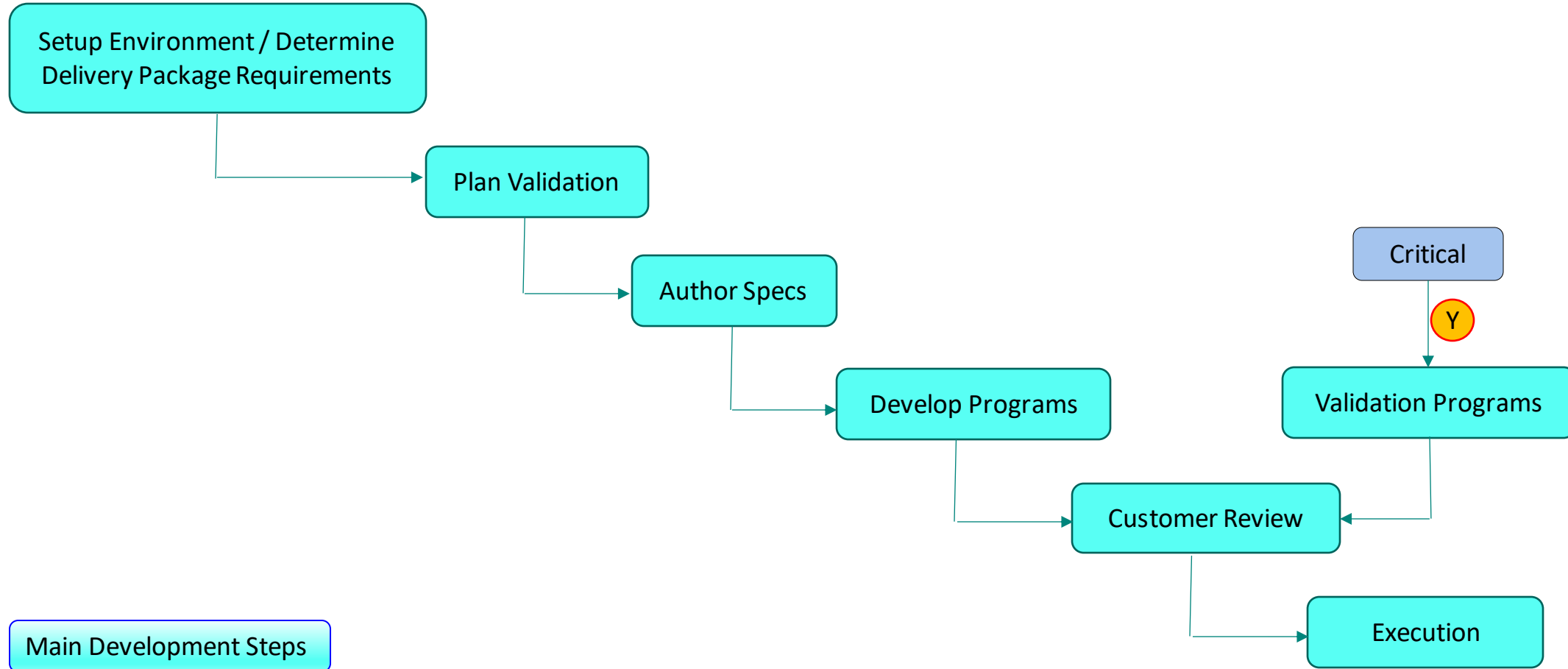
- Manual steps are time consuming
- Chances of human error
- Lack of consistency

Scope:

