

Guidance Number: 065

Appendix 1

Knowledge Based Training Curriculum for APA and PAA Personnel

APA / APA Support and PAA / PAA Support	Additional Training for APA/PA Support Only
<i>Knowledge Based Training Topics</i>	
Job functions	
Gowning practices	
Personal practices including hygiene	
Elementary microbiology	
Principles of contamination control	
APA airlock/passthrough practices	
Manufacturing Process Overview	
	Aseptic techniques and practices
<i>Gowning Practices Training</i>	
Proper hand and arm washing and drying procedure, or use of sanitizer from dispenser	
Area dedicated shoes and use of shoe covers	
Articles needed for proper gowning	
Gowning room and degowning room practices	
	Demonstration by trainer on donning APA gowning articles
	Critique of trainee gowning and additional practices as needed
	Video tape of trainee during gowning practice
<i>Personal Practices Training</i>	
Personal hygiene	
Freshly cleaned uniform	
No jewelry except smooth wedding band	
No make-up, artificial nails or false eyelashes	
Proper hair covering, including facial hair	
Report apparent illness or open sores	

Classroom Training Curriculum for APA and PAA Personnel

<i>APA / APA Support and PAA / PAA Support</i>	<i>Additional Training for APA/PA Support Only</i>
<i>Aseptic Techniques and Practices Training</i>	
	Sanitization of gloves in the critical zone
	Prevention of contamination of sterile equipment containers, closures, in-process materials, intermediates, API and/or drug products
	Prevention of disruption of Laminar Airflow
	Simulation of APA activities
	Control of traffic and activity levels in the APA
<i>Elementary Microbiology</i>	
Viable and non-viable particulates	
Bacterial endotoxins	
Sources and spread of contamination	
<i>Principles of Contamination Control</i>	
Air Classification Grades A-D	
Sanitization program	
Roles of cleaning, sanitizing, sterilization and gowning in minimizing contamination	
Environmental Monitoring and control programs	
Personnel monitoring	
<i>APA Airlock Practices Training</i>	
	Staging materials for transfer into and out of the APA airlock
	Gowning requirements and glove sanitization
	Timing of APA airlock transfers
	Use of dedicated transfer cart
	Sanitization of materials to be transferred
<i>Visiting Personnel Procedures</i>	
Shoe cover use	
Supervision of gowning procedures by a qualified colleagues	
Visitor escort	