Quality Assurance Competencies List	QC CHEM	QC MICRO	MANUF UP	MANUF DOWN	MAINT
Regulatory, Safety, and Environmental Compliance					
Regulatory (cGMP, FDA, etc..)					
Apply and understand batch records and related documentation.	x	x	x	x	x
Understand rationale and methodology for change control when revising documents or procedures.	x	x	x	x	x
Understand SOP writing practices.	x	x	x	x	x
Use of SOPs.	x	x	x	x	x
Understand the consequences of non-compliance.	x	x	x	x	x
Apply GMP documentation practices for recording data including not back dating documents, not forging, proper time/date format, documentation from source, and not falsifying data.	x	x	x	x	x
Ensure that all batch record steps are signed and verified by a present verifier.	x	x	x	x	x
Ensure that most recent version of SOP, batch record, or other document is used.	x	x	x	x	x
Understand working in a GLP environment.	x	x	x	x	x
Knowledge of typical types of documentation related to facilities and equipment. Examples include maintenance logs, calibration certificates, out of tolerence reports, and installation reports.	x	x	x	x	x
Knowledge of electronic documentation (control and data capture storage systems) practices.	x	x	x	x	x
Knowledge of the FDA 6 systems concept.	x	x	x	x	x
Knowledge of use and history of key regulatory guidance documents including 21 CFR Part 11, 210, 211, 600 Subparts A-D, Sterile Drug Products Prod. By Aseptic Proc., FDA Guidance August 2003, EC Guide on Good Mfg. Practice written by the European Commiss	x	x	x	x	x
Knowledge and use of the United States and European Pharmacopoeia.	x	x	x	x	
Knowledge of ISA and BPE standards.			x	x	x
Principles of ISO standards related to maintenance and repair functions			x	x	x