- Increase efficiency in A&R process
- Maintain standards

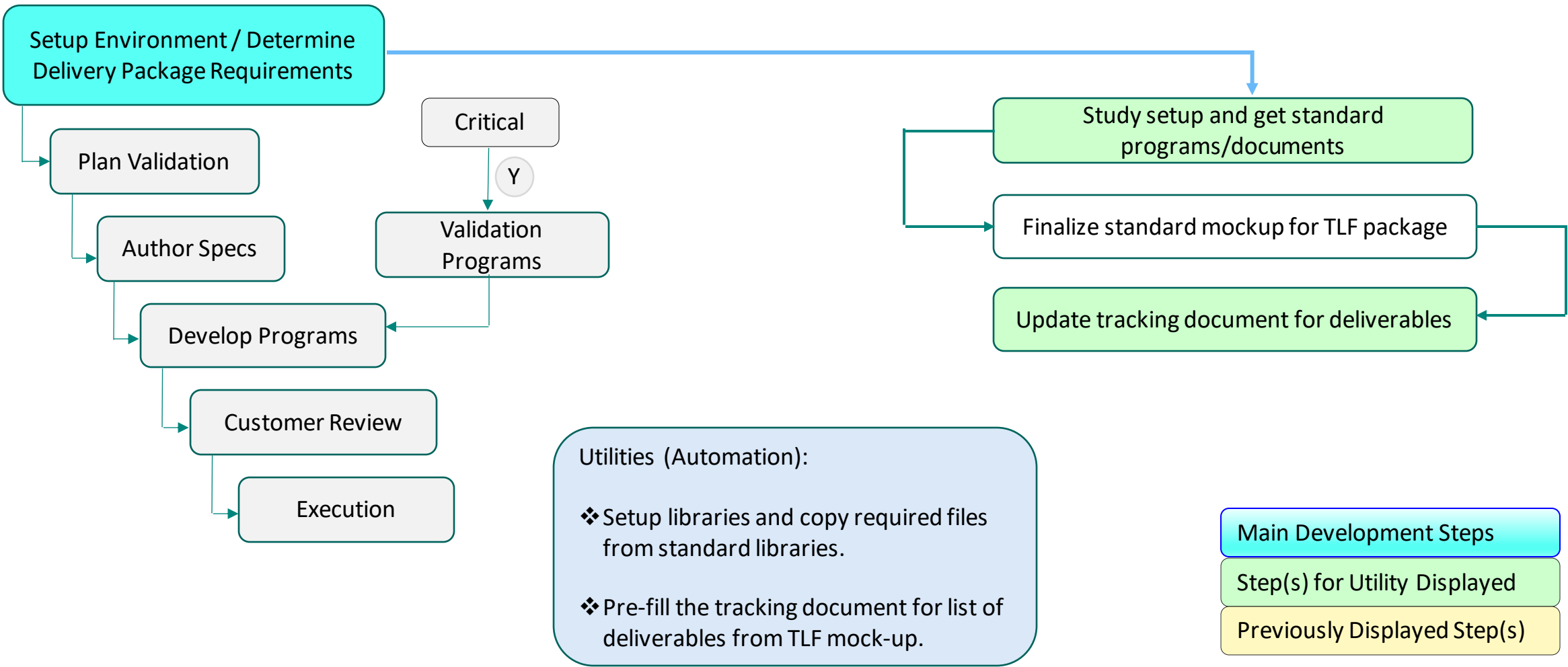


