

TRAINING TOPICS/OUTCOMES

	Microbiology Quality Control Technician	Chemistry Quality Control Technician	Clinical Research Coordinator	Clinical Data Coordinator	Quality Assurance Associate	Drug Safety Associate	Regulatory Affairs Specialist	Regulatory Compliance Associate
Microbiological testing finished products	•							
Laboratory test methods & microbiology data analysis	•							
Calibrate/maintain testing equipment/inventory control	•							
Aseptic techniques & good laboratory practices (GLP)	•							
Quality assurance concepts/techniques	•							
Quality improvement tools	•	•					•	
Industry regulatory guidances & good documentation practices	•	•	•	•	•	•	•	•
Product testing & inspection	•							
Environmental monitoring & good laboratory practices (GLP)	•							
Validate data with written reports	•							
Apply good manufacturing practices	•						•	
Continuous improvement techniques	•						•	
Clinical trial team support & operational/logistical assistance			•	•	•			
Collect essential clinical trial data applying good clinical practices (GCP)			•					
Data entry, maintenance, queries/resolutions, verification			•					
Electronic data capture			•					
Clinical trial data oversight & support			•					
Laboratory & medical terminology			•	•	•			
Collect, maintain, & file clinical trial documentation				•	•			
Clinical trial oversight & support				•	•			
Trial master file oversight & support				•	•			
Drug safety management support						•		
Medical monitoring support						•		
SOP & regulatory compliance						•		
Triage incoming reports (complete, legible, valid)						•		
Safety & adverse event reporting						•		
Investigator, sponsor, monitor roles/responsibilities						•		
Inspect vendor products (stds/specs compliance)							•	
Inspect vendor facilities (stds/specs compliance)							•	
Submit audit reports (compliance, correctives)							•	
Coordinate & document internal regulatory processes								•
Assist in compile/prepare submission docs								•
Regulatory pathways/operations								•
Regulatory submissions/review process								•
Manage/integrate quality management program								•
Manage/integrate quality improvement program								•
Guidance/tech support for quality programs								•
Strategic planning for recalls								•
Industry-recognized 3rd party certification*								
CQIA	•	•	•	•	•	•	•	•
RAC	•							
OSHA 30	•	•					•	•
OSHA HAZWOPER40	•	•					•	•
CRCC				•	•			
CCDM			•					
CQA							•	

*Food Industry - specific options include CHA and PCQI certifications

