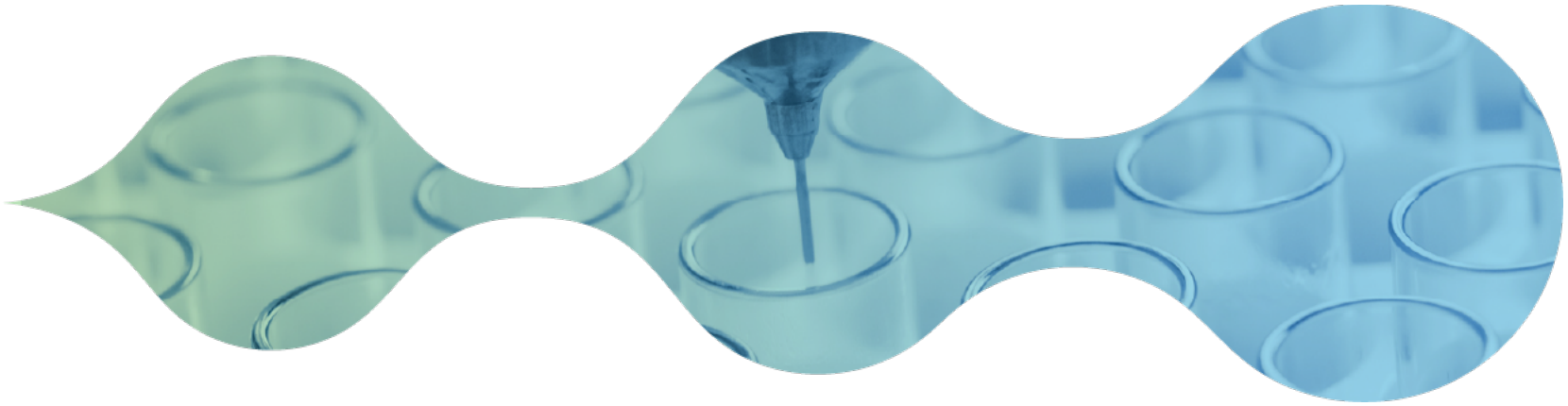
SfSAP
society for sterility assurance professionals

Pathways to develop expertise in different sterilization modalities by acquiring knowledge, skills, and experiences.

LEARNING FRAMEWORKS AND OUTCOMES

ASEPTIC PROCESSING STERILIZATION



VERSION 1.0-05-23

Aseptic Processing Sterilization Professional Learning Framework

DOCUMENT NUMBER: APSF001
Revision: 1

MODULE	KNOW What are the topics in this module that I need to know and understand?	APPLY How does an expert use (apply) this knowledge?	EXECUTE What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	DEMONSTRATE How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence	
Contamination control Cleaning, disinfection, and qualification CFR 211.113						Acknowledge Competence
Contamination control Personnel – gowning and qualification CFR 211.113						
Microbiology basics Identification, classification, and sources of microbiological isolates						
Sterilization, depyrogenation, and decontamination Steam sterilization						
Sterilization, depyrogenation, and decontamination Dry heat						
Sterilization, depyrogenation, and decontamination Sterile filtration						
Sterilization, depyrogenation, and decontamination Sterilization by gas, radiation, and other advanced techniques						
Sterility assurance principle Container closure integrity (CCI) and Container closure integrity testing (CCIT)						
Sterility assurance principle Aseptic Process Simulation (APS) ("Media Fills")						
Monitoring and testing Environmental monitoring (EM)						
Monitoring and testing Sterility testing (ST)						
Personnel Aseptic technique and personnel behavior (ATPB) (including first-air principles)						
Manufacturing Technologies Conventional filling (filling suites) and manual filling (CFMF)						
Manufacturing Technologies Advanced filling technologies (AFT) including isolators, RABS, closed vial, BFS, and robotics						
Manufacturing Technologies Other special aseptic processes: bulk materials, suspensions, lyophilization, medical device packaging, etc.						

Aseptic Processing Sterilization Professional Learning Outcomes

DOCUMENT NUMBER: APSO001
Revision: 1

This document is used in conjunction the **Aseptic Processing Sterilization Professional Learning Framework** above to define expected learning outcomes from each of the modules within the Learning Framework.