Analysis and Reporting (A&R) Process

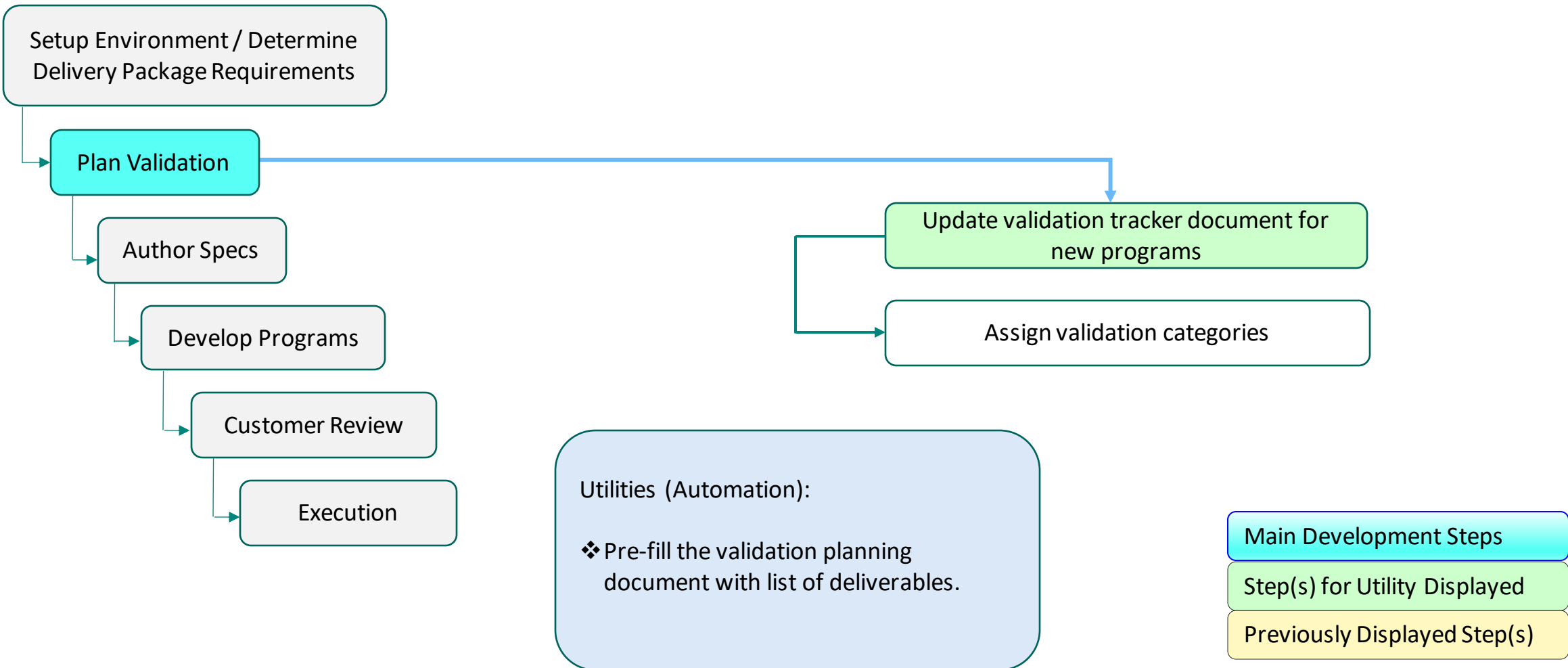


Main Development Steps

