

FDA Process Validation Guide

Stage	Purpose	Activities
Process Design	Define commercial process based on knowledge gained through development and scale up activities Outcome: design a process for routine manufacture that will consistently deliver product meeting its critical quality attributes	<ul style="list-style-type: none">• Integrated product and process design• Product development activities• DOE combined with Risk Assessment to explore process parameters, variability, effect on quality attributes and process controls
Process Qualification	Confirm process design as capable of reproducible commercial manufacturing	<ul style="list-style-type: none">• Facility design• Equipment & utilities qualification• Performance qualification• Emphasis on use of statistically based sampling plans, statistically valid acceptance criteria and statistical analysis of process data to understand process consistency and performance
Continued Process Verification	Provide ongoing assurance that the process remains in a state of control during routine production through quality procedures and continuous improvement initiatives	<ul style="list-style-type: none">• Organized data collection every batch• Data trending and statistical analysis• Product review• Equipment and facility maintenance• Calibration• Management review and production• Employee feedback• Continuous improvement

Fda Validation Guide

L Darling-Hammond



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