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Core Foundational Microbiology basics - Identification, classification, and sources of microbiological isolates

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of relationship between microbiological contamination control personnel practices. • Knowledge of typical sources and life cycles of microbes • Knowledge of the practical differences of various microbiological identification approaches • Knowledge of ways data can be trended and practically used • Knowledge of current regulatory expectations, current industry thinking, options, and practices on how microbiology laboratories can support manufacturing.	• Collaborates with microbiologists and other stakeholders to identify, evaluate, and reduce microbiological risks to facilities and products. • Provides practical input into the need for identifying microbiological isolates and the use of such information to prevent, reduce, or react to bioburden excursions and microbiological contamination. • Helps interpret regulatory requirements and expectations related to organism identification, classification, and trends. • Explains and promotes the proper use of relevant concepts and terms (e.g., SAL, PNSU, LRV, RNSU); corrects the misuse of such concepts and terms. • Utilizes and helps interpret trends derived from monitoring data. • Participates in regulatory meetings and discussions concerning production of sterile products and microbiological concerns.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Core Foundational Modalities of sterilization

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of the mode of action of sterilization modalities including steam, dry heat, radiation, ETO, chemical • Knowledge of the differences between different modalities • Knowledge of the limitations of modalities of sterilization • Knowledge of the appropriate applications of different modalities	• Describe how the sterilization modality works. • Describe the limitations of a modality and when it is most appropriate to use. • Matches process equipment, materials, and products to the most appropriate sterilization modality. • Participates in failure and troubleshooting discussions concerning sterilization methods and modalities. • Participates in regulatory meetings and discussions concerning production of sterile products and microbiological concerns.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Core Foundational Quality risk management (QRM)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Foundational knowledge concerning QRM, risk-based thinking • Skills in applying risk-based tools to aseptic processing (AP) issues. • Knowledge of aseptic processing in general, hazards, and process vulnerabilities. • Knowledge of specific aseptic processing operations of interest/in use. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to AP and CCS.	• Identifies, along with other stakeholders, where AP risk assessments would be useful, e.g., process suitability and performance, product sterility, investigations, and CAPAs. • Applies risk-based thinking and QRM to make decisions concerning aseptic processing (AP) including those related to contamination control strategies (CCS). • Provides risk-based guidance with other stakeholders related to AP risks, cleaning/disinfection, sources of contamination, etc. • Participates as an SME or leads risk assessments on aseptic processing and CCS. • Reviews and (may) approve completed risk assessments regarding AP for accuracy, completeness, and effectiveness. • Participates in regulatory meetings and discussions on AP QRM.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Core Foundational Deviation management, root cause investigations, CAPA

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of how quality management system (QMS) programs and processing systems affect aseptic processing (AP) and sterility assurance (SA). • Knowledge and skills in using various appropriate tools for root cause analysis. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to deviation management, change control, investigations, and CAPA.	• Provides input to AP deviation root cause investigations, potential root causes, corrections, resolution, and CAPA implementation and evaluation. • Provides input regarding impact of deviation or nonconformance on filled and in-process products and container closure systems. • Provides input and support in identifying and evaluating potential risks to AP and SA associated with CAPAs, changes, and trends. • Writes or contributes to final investigation report and change requests concerning AP. • Participates in regulatory meetings and discussion on AP-related investigations, CAPAs, and changes.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Core Foundational Regulatory inspections and audits

