

➤➤ PROCESS VALIDATION LIFE-CYCLE



PROCESS DESIGN

Quality Attributes
Critical Process
Parameters
Risk Assessment
DoE



PROCESS QUALIFICATION

Equipment Qualification
Process Performance
Qualification
Training



CONTINUED PROCESS VERIFICATION

Monitoring Process
Parameters and Controls
Data Analysis
Corrective and Preventive
Actions

Process Validation A Lifecycle Approach

Leon Shargel, Andrew B. C. Yu



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