

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 1 General Requirements	Facility and Personnel Specifications	SOP-102
	Good Pharmacy Documentation Practices Overview	SOP-104
	<ul style="list-style-type: none"> • Signature Log 	F-104.a
	Developing Standard Operating Procedures, Forms, and an Effective Change Control System	SOP-106
	<ul style="list-style-type: none"> • Master Table of Contents 	F-106.a
	<ul style="list-style-type: none"> • SOP Template 	F-106.b
	<ul style="list-style-type: none"> • Vertical Form Template 	F-106.c
	<ul style="list-style-type: none"> • Horizontal Form Template 	F-106.d
	<ul style="list-style-type: none"> • SOP/Form Change Request Template 	F-106.e
	Inspections and Communications from External Agencies	SOP-108
	<ul style="list-style-type: none"> • Inspection Guide Checklist 	F-108.a
	General Facility and Pharmacy Pest Control	SOP-110
	Management and Oversight of Outsourced Services	SOP-112
	<ul style="list-style-type: none"> • Quality Agreement 	F-112.a
	Section 2 Facility and Personnel Monitoring	Quality Management Considerations in Environmental Monitoring and Personnel Sampling
<ul style="list-style-type: none"> • Sample Environmental Viable Sampling Plan Diagram 		F-204.a
Viable Air Sampling		SOP-200
<ul style="list-style-type: none"> • Viable Air and Surface Sampling Log 		F-200.a
<ul style="list-style-type: none"> • Job Aid: Viable Air and Surface Sampling 		F-200.b
Surface Sampling		SOP-202
<ul style="list-style-type: none"> • Surface Sampling Log (combined with F-200.a) F-202.a retired 		F-202.a
Collecting Environmental Monitoring Samples		SOP-203
Airflow Considerations and Pressure Differential Monitoring		SOP-208
<ul style="list-style-type: none"> • Pressure Differential Log 		F-208.a
Temperature and Humidity Monitoring in Compounding and Controlled Storage Areas		SOP-210
<ul style="list-style-type: none"> • Temperature and Humidity Monitoring Log 		F-210.a
<ul style="list-style-type: none"> • Temperature and Humidity Correction Action Log 		F-210.b

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 2 Facility and Personnel Monitoring (continued)	Incubation and Inspection of Solid and Liquid Media for Microbial Growth	SOP-212
	Investigation and Remediation in the Event Sampling Exceeds Alert or Action Levels	SOP-205
	<ul style="list-style-type: none"> • Facility and Personnel Sampling Action Report 	F-205.a
	<ul style="list-style-type: none"> • Matrix of Actions for First-Time Excursions 	F-205.b
	<ul style="list-style-type: none"> • Matrix of Actions for Consecutive and Repeat Excursions 	F-205.c
Section 3 Sterile Compounding Facility Management	Facility Management Overview	SOP-300
	Certification and Preventative Maintenance of Sterile Compounding Controlled Environments and Related Equipment	SOP-302
	<ul style="list-style-type: none"> • Prefilter Maintenance Log 	F-302.a
	Total Particle Count Testing	SOP-303
	Sanitization of the Controlled Sterile Compounding Environments	SOP-304
	<ul style="list-style-type: none"> • Cleaning Solution Preparation Log for Agents Requiring Dilution 	F-304.a
	<ul style="list-style-type: none"> • Daily/Monthly Cleaning Log for Controlled Sterile Compounding Environments and Adjacent Areas 	F-304.b
	<ul style="list-style-type: none"> • Three-Time Cleaning Log for Sterile Compounding Controlled Environments 	F-304.c
	<ul style="list-style-type: none"> • Job Aid: Daily/Monthly Cleaning of Nonhazardous Sterile Compounding Controlled Environments 	F-304.d
	Material Handling	SOP-305
	Maintenance and Use of Compounding RABS (CAIs and CACIs)	SOP-306
	Actions in the Event of Unexpected or Planned Power Loss in a Sterile Compounding Facility	SOP-308
<ul style="list-style-type: none"> • Facility Power-Up Log 	F-308.a	
Section 4 Training, Conduct, and Competency of Sterile Compounding Personnel	Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding	SOP-404
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Sterile-to-Sterile Nonhazardous Compounding with Sink on Clean Side of Ante-room 	F-404.a
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Sterile-to-Sterile Nonhazardous Compounding with Sink on Dirty Side of Ante-room 	F-404.b