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Communicates technical information in a clear manner appropriate for situation. • Able to obtain data and information required to support an inspection or audit. • Knowledge of relevant current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to regulatory (e.g., preapproval, routine) inspections and quality audits.	• Answers questions and contributes AP/SA information to quality representatives, auditors, and health authority inspectors concerning products, processes, controls, and equipment. • Provides details in a clear, concise manner of the firm's contamination control strategy.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Aseptic technique and personnel behaviour (ATPB) (including first-air principles)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits and limitations of ATPB. • Strong knowledge of relationships between ATPB, contamination control, and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to ATPB.	• Provides input on the importance, value, and limitations of ATPB to sterility assurance of sterile dosage forms. • Applies risk-based assessments and thinking to identify potential risks and ways (controls) to reduce risks by using ATPBs. • Provides input and coaching on correct ATPBs to perform and incorrect ATPBs to avoid. • Provides training and coaching for clean room and aseptic processing personnel on first air principles, specific behaviors (e.g., minimizing movement and verbal communication, material/product handling) in order to minimize contamination. • Provides input on the frequency of training and personnel qualification, disqualification, and requalification regarding ATPBs. • Provides input for evaluation and responses to unplanned ATPB deviations, emergency interventions, and lapses in ATPB. • Provides input on what and how to include ATPBs into aseptic process simulations (“media fills”). • Participates in regulatory meetings and discussions concerning ATPBs.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Conventional filling (filling suites) and manual filling (CFMF)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits and limitations in using filling suites and manual filling operations. • Strong knowledge of relationships between conventional and manual filling activities, contamination control, and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to conventional and manual filling.	• Can explain the strategies for and limitations of decontamination, cleaning, and sterilization of facilities and equipment using different techniques and agents • Considers human factors (ergonomics), cleanability, equipment/HVAC placement, and personnel access so as to minimize contamination risks and deviations. • Can explain and evaluate air pressure cascades in filling rooms, interlocks. transfers, and "sinks". • Provides input on the design of automated, semi-automated, and manual filling equipment and the protocols used to qualify them. • Can help establish clean-up times, proper decontamination, and cleaning strategies for product contact equipment • Participates in regulatory meetings and discussions concerning CFMF approaches and activities.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Advanced filling technologies (AFT) including isolators, RABS, closed vial, BFS, and robotics

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of the capabilities, benefits and limitations of various AFTs. • Strong knowledge of relationships between AFTs, contamination control, and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to AFTs.	• Provides overviews and inputs on the availability, advantages/ disadvantages (benefits/ risks), processing, and implementation challenges of various AFTs in regards to that can contribute to selecting the appropriate technology and controls. • Explains regulatory expectations, potential issues, and options regarding AFTs. • Can identify and control risks related to transfer of materials to critical areas, e.g. transfer of resins and other materials into the BFS equipment. • Provides input on end-to-end risk assessments to identify potential risks and controls for AFTs. • Provides informed input on AFT equipment design, operation, cleaning, decontamination methods/agents, aseptic techniques, personnel behaviors, and qualification/validation. • Provides input on the impact of production requirements (volumes, single/ multiple products) on facilities, critical utilities, and personnel levels. Continued on next page		

Framework Category / Module - CONTINUED
Facility / operations / processing Advanced filling technologies (AFT) including isolators, RABS, closed vial, BFS, and robotics

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
	• Provides input on qualification, validation, routine testing, operation, cleaning, and changeovers of AFTs. • Provides input in the event of deviations and breaches of closed systems (e.g., glove failures), ways to respond their impact on product, and CAPAs. • Provides input on selecting AFTs considering factors such as return-on-investment (ROI), risk reduction, regulatory reviews and expectations. • Participates in regulatory meetings and discussions concerning AFTs.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Other special aseptic processes: bulk materials, suspensions, lyophilization, blow-fill-seal, medical device packaging, etc.

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of the fundamentals of all aspects of aseptic processing. • Strong knowledge of relationships between special aseptic processes, contamination control, and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to various types of special aseptic processing.	• Applies principles of identifying and controlling microbial risks to special applications of aseptic processing • Provides input in the event of deviations and breaches of special aseptic processing, ways to respond their impact on product, and CAPAs. • Participates in regulatory meetings and discussions concerning special aseptic processes.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Qualification and Validation

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of calibration, qualification and validation in an aseptic processing (AP) context. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to qualification and validation.	• Provides input to planning and performance of qualifications and validations of AP-related equipment and processes. • Provides input concerning process/product impact of equipment and instruments that have been used outside of their calibrated, qualified range. • Participates in regulatory meetings and discussions on AP-related calibration, qualification, and validation.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Clean room and critical area classification and performance