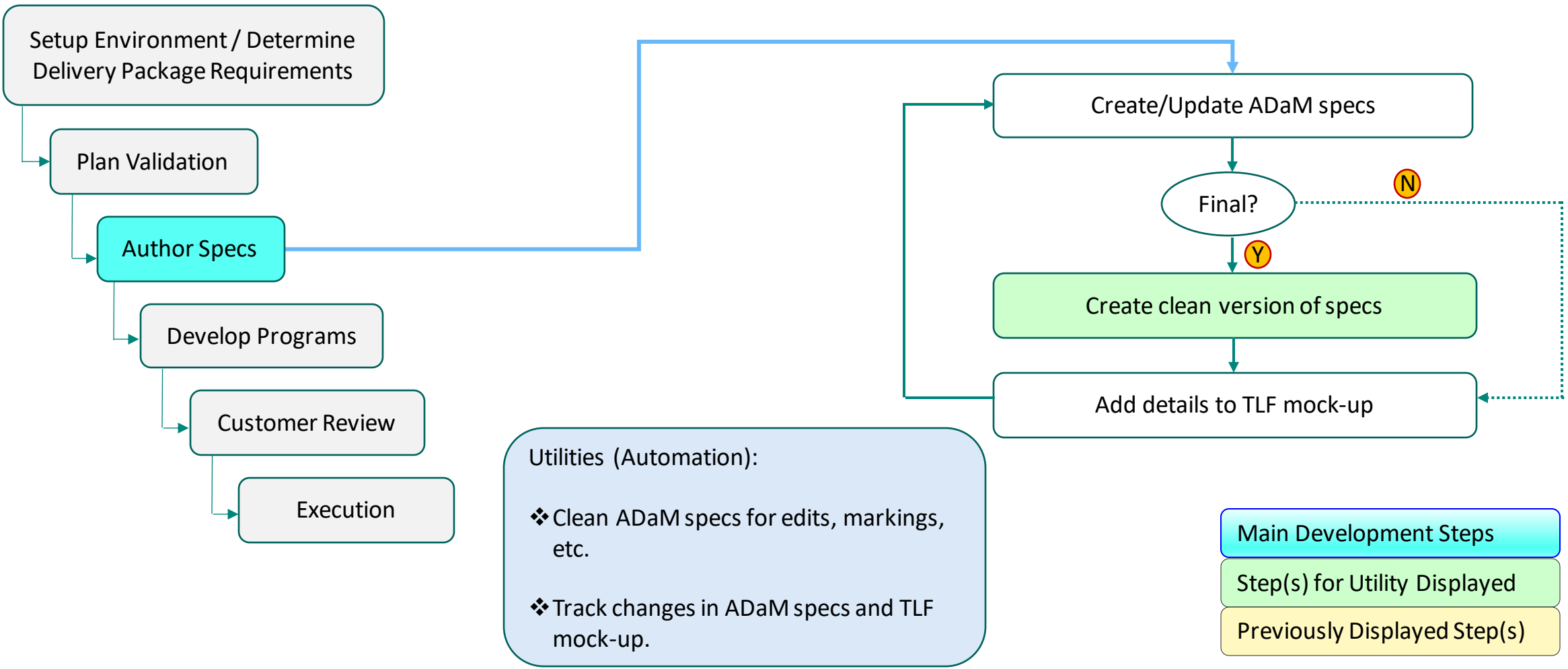
A&R Process : Study Setup



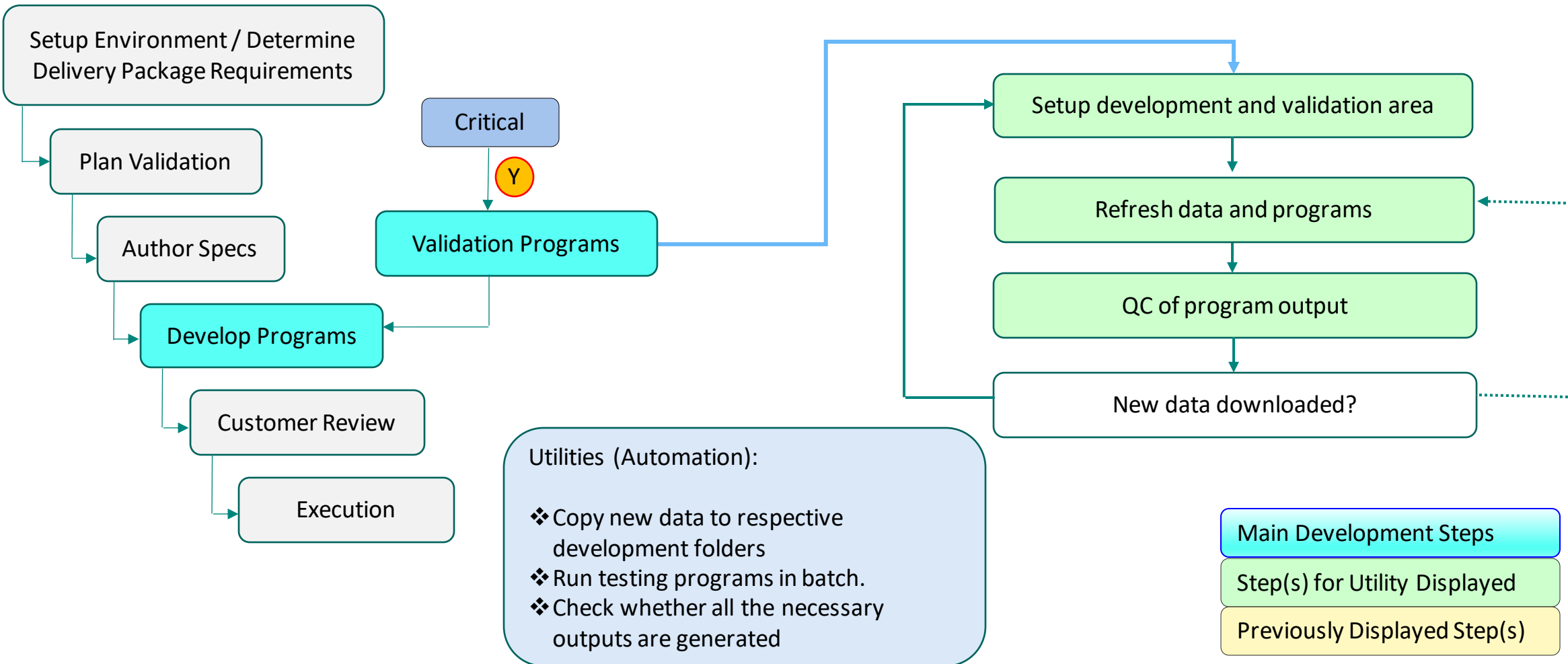
