Job Analysis

Compounded Sterile Preparations Pharmacy

September 2024

Board of Pharmacy Specialties®

Table of Contents

Executive Summary

The Board of Pharmacy Specialties (BPS) performed a job analysis, a multi-method approach into defining a job role or competency area in terms of the relevant tasks and associated knowledge areas, in 2024 to develop the content outline and other specifications for the specialty certification examination for pharmacists who specialize in compounded sterile preparations pharmacy. In accordance with relevant professional and accreditation standards, the study consisted of three major phases:

1. Definition of tasks and knowledge areas
2. Development, administration, and analysis of a survey
3. Finalization of the exam content outline

This report provides evidence for the exam content outline developed and its applicability to the compounded sterile preparations pharmacy specialty practice area. The outcome of this study was the creation of an examination blueprint that will be used to construct the compounded sterile preparations pharmacy specialty certification examination such that it aligns with the competencies identified and in equal proportions across all forms (versions) of the examination.

Examination Content Domains and Subdomains		
1	Compounded Sterile Preparations	**60%**
1A	Materials and Equipment	18%
1B	Compounding Process and Release	16%
1C	Facilities and Environmental Control	26%
2	Therapeutics and Patient Management	**15%**
2A	Therapeutic Implementation	8%
2B	Therapeutic Outcomes and Monitoring	7%
3	Professional Practice	**25%**
3A	Quality Management	15%
3B	Practice Management	10%

Introduction

The Board of Pharmacy Specialties (BPS) performed a job analysis in 2024 to develop the content outline and other specifications for the specialty certification examination for pharmacists who specialize in compounded sterile preparations pharmacy.

A job analysis[1], sometimes called a role delineation study or practice analysis in healthcare certification settings, is a multi-method approach to defining a job role or competency area in terms of the relevant tasks or work activities and the associated competencies (operationalized as knowledge, skills, and abilities) and/or other attributes. Indeed, job analysis can also be thought of as referring to a family of related approaches to establishing the foundations of content validity[2] for an assessment[3], in this case applied to the assessment of competencies associated with a specialty area in the licensed practice of pharmacy. A job analysis is considered a multi-method approach because it incorporates both qualitative and quantitative evidence in support of the definition the practice area in question. The job analysis consisted of three major phases:

1. Definition of tasks and knowledge areas, organized in a content outline format and completed by an assembled panel of qualified pharmacists who are currently engaged in compounded sterile preparations pharmacy
2. Development, administration, and analysis of a survey to other qualified pharmacists who are currently engaged in compounded sterile preparations pharmacy, requesting their ratings either endorsing the inclusion or exclusion of each task and knowledge area identified by the committee
3. Finalization of the exam content outline, completed by the assembled panel and with consideration given to the survey results to help determine the retention, discard, or editing of knowledge and task lists, as well as the relative weights assigned to each content area

The study described in this report was conducted according to the Standards for Educational & Psychological Testing[4] and applicable accreditation standards (NCCA[5] and ISO/IEC 17024[6]). The subsequent sections describe the methods, results, and outcomes of the study, complemented by appendices which describe the qualifications and professional characteristics of the subject matter experts who contributed to this study, the actual text of the survey administered, and the final exam content outline produced by this study.

[1] Sackett, P.R., Laczo, R.M. (2003). Job and Work Analysis. Handbook of Psychology.
[2] Cronbach, L.J., Meehl, P.E. (1955). Construct Validity in Psychological Tests. Psychological Bulletin, 52(4), 281-302.
[3] Kane, M.T. (2013). Validating the Interpretations and Uses of Test Scores. Journal of Educational Measurement, 50(1), 1-73.
[4] American Educational Research Association, the American Psychological Association, National Council on Measurement in Education. (2014). Standards for Educational & Psychological Testing.
[5] National Commission for Certifying Agencies. (2014). Standards for the Accreditation of Certification Programs.
[6] International Organization for Standardization, International Electrotechnical Commission. (2012). Conformity Assessment: General Requirements for Bodies Operating Certification of Persons.

1. Definition of Tasks and Knowledge

BPS assembled a panel that consisted of 19 subject-matter experts in compounded sterile preparations pharmacy, who were representative of the diversity of professional characteristics within the specialty with respect to practice setting, patient populations served, years of experience, and geographic dispersion within the United States. Four additional subject-matter experts in compounded sterile preparations pharmacy were interviewed individually on a 1-hour teleconference. See Appendix A for the qualifications and professional characteristics of the job analysis panel and interviewees.