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of cleanroom classifications and how defined in different regions and standards. • Practical knowledge of operation of HEPA and HVAC systems used in classified areas. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to classified areas and activities performed/permitted in such areas.	• Describes and compares air classifications/room grades using regional-specific terms (e.g., grades, ISO classifications). • Assists in defining the correct/appropriate clean room classifications/operations to support AP process steps and personnel activities. • Provides input into design of rooms, support areas, transitions (i.e., airlocks, transfer portals) between different classification levels as well as placement of activities. • Assesses how clean room design contributes to the required cleanability and aseptic conditions. • Provides input into operation and monitoring of classified areas. • Ensures the area classifications are as defined and being maintained based on the markets being supplied, the equipment /processes, and activities that can and cannot be performed in such areas. • Provides input to design and placement of HEPA HVAC system using air flow visualization (smoke studies) • Contributes to user requirement specifications (URS) of classified areas; evaluates designs, installation, and operation of classified areas to URS.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Critical utilities

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of design, operation, and risks of CU systems. • Knowledge of testing and monitoring methods • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to CU.	• Identifies CU used to support cleanrooms and aseptic manufacturing processes (e.g., compressed air, inert gases [nitrogen, others], vacuum systems, water [WFI, purified], condensate removal, and cooling systems [for blow-fill-seal]). • Identifies risks of these CU systems that can potentially impact product sterility. • Defines appropriate methods for monitoring and controlling the CU systems. • Provides guidance on maintaining such systems so that they are properly identified (e.g., labels of what is in the lines and direction of flow), enter/exit cleanrooms or isolators, are qualified and validated (e.g., correct sloping of pipes, drainage; weld checks and identification of dead legs), and operate in a calibrated, well-controlled state. • Provides information and participates in investigations of CU deviations, CAPAs, and changes management. • Participates in regulatory meetings and discussions on CU design and monitoring.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Equipment design

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Practical knowledge of aseptic processing (AP) equipment, performance standards, their vulnerabilities to contamination, and controls. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to AP operational equipment.	• Assesses the AP needs and how full range of AP equipment, placement, operation, cleaning, disinfection, and maintenance contribute to aseptic conditions required to produce sterile products. • Identifies human factors/ergonomic issues of people/equipment interactions that could contribute to a sterility assurance (SA) risk to products. • Provides input for development of user requirement specifications (URS) for equipment. • Provides input into monitoring and testing needed to ensure proper performance of equipment and systems. • Provides input on potential equipment-related risks to SA and ways to control the risks. • Evaluates the final design, installation, and operation of equipment to URS. • Participates in regulatory meetings and discussion on AP-related related equipment and controls.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Flow of materials, personnel, waste

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of material and personnel flows in specific building configurations. • Knowledge of general risks and controls that exist regarding flow of materials, tools, equipment, personnel and waste. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to flows and movements into and within cleanrooms and critical areas.	• Assesses material and personnel designs and flows to prevent sterility assurance risks to aseptic processing (AP) and adjacent/surrounding areas, equipment, materials/components and products. • Provides input to various flow-related controls, including procedures and practices required to reduce sterility assurance risks to facilities, equipment, processes, and products. • Provides input and recommendations on procedures and practices for cleaning, decontamination, sterilization, including wrapping, holding, handling, and transfer of materials into cleanrooms. • Provides input and recommendations on procedures and practices for personnel gowning, entry into cleanroom, and working in critical zones. • Provides input on maximum/optimal number of personnel in a cleanroom and working in critical areas given HVAC and other controls. • Provides input in the event of air flow-related deviations/non-conformities. • Participates in regulatory meetings concerning flows of material and personnel.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Facility / operations / processing Air pressure differentials

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of the rationale behind air pressure differentials (APDs). • Practical knowledge and experience in designing, implementing, monitoring, and controlling APDs. • Knowledge of the limitations and potential risks associated with APDs. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to APDs.	• Provides input on the general principles and benefits of using air pressure differentials (APDs) in an aseptic processing (AP) facility. • Provides input on the regulatory and engineering requirements of APDs and the impact to the processing/cleanroom environment when APDs are functioning correct and incorrectly. • Provides input on strategies for APD and approaches for calibrating, monitoring, and controlling APD systems. • Provides input when designing APD controls in complex processing areas (e.g., AP of a high-potency product). • Provides input in the event of APD-related deviations/non-conformities. • Participates in regulatory meetings concerning APDs.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Cleaning, disinfection, and qualification CFR 211.113