A&R Process : Plan Validation



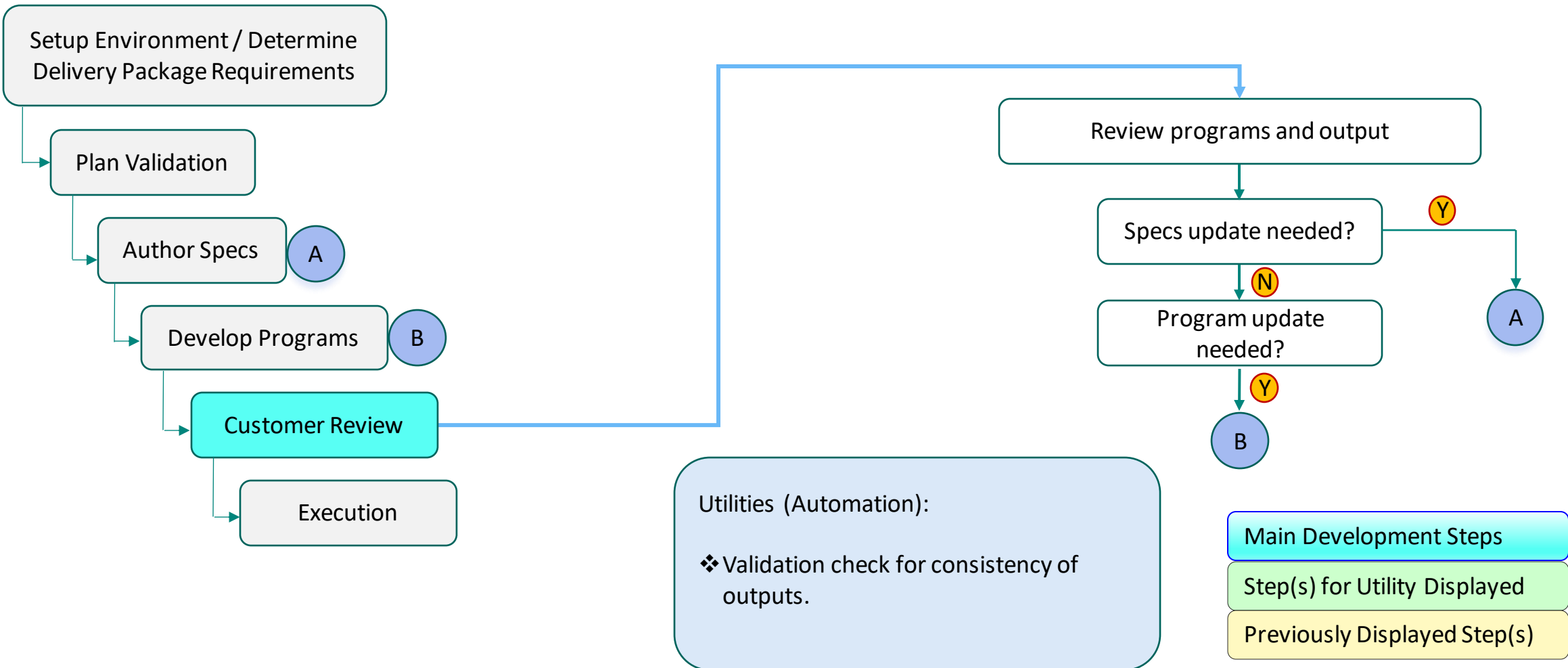
