




















Validation Steps *	Purpose & Activities *	Desired Outputs	Responsibility / Documents
 <div style="background-color: #f4a460; padding: 10px; text-align: center; border: 1px solid black;">5.1 Check Info</div>	<p>Locate information necessary for Startup</p> <p>5.1.1 Examine formula (or bill of materials) 5.1.2 Find set points & processing speed for startup from EMO Report 5.1.3 Locate Key Product Characteristics & Spec Limits 5.1.4 Start equipment when ready</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Set Points <input type="checkbox"/> KPCs and Spec Limits 	<p>Quality = </p> <p>Plant personnel Technical Services</p> <p> (Formulas)</p> <p></p>
<div style="background-color: #d8bfd8; padding: 10px; text-align: center; border: 1px solid black;">5.2 Plot Data</div>	<p>“See” how the process is doing</p> <p>5.2.1 Collect data acc. to Test Plan 5.2.2 Plot data 5.2.3 Verify no special causes of variability exist (trends, outliers) 5.2.4 Check centering & spread vs. Spec Limits 5.2.5 Use plots (Snee, Dot, Box) to see variability</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Data plots <input type="checkbox"/> Knowledge of which KPCs need improvement in centering or spread 	<p>Quality = </p> <p>Plant personnel Technical Services</p> <p> (Test Plan)</p> <p></p>
<div style="background-color: #ffff00; padding: 10px; text-align: center; border: 1px solid black;">5.3 Study Variability</div>	<p>Find & reduce sources of variability</p> <p>5.3.1 Brainstorm to discover factors. 5.3.2 Narrow down factors (Cause & Effect & problem solving methods) 5.3.3 Use ANOVA or Design of Experiments to analyze variations from fixed factors 5.3.4 Use Components of Variance to analyze variations from random factors 5.3.5 Relate variability factors to KPCs through Regression</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Factors responsible for excessive variation <input type="checkbox"/> Relationships between variability factors and KPCs 	<p>Quality = </p> <p>Plant personnel Technical Services</p> <p></p>
<div style="background-color: #add8e6; padding: 10px; text-align: center; border: 1px solid black;">5.4 Adjust (if necessary)</div>	<p>Optimize process for best process capability</p> <p>5.4.1 Use info from steps 2 & 3 to adjust set points and/or practices to lower variability 5.4.2 Use techniques in steps 2 & 3 to recheck process 5.4.3 Continue until variability well within Spec Limits and process appears stable</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Variability well within Spec Limits 	<p>Quality = </p> <p>Plant personnel Technical Services</p> <p></p>
<div style="background-color: #00ff00; padding: 10px; text-align: center; border: 1px solid black;">5.5 Control Limits & Process Capability</div>	<p>Confirm process is operating correctly & is capable of producing to specification</p> <p>5.5.1 Calculate Control Limits 5.5.2 Check Process Capability 5.5.3 Analyze Control Charts for further opportunity to reduce variability 5.5.4 Further refine process using techniques of steps 2 & 3 5.5.5 Recheck Control Limits & Process Capability until Cpk's for all KPC's ≥ 1.33 with $n \geq 30$</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Process stable & in control (SPC) <input type="checkbox"/> Control limits established <input type="checkbox"/> Process capable for all KPC's <input type="checkbox"/> Finalized SOPs 	<p>Quality = </p> <p>Plant personnel Technical Services</p> <p> </p>
<div style="background-color: #ffcccc; padding: 10px; text-align: center; border: 1px solid black;">5.6 Official Signoff</div>			
 <div style="background-color: #800080; padding: 10px; text-align: center; border: 1px solid black;">Ongoing Production</div>	<p>Provide evidence of process capability (regulatory and / or CP requirement)</p> <p>5.6.1 Run three commercial-sized lots in a row meeting spec and with Cpk's ≥ 1.33 5.6.2 PQ Report</p>	<ul style="list-style-type: none"> <input type="checkbox"/> 3 Commercial Lots meeting spec <input type="checkbox"/> Cpk ≥ 1.33 on all KPC <input type="checkbox"/> Bundle Book: PQ Report 	<p>Plant/ Tech Sv = </p> <p>Quality = </p> <p> </p>

* Note: depending on the situation, the order in which the validation steps and their respective activities are performed may vary