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of relationship between microbiological contamination control and the use/ application of cleaning and disinfection materials and practices. • Knowledge of the current regulatory requirements and expectations concerning cleaning and disinfection. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to cleaning and disinfection.	• Provides practical input into the cleaning and disinfection program, including selection of materials (e.g., sporicides) their effectiveness/limitations proper handling, and how they are applied. • Provides input on materials (e.g., wipes, tools) used for applying cleaning and disinfecting agents • Provides input into the appropriate frequency of cleaning and disinfection based on testing/monitoring data and use of area or surfaces. • Can design a comprehensive program for cleaning and sanitization. • Provides input on methods to sanitize tools, equipment and materials that enter classified areas by ways other than autoclaves or sterilizing ovens. • Evaluates the effectiveness of the cleaning and sanitization program through qualification/validation and ongoing monitoring (sampling and testing) results. Continued on next page		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module - CONTINUED
Sterility Assurance Cleaning, disinfection, and qualification CFR 211.113

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
	• Provides subject matter expertise for cleaning/sanitization-related risk assessments related to aseptic manufacturing and related preparation tasks. • Provides input in the event of cleaning/sanitization-related deviations/non-conformities. • Participates in regulatory meetings concerning cleaning/sanitization.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Personnel – gowning and qualification CFR 211.113

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of relationship between microbiological contamination control and personnel practices. • Knowledge of the current regulatory requirements and expectations regarding the use of personnel in aseptic processing. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to the use of personnel in aseptic processing.	• Provides practical input into identifying the personnel-related hazards, vulnerabilities, impacts, and risks involved in aseptic production. • Provides practical input on personnel-related controls including gowning and aseptic technique so as to reduce the risks of contamination. • Differentiates between the different grades/room classifications and the types of gowning that are appropriate for each. • Provides input into selection / handling / cleaning / sterilization of uniforms gowns, goggles so as to minimize microbial (shedding), chemical, cross-, and non-viable particulate contamination. • Provides guidance into personnel training and qualification of gowning practices. • Provides subject matter expertise for gowning risk assessments. • Provides input in the event of gowning-related deviations/non-conformities. • Participates in regulatory meetings concerning gowning and gown training/qualification.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Steam sterilization

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of steam sterilization process and systems. • Strong knowledge of impact of steam sterilization on bioburden, components, and drug/biological products. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to steam sterilization.	• Provides input on the impact of steam sterilization on materials, equipment, and components in terms of quality, preparation (e.g., wrapping), storage, handling, logistics, inspection of items, and transfer of items being steam sterilized. • Provides practical input on the design and operation of steam-in-place systems, including condensate, sloping, and back pressure. • Provides practical input on the use of biological indicators, thermocouples, and indicator chemicals that could be used for qualification, validation, and routine monitoring. • Provides input into investigations and CAPAs in the event of a steam-sterilization related deviation or failure. • Participates in regulatory meetings and discussions concerning steam sterilization and microbiological concerns.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Dry heat

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of dry heat sterilization and depyrogenation process and systems. • Strong knowledge of impact of dry heat on bioburden, endotoxins, and components. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to dry heat sterilization/ depyrogenation.	• Provides input on the impact and risks of using dry heat sterilization/depyrogenation on equipment, glassware, and components in terms of quality, storage, handling, logistics, and transfer. • Provides practical input on the design and operational requirements of dry heat ovens, tunnels, and systems and the role of airflow patterns and temperature distribution. • Provides practical input on the use of biological indicators, thermocouples, and indicator chemicals that could be used for qualification, validation, and routine monitoring. • Provides input for development of loading patterns. • Provides input into investigations and CAPAs in the event of a dry heat related deviation or failure. • Participates in regulatory meetings and discussions concerning dry heat and microbiological and endotoxin concerns.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Sterile filtration