A&R Process : Author Specs



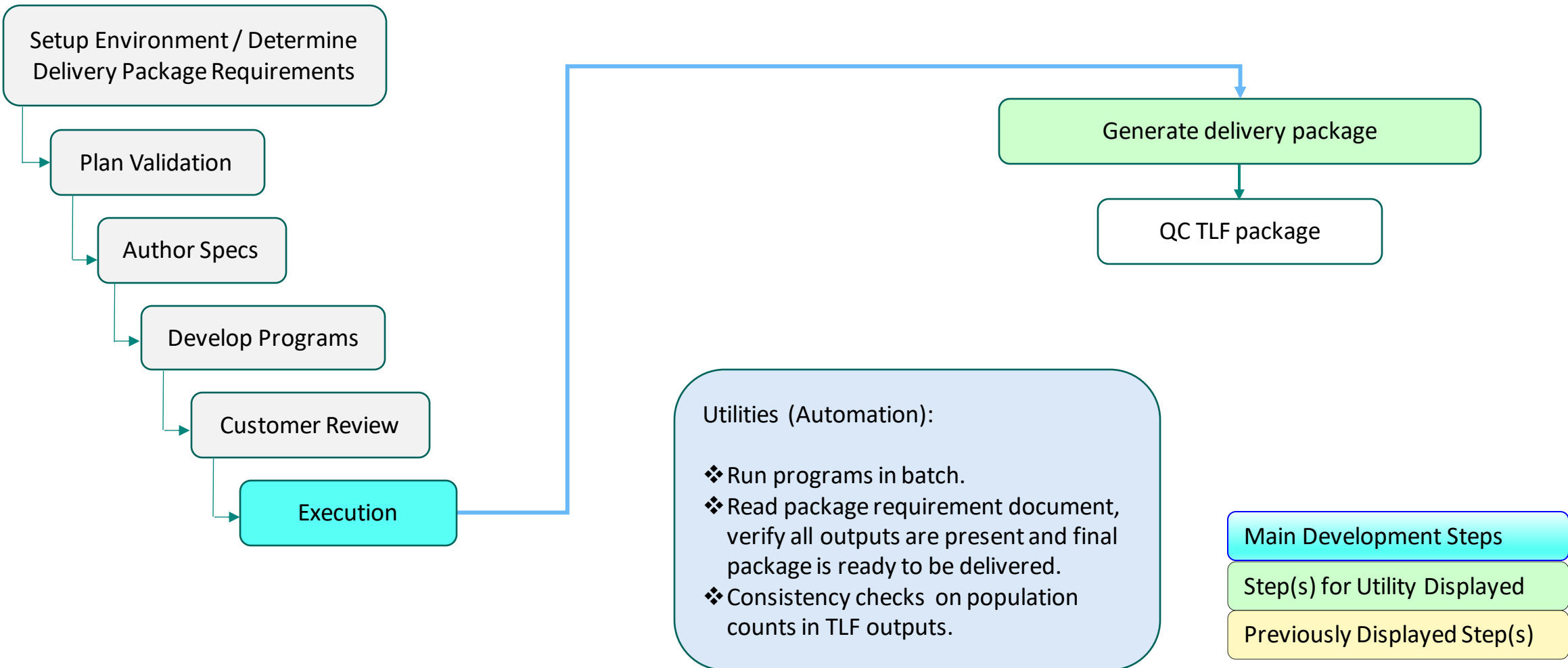
A&R Process : Development and Validation



