

Requirement	Recommended Method	Expected Benefits
<b>Daily scrum</b>	Establish a daily 30-minute meeting to review task progress and priorities for the next five days. Reprioritize resources and tasks as needed.	Create a dynamic environment to adjust resources to focus on "value add" tasks that will accelerate progress.
<b>Customer Engagement</b>	Involve the customer in scrum meetings. Alignment and transparency are paramount for the success of NPI.	Make the customer part of the solution. The objective is continuous collaboration with the customer to assure expectations are met frequently.
<b>Minimize Formal Design Reviews</b>	Design reviews are a mechanism to lock down decisions and prevent further churn. In theory, design reviews are a formidable phase gate approval process and are a conduit for a robust QMS. However, in practice, design reviews can slow down NPI and create constraints for optimization. Minimize the number of formal design reviews during the NPI process.	Use the scrum environment to have frequent and informal design transfer reviews and make frequent changes to achieve optimal results. Formal design reviews should be limited to the end of the NPI process once customer expectations have been met.
<b>Smart ECOs</b>	Engineering change orders are great mechanisms to document changes to drive consensus and notification when changes are made. A pitfall that occurs often is driving multiple ECOs during the NPI process. Each ECO requires a great deal of effort and approval. Only issue an ECO at the end of the NPI process before serial manufacturing is approved to start.	Limiting the number of ECOs until a formal change has consensus by the team and customer will minimize the administrative burden in the NPI process. ECOs can slow down development when not used carefully.
<b>Process Validation</b>	Make process validation the cornerstone of your NPI process. Prepare a robust process validation plan to assure IQ, OQ and PQ stages have been completed thoroughly. The success of the design transfer to manufacturing relies on good process definition, well defined work methods, equipment testing, verification and validation of initial pilot builds.	Process validation is used in the life science industry as a fundamental process to achieve operational success in manufacturing. Guidance can be obtained via this link: <a href="https://www.fda.gov/media/71021/download">fda.gov/media/71021/download</a>