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 4 Training, Conduct, and Competency of Sterile Compounding Personnel (continued)	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Sterile-to-Sterile Nonhazardous Compounding with Sink Outside of Ante-room in Adjacent Space 	F-404.c
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Sterile-to-Sterile Nonhazardous Compounding for Segregated Compounding Area (SCA) with Sink Inside of the SCA but Outside of the Perimeter Line 	F-404.d
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Sterile-to-Sterile Nonhazardous Compounding for Segregated Compounding Area (SCA) with Sink Outside of the SCA that Is a Separate Room 	F-404.e
	Orientation, Training, and Competency Evaluation of Compounding Personnel	SOP-410
	<ul style="list-style-type: none"> • Training Roster 	F-410.d
	<ul style="list-style-type: none"> • Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding with Sink on Clean Side of Ante-room 	F-410.a
	<ul style="list-style-type: none"> • Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding with Sink on Dirty Side of Ante-room 	F-410.r
	<ul style="list-style-type: none"> • Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding with Sink Outside of Ante-room in Adjacent Space 	F-410.s
	<ul style="list-style-type: none"> • Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding for Segregated Compounding Area (SCA) with Sink Inside SCA but Outside Perimeter Line 	F-410.t
	<ul style="list-style-type: none"> • Competency Assessment: Hand Hygiene and Garbing for Nonhazardous Sterile-to-Sterile Compounding for Segregated Compounding Area (SCA) with Sink Outside SCA that Is a Separate Room 	F-410.u
	<ul style="list-style-type: none"> • Competency Assessment: Aseptic Technique and Conduct in Controlled Environments 	F-410.b
	<ul style="list-style-type: none"> • Competency Assessment: Sanitization of Nonhazardous Sterile Compounding Areas 	F-410.c
	<ul style="list-style-type: none"> • Competency Assessment: Material Handling 	F-410.e
	<ul style="list-style-type: none"> • Competency Assessment: Environmental Monitoring and Personnel Sampling 	F-410.f
	<ul style="list-style-type: none"> • Competency Assessment: Secondary Engineering Controls and Conduct in Controlled Environments 	F-410.g

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 4 Training, Conduct, and Competency of Sterile Compounding Personnel (continued)	• Competency Assessment: Use of Biological Safety Cabinets (BSCs)	F-410.h
	• Competency Assessment: Use of Restricted Access Barrier Systems (RABS) (CAIs and CACIs)	F-410.i
	• Competency Assessment: Use of Laminar Airflow Workbenches (LAFWs)	F-410.j
	• Competency Assessment: Final Release Tests (Sterility Testing — Membrane Filtration) Retired 10/28/19	F-410.k
	• Competency Assessment: Final Release Tests (Pyrogen Testing) Retired 10/28/19	F-410.l
	• Competency Assessment: Filter Integrity Testing (Bubble Point)	F-410.m
	• Competency Assessment: Automated Compounding Devices and IV Workflow Devices	F-410.n
	• Competency Assessment: Qualified • Evaluator	F-410.o
	• Competency Assessment: Reading Solid and Liquid Media for Microbial Growth	F-410.p
	• Competency Assessment: Use of Non-Compounding Equipment	F-410.q
	Gloved Fingertip Sampling	SOP-408
	• Job Aid: Best Practices for Personnel Sampling in LAFWs or BSCs	F-408.a
	Personnel Aseptic Media-Fill Testing and Process Verification	SOP-402
	• Personnel Sampling Log	F-402.a
	• Process Verification Unit Sampling Log	F-402.b
	Conduct of Personnel in Controlled Areas and Aseptic Technique Overview	SOP-412
Section 5 Component Inventory and CSP Handling	Inventory Storage, Handling, and Disposal Procedure	SOP-502
	• Component Disposal Log	F-502.a
	CSP Handling, Storing, Packaging, Shipping, and Transporting	SOP-508
	• CSP Delivery Verification Form	F-508.a
Section 6 General Sterile Compounding Process	CSP Stability and Assignment of Beyond-Use Dating	SOP-602
	• CSP Stability and Beyond-Use Dating Documentation Form	F-602.a
	Documentation of Compounding	SOP-603