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of sterile filtration processes and systems. • Strong knowledge of impact of sterile filtration on bioburden and drug/biological products. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to sterile filtration.	• Provides input on the impact and risks of using sterile filtration on liquids and products in terms of quality, storage, handling, and transfer. • Provides input into investigations and CAPAs in the event of a sterile filter-related deviation or failure. • Provides input for process and compliance issues related to pre-use post sterilization [filter] integrity testing (PUPSIT). • Provides information on filtration pore size and ratings for products (e.g., 0.1, 0.22, 0.45, and combinations (including pre-filtration)). • Provides input for sterile filter and filter assembly interventions (PUPSIT) into aseptic processing simulations and routine use. • Provides input for the use of sterile filters in long run production campaigns, including sterile filter capacity and replacement strategies. • Participates in regulatory meetings and discussions concerning sterile filtration and microbiological and endotoxin concerns. Continued on next page		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Sterile filtration

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
	• Provides input for sterile filter validation (i.e., bacterial challenge testing (BCT)), integrity testing (IT), compatibility, E&L, absorption, surface area, size, clogging, and need (benefit and limitation) for redundant filtration. • Provides input for selection and use of sterile vent, compressed air, and gas filtration. • Provides input for filter membrane integrity testing (IT), including the methods, criteria (specifications), evaluation, and frequency of IT and the response should there be an IT failure. • Provides input for the sterilization of filters - effectiveness and 'damage' - steam in autoclave, sterilizing in place (SIP), gamma and risk-based decisions on vent filter IT. • Provides input into risk assessments, sterilization results analysis, excursions, deviation and on-conformity resolution, failure investigation, and CAPA implementation.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Sterilization by gas, radiation, and other advanced techniques

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of various approaches to sterilization. • Strong knowledge of impact of alternative/advanced sterilization techniques on equipment, bioburden, components, and drug/biological products. • Strong knowledge of residual gases, their potential impact on products, and how they are removed and monitored. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to use of alternative/advanced techniques.	• Provides input for the uses and limitations of the decontamination approach to the process, equipment, components, and product. • Provides input for handling, storage, hold times, wrapping/unwrapping of sterilized components, materials, surfaces, and equipment. • Provides input in determining the potential impact of alternative/advanced techniques on product quality, equipment, and personnel. • Provides input into the selection and qualification of third-party sterilization vendors. • Provides input for establishing qualification and validation of the process for the holding and transfer of components and products. • Provides practical input on the use of biological indicators and other approaches that could be used for qualification, validation, and routine monitoring. Continued on next page		

Framework Category / Module - CONTINUED
Sterility Assurance Sterilization by gas, radiation, and other advanced techniques

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
	• Provides input into risk assessments, validation protocols, investigations and CAPAs in the event of a deviation or failure. • Provides input on the selection and use of alternative/advanced techniques for specific applications. • Participates in regulatory meetings and discussions concerning alternative/ advanced sterilization techniques and microbiological concerns.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Container closure integrity (CCI) and Container closure integrity testing (CCIT)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits, and limitations of CCI/CCIT techniques and the relationship between microbiological contamination controls and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices related to CCI and CCIT.	• Provides input on the importance of CCI/CCIT in regard to sterility assurance of sterile dosage forms. • Provides input on CCI/CCIT mechanisms, test methods, acceptance criteria. • Provides input for CCI/CCIT monitoring, sampling, testing, qualification, and validation methods and the correlation to microbial ingress. • Provides input for conditions that impact or stress CCI/CCIT performance including product presentations (e.g., vials or blow-fill-seal) transportation, storage, manufacturing, and packaging. • Provides input for determination of appropriate test methods (i.e., high voltage leakage detection, laser-based headspace analysis, etc.), detection levels and limits in regards to product formulation, container-closure system, material used in the primary container, and other relevant factors. • Provides input for determining risk and potential problems regarding the impact to sterility assurance. Continued on next page		

Framework Category / Module - CONTINUED
Sterility Assurance Container closure integrity (CCI) and Container closure integrity testing (CCIT)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
	• Provides input for impact of change and change control on sterility assurance and product stability for changes to container closure system. • Provides input into risk assessments, validation protocols, investigations and CAPAs in the event of a deviation or failure. • Participates in regulatory meetings and discussions concerning CCI and CCIT.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Aseptic Process Simulation (APS) ("Media Fills")

