

We found microbial contamination in your clean room that exceeds Alert or Action Levels. Now what? The natural reaction is to clean and re-sample, but are you sure that will solve the problem? We share this checklist with you to help determine potential root cause and implement a meaningful corrective and preventive action.

Component	Question	Yes or No?	Observations
Human:	Were personnel properly gowned in the area?		
	Do gowning procedures ensure adequate coverage of skin and hair for the ISO classification, in order to prevent human contamination?		
	Are new sterile gowns donned upon entering controlled space?		
	Are gowning procedures up to date and followed?		
	Have gowning qualifications been performed on all employees in the area in question?		
Facility:	Are intake air filters or pre-filters clean and changed on an ongoing schedule?		
	Are room pressure differentials monitored and in specification that day?		
	Was room temperature and humidity within specification?		
	Was there any compromise to room integrity (ceiling tiles moved, floor paint chipped, etc.)?		
	Is there equipment in the room that might contribute to moisture and therefore microbial contamination (sinks, refrigerators, lyophilizer condensers, etc.)?		
	Is only one door allowed to open at the time between classification areas?		
Cleaning:	Are room cleaning records up to date and complete?		
	Was disinfectant properly prepared and applied?		
	Were disinfectant contact times met?		
	Were disinfectants appropriate for type of contaminant?		
	Is a sporicide rotated into the sterilization process? How often? When was the last time?		
Microbe:	Was microbial identification performed? If so, list them in comment. If not, explain why.		
	What does microbial contamination tell you about potential root cause?		
Process:	Was there any unusual activity in the room that day?		
	Are products and supplies disinfected before they are brought into clean room?		
	Is all cardboard and paper removed from product and supplies before they are brought into clean room?		
	Are training records up to date for all personnel in clean room?		
	Is powder weighed in containment hoods		
Impact:	Did product directly contact the source of the alert or action level (ie glove, air, surface)		