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 6 General Sterile Compounding Process (continued)	<ul style="list-style-type: none"> • CSP Anticipatory Compounding Roster 	F-603.a
	<ul style="list-style-type: none"> • Example of Completed Compounding Record (This is a PDF example and not a template for use.) 	F-603.b
	<ul style="list-style-type: none"> • Example of a Master Formulation Record (that when used, becomes a Compounding Record) (This is a PDF example and not a template for use.) 	F-603.c
	Use of Conventionally Manufactured Products and CSPs as Components	SOP-604
	<ul style="list-style-type: none"> • USP 797 and CriticalPoint Guidance on Use of Compounded CSPs as Components 	F-604.a
	Use of Compounding and Compounding-Related Equipment	SOP-605
	Non-Automated Pooling Process	SOP-606
	Elastomeric Compounding	SOP-608
	CSP Labeling	SOP-610
	Considerations for Nonsterile-to-Sterile Compounding	SOP-612
	Sterilization and Depyrogenation	SOP-613
	Visual Inspection of Ingredients and Compounded Sterile Preparations	SOP-614
Section 7 Hazardous Drug Compounding	Hazardous Drug Employee Training and Safety Program	SOP-700
	<ul style="list-style-type: none"> • Hazardous Drug Acknowledgement of Risk 	F-700.a
	<ul style="list-style-type: none"> • Competency Assessment: HD Inventory Receiving 	F-700.b
	<ul style="list-style-type: none"> • Competency Assessment: Donning and Doffing PPE in HD Cleanroom Suites 	F-700.c
	<ul style="list-style-type: none"> • Competency Assessment: Donning and Doffing PPE in C-SCAs with Sink Outside the SCA 	F-700.h
	<ul style="list-style-type: none"> • Competency Assessment: Donning and Doffing PPE in C-SCAs with the Inside the SCA 	F-700.i
	<ul style="list-style-type: none"> • Compounding Assessment: HD Compounding 	F-700.d
	<ul style="list-style-type: none"> • Competency Assessment: Decontamination, Cleaning, and Disinfection of C-PECs and C-SECs 	F-700.e
	<ul style="list-style-type: none"> • Competency Assessment: HD Spill Management 	F-700.f
	<ul style="list-style-type: none"> • HD Assessment of Risk Template (moved to F-701.a) F-700.g retired 	F-700.g
	Performing an Assessment of Risk	SOP-701
	<ul style="list-style-type: none"> • Hazardous Drug List and AoR Designation Table Template 	F-701.a

Sterile Compounding Standard Operating Procedure Templates
Table of Contents

Section	Name of Standard Operating Procedure/Form	Document Number
Section 7 Hazardous Drug Compounding (continued)	<ul style="list-style-type: none"> • Categories of Alternative Containment Strategies and Work Practices Template 	F-701.b
	<ul style="list-style-type: none"> • Categories of Alternative Containment Strategies and Work Practices (Example only to show form use; PDF file not for use as a template.) 	F-701.c
	<ul style="list-style-type: none"> • Portion of an HD Drug List and AoR Designation Table (Example only to show form use; PDF file not for use as a template.) 	F-701.d
	Receiving Hazardous Drugs into Inventory	SOP-702
	Storage, Labeling, Packaging, and Transport of Hazardous Drugs	SOP-703
	Donning and Doffing Garb for Hazardous Drug Sterile Compounding	SOP-704
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Garbing for Entry to the HD Buffer Room with the sink on the clean side of ante-room 	F-704.a
	<ul style="list-style-type: none"> • Job Aid: Steps for Best Practice Doffing of Garb when Exiting an HD Buffer Room with the sink on the clean side of ante-room 	F-704.b
	Compounding and Material Handling in C-PECs and C-SECs	SOP-705
	Hazardous Drug Decontamination, Spill, and Waste Management	SOP-706
	<ul style="list-style-type: none"> • Hazardous Drug Spill Report Form Template 	F-706.a
Section 8 Quality Management	Quality Management System Overview for Facilities Compounding Sterile Preparations	SOP-802
	Corrective Action Preventive Action	SOP-803
	<ul style="list-style-type: none"> • Corrective and Preventive Action (CAPA) Plan Form 	F-803.a
	<ul style="list-style-type: none"> • Corrective and Preventive Action Tracking Log 	F-803.b
	Handling Customer Complaints	SOP-804
	<ul style="list-style-type: none"> • Customer Complaint Form (CCF) 	F-804.a
	<ul style="list-style-type: none"> • Complaint Tracking Log 	F-804.b
	Reporting Adverse Events	SOP-806
	Recalls and Quarantine	SOP-808
	<ul style="list-style-type: none"> • Recall Documentation Form 	F-808.a