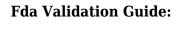
# FDA Process Validation Guide

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> <li>Integrated product and process design</li> <li>Product development activities</li> <li>DOE combined with Risk Assessment to explore process parameters, variability, effect on quality attributes and process controls</li> </ul>
Process Qualification	Confirm process design as capable of reproducible commercial manufacturing	<ul> <li>Facility design</li> <li>Equipment &amp; utilities qualification</li> <li>Performance qualification</li> <li>Emphasis on use of statistically based sampling plans, statistically valid acceptance criteria and statistical analysis of process data to understand process consistency and performance</li> </ul>
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> <li>Organized data collection every batch</li> <li>Data trending and statistical analysis</li> <li>Product review</li> <li>Equipment and facility maintenance</li> <li>Calibration</li> <li>Management review and production</li> <li>Employee feedback</li> <li>Continuous improvement</li> </ul>

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**Brendan G. Carr** 



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