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits, and limitations of APS methods and theories. • Strong knowledge of relationships between APS, contamination control, and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices regarding APS.	• Provides input on the importance, value, and limitations of APS to sterility assurance of sterile dosage forms and how APS fits into an overall validation program. • Provides input based on risk assessments to the objectives, design, frequency, execution, and evaluation of the APS program and specific APS's. • Provides input on media selection, inclusion of aseptic techniques and personnel behaviors, types and numbers of interventions, number of runs, process steps to include, conditions (worst-case or most challenging), line speeds, numbers of personnel to be involved, container closure configurations, and bracketing strategy (if used). • Provides input on filled-unit inspection approach, criteria for inclusion/ exclusion of media-filled units, incubation conditions (including time and temperatures), and other related criteria. • Provides input on APS acceptance criteria, evaluation methods of media-filled units post-incubation, investigations of deviations and failures, impact of an APS failure on released lots, and APS-related CAPAs. • Participates in regulatory meetings and discussions concerning APS.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Environmental monitoring (EM)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits, and limitations of EM strategies and methods • Familiarity with risk tools (e.g., HACCP) for establishing EM strategies. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices regarding EM.	• Explains classifications of different areas, the requirements (including EM) of such areas and activities that are appropriate to be performed in those areas. • Explains the differences when sampling and testing for viable and nonviable particles. • Explains the role of airflow (e.g., unidirectional airflow) and how airflow is linked to EM (positioning of the probes). • Discusses the differences between active (e.g., using a defined quantity of air in a time period) and passive (using settling agar plates and other techniques) air sampling. • Can apply risk assessment tools (e.g., HACCP) to identify appropriate sampling locations, sampling methods, and sampling frequencies. • Explains the advantages and disadvantages of these and alternative techniques such as rapid micro methods. • Recommends appropriate tests used to monitor viable and nonviable particulates based on the goal/strategy and process. • Provides input for monitoring plans for routine and non-routine sampling based on the area classification and the number of particulates allowed (i.e., specifications).		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Sterility testing (ST)

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of capability, benefits, and limitations of sterility testing strategies and methods. • Knowledge of the relationship between ST and microbiological contamination control and aseptic process performance. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices regarding ST.	• Explains the benefits, theory, limitations, and reliance on the sterility testing (ST) as an indicator of aseptic process control. • Provides input for the ST sampling plan (where samples are taken - beginning, middle, end) for sterility sampling. • Provides input on interpreting a ST failure and implications to products and product release. • Provides input into use and role of ST in risk assessments, decontamination results analysis, excursions, deviation and on-conformity resolution, failure investigation, and CAPA implementation. • Participates in regulatory meetings and discussions on ST product sterility assurance related matters, questions, and issues.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Regulations and standards

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Strong knowledge of current jurisdiction-applicable regulatory requirements (e.g., GMPs, guidelines), expectations, and trends related to aseptic processing (AP). • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, and practices (good and bad) related to aseptic processing.	• Considers current regulatory requirements and expectations related to AP when sharing information and making decisions. • Effectively communicates regulatory requirements, expectations, and trends to stakeholders. • Supports site self-audits and inspections. • Assists in setting AP user requirements and specifications along with procedures, operational standards, and qualification/validation protocols. • Evaluates AP facilities, processes, and operations against current requirements and expectations. • Provides recommendations for improvement to meet requirements and expectations. • Assists in developing positions and responses for regulatory filings (i.e., chemistry, manufacturing, and control [CMC]) and audit/inspectional observations and citations.		

Aseptic Processing Sterilization Professional Learning Outcomes

Framework Category / Module
Sterility Assurance Airflow pattern and visualization studies

Knowledge and skills required	Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Knowledge of the rationale behind airflows in aseptic processing (AP) areas. • Practical knowledge and experience in airflow visualization methods and related standards. • Knowledge of the limitations of airflow visualization studies. • Knowledge of current compendial requirements, regulatory expectations, and current industry thinking, options, video recording, interpretation, data handling, and other practices related to airflow visualization studies.	• Provides input into design/placement of equipment, processes and HVAC outlets and inlets to prevent contamination to product. • Provides input into environmental monitoring strategy and sampling locations based on airflow patterns. • Provides input into air visualization study strategies, protocols, procedures, frequency, criteria, and reports. • Assesses airflow patterns accurately and validly based on airflow visualization video recordings and images. • Provides input in the event of air flow-related deviations/non-conformities. • Participates in regulatory meetings concerning air flow patterns and visualization.		