Common TGA Laboratory Deficiencies

Clause(s)	What to look for.	Compliant? Y/ N
Training 2.10, 2.11	Is there a procedure that prescribes the requirements for operator training in sterility testing?	
	Does the current training process for analysts undertaking sterility testing specifically address the techniques or nuances associated with the testing of the range of products?	
	Are failed tests during analyst training reported, investigated and explained?	
	Have you implemented a system for ongoing re-qualification for sterile gowning including the actions required if gowning qualification requirements are not met?	
Test Method Validation 1.9(iii), 6.15, Annex 15 §22	Have all your test methods been validated?	
	Have you investigated, justified and recorded your reasons for repeating any failed validations including any modifications to the test?	
	Is the method for the microbiological testing of filtered ethanol used in aseptic sterility testing areas of your facility validated?	
Culture media and laboratory reagents 6.19, 6.21, 6.23	Have you conducted QC testing (growth promotion) on media received for the microbiological environmental monitoring of your facility?	
	Do you sterilise (irradiate) media used for environmental monitoring prior to use in the grade A/B areas?	
	Is there routine QC testing performed on semi-solid media that has been melted by microwave and is this process clearly defined in a procedure?	
OOS Management 1.4 (xiv) 1.8 (vii) 1.9(vi)	Does your procedure for microbial Out of Specification (OOS) results permit a single retest which, if passed, would allow acceptance of the product?	
	Have you established a statistically valid re-sampling plan for retesting activities?	

Clause(s)	What to look for.	Compliant? Y/ N
	Do you have a formal procedure in place to review and asses your products for the presence of objectionable organisms?	
	Have you fully recorded and investigated any OOS and conducted a thorough root cause analysis?	
Environmental Monitoring 1.9 (i) 4.29 6.7 (vi)	Have all your relevant rooms/areas been included in the routine environmental monitoring program?	
	Do you have scientific justification for the frequency of your environmental monitoring program?	
	Have the incubation conditions stated in the procedure for environmental monitoring plates been validated?	
	Is the specification applied to environmental monitoring scientifically justified?	
	Have microbial identifications been performed for environmental action limit breaches?	
	Do you require a heightened level of monitoring in the event of an action limit breach to verify the state of control?	
Data Integrity 6.7, Annex 1 §8 and §18	Do you check the accuracy of electronically produced records?	
	Are lab reports reviewed in a timely manner?	
	Are all raw data reports available to demonstrate that environmental monitoring has been performed as planned?	
	Are lab records being completed in real time?	