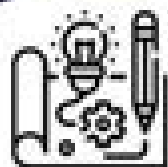


# ➤➤ PROCESS VALIDATION LIFE-CYCLE



## 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

**Murray P. Ducharme, Leon  
Shargel, Andrew B. C. Yu**



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