

➤➤ 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

Daniela Niemeyer

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buffers typically consist of an acid base pair with the acid and base differing by the presence or absence of a proton a conjugate acid base pair for instance one of the buffers that maintain the ph of human blood involves carbonic acid H_2CO_3 and its conjugate base the bicarbonate ion HCO_3^-

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