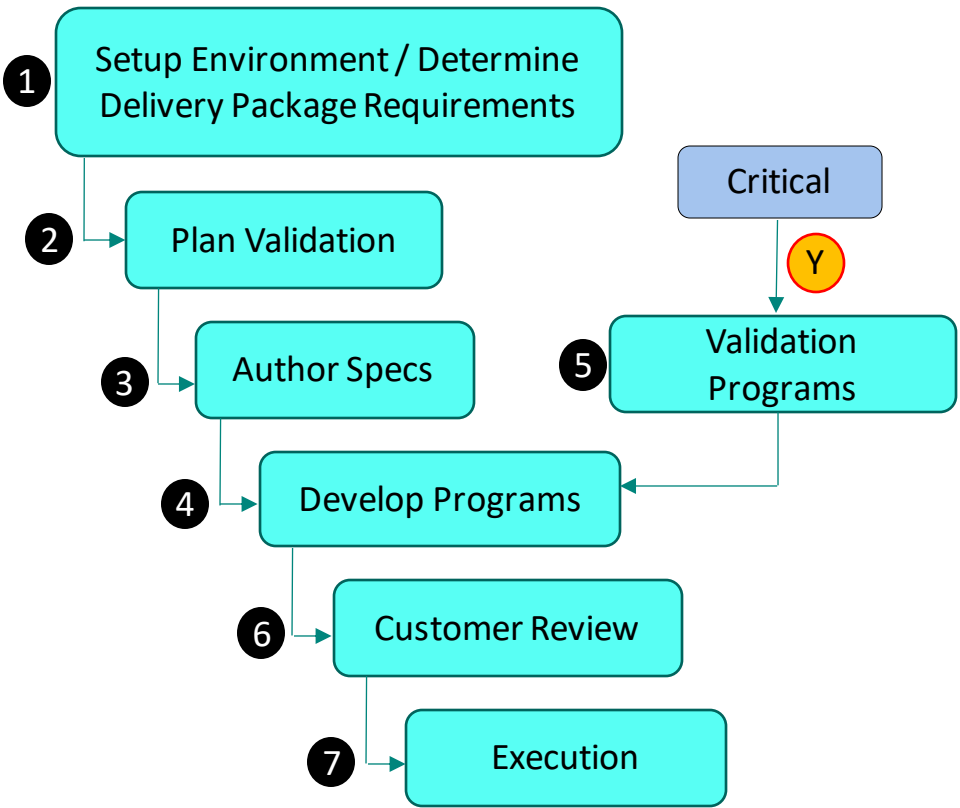
A&R Process : Customer Review



A&R Process : Execution



A&R Process : Metrics



Step No.	Automation	Metrics (time savings)
1	- Study setup - Identify requirements	~ 8 hr
2	Pre-fill validation tracker	~ 6 hr
3	- Track updates - Generate clean specs	~ 15 hr
4	- Setup environment - Refresh data - Run batch programs	~ 6 hr
5	- Refresh data - Run batch programs	~ 8 hr
6	Updates needed: Steps 3 and 4	~ 8 hr
7	- Run batch programs - QC outputs	~ 6 hr

Conclusion

- Maintain consistency with high quality deliverables
- Less chances of human error
- Efficiency increased with elimination of manual steps
- Significant time savings (60-80 hrs.) in one study cycle

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