

<b>Validation Competencies List</b>	<b>QC CHEM</b>	<b>QC MICRO</b>	<b>MANUF UP</b>	<b>MANUF DOWN</b>	<b>MAINT</b>
<b>General Industry Knowledge</b>					
<b>Industry Overview</b>					
Understand the biomanufacturing and pharmaceutical industry, including understanding of the typical product development and manufacturing process, as well as the regulatory environment.	x	x	x	x	x
Appreciate the design and validation of biomanufacturing and/or other types of pharmaceutical manufacturing facilities.			x	x	x
Understand common materials of facility construction Knowledge of principles of adjacency and flow in pharmaceutical operations			x	x	x
Understand and apply principles of adjacency, flow, and product segregation in pharmaceutical operations.			x	x	x
<b>Validation</b>					
Understand principles of validation, commissioning, and qualification.	x	x	x	x	x
Execute IQ/OQ/PQ protocols for facilities and/or process equipment and/or laboratory equipment	x	x	x	x	x
Understand the principles involved in choosing key process parameters to validate and setting operational specifications.	x	x			
Understand the principles involved in validating new analytical methods					x

