

# Contamination Control

	Validation	Control	Monitoring
Sanitization	Validation of Cleaning, sanitization and sporicidal treatments	Regular cleaning and sanitization of facilities and equipment	Environmental Monitoring (EM)
HVAC	Qualification of the Clean Room area and HVAC System	Certification and Preventative Maintenance (PM) of System; Repair of HEPA Filters	EM
Facility	Qualification of the Clean Room area and HVAC System	Maintenance of Facilities Sanitization; Revision of Barriers, Traffic Patterns, or Air Balance	EM
Equipment	Qualification of the Equipment as Suitable for its Intended Use	Certification and PM Regular Sanitization	EM Finished Product Release Testing
Process	Process Validation	Acceptance Testing of Raw Materials and Containers	In-process Bioburden Monitoring Finished Product Release Testing
Water	Qualification of Water System	Certification and PM Regular Sanitization of System	Bioburden Monitoring of Water System
Personnel	Proficiency Criteria Participation in Media Fills Trending Data by Operator	Training Discipline	Personnel Monitoring Trending Data by Operator