The interviews took place on 28-31 June 2024. The interview questions focused on changes in the specialty area, key competency areas, and any limitations of the outgoing examination content outline that should be addressed by the job analysis.

The panel met via teleconference on two occasions to develop, define, and update the tasks performed and knowledge required to practice as a specialist in compounded sterile preparations pharmacy. The dates of the meetings were 3 and 26 June 2024.

On the first session, the panelists were oriented to the objectives of the study and the meeting, and then were presented a draft examination content outline and list of associated tasks that drew from the outgoing examination content outline and the interview notes. See Appendix B for the presentation used to orient the job analysis panelists.

The panel developed 21 task statements that describe the work activities performed by a compounded sterile preparations pharmacist.

1	Evaluate, establish, and/or align policies and procedures according to practice standards and regulatory and accreditation requirements
2	Evaluate and/or address inspection, survey, certification, and other assessment reports and findings
3	Participate in the design and evaluation of the facility layout and engineering controls
4	Ensure proper cleaning, disinfection, deactivation, and decontamination of engineering controls, equipment, materials, and compounding environments is completed
5	Ensure proper personal hygiene and garbing procedures are performed
6	Ensure usage and maintenance of compounding equipment is in accordance with manufacturer specifications and other standards
7	Specify requirements for equipment, supplies, active pharmaceutical ingredients, and other ingredients
8	Evaluate compounding components and consumables in accordance with manufacturer specifications and other requirements
9	Perform compounding and/or repackaging of sterile preparations in accordance with regulations, standards, and best practices
10	Ensure compounding and/or repackaging of sterile preparations is performed in accordance with regulations, standards, and best practices
11	Evaluate and remediate conditions that may present a risk to compounded sterile preparations and/or patients
12	Ensure proper quality checks and quarantine of compounded sterile preparations are performed before release or rejection of final product
13	Educate patients and healthcare professionals on compounded sterile preparations, including their administration and use
14	Evaluate, report, and/or address adverse events and out-of-specification events
15	Ensure competency of staff persons through training, assessment, and/or remediation of knowledge and skills
16	Participate in the design, implementation, evaluation, and maintenance of quality control, quality assurance, and process improvement programs
17	Ensure documentation and document retention is performed for all aspects of the compounding and quality control process
18	Ensure outsourced products and services comply with established process, standards, and regulatory requirements
19	Engage in professional development in compounded sterile preparations practice, such as professional advocacy, committee involvement, scholarly activities, and continuing education
20	Evaluate research literature and other published information to determine the quality and applicability to compounded sterile preparations
21	Collaborate with interdisciplinary professional teams to promote and optimize workplace and medication safety

The panel identified three content domains that describe the key high-level components of compounded sterile preparations pharmacy. Across the three content domains, the panel identified seven content sub-domains and developed 41 knowledge areas that describe specific job knowledge associated with the practice of compounded sterile preparations pharmacy. In some cases, the panelists wrote examples in parenthesis, which are meant to be non-exhaustive, to help better illustrate the intended scope of the knowledge area listed.

1	**Compounded Sterile Preparations**
1A	Materials and Equipment
1A1	Source Components (e.g., quality, storage, acceptance criteria, certificate of analysis, safety data sheet, visual inspection)
1A2	Compounding Equipment and Technology (e.g., robotic technology, automated compounding devices, balances)
1A3	Compounding Supplies
1A4	Containers and Closures
1A5	Handling Procedures for Components (e.g., receiving, material transfer, storage, transport)
1A6	Disposal Procedures
1A7	Sterilization Methods
1A8	Calibration, Verification, Validation, and Maintenance of Equipment
1B	Compounding Process and Release
1B1	Physicochemical Characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)
1B2	Compounding Documentation and Reproducibility (e.g., master formulation records, compounding logs, beyond-use dating)
1B3	Compounding Workflow (e.g., SOPs, workflow software, production queues)
1B4	Aseptic Technique and Appropriate Manipulations
1B5	Release Inspection and Testing
1B6	Handling Procedures for Compounded Sterile Preparations (e.g., receiving, material transfer, storage, transport, disposal)
1C	Facilities and Environmental Control
1C1	Primary and Secondary Engineering Controls
1C2	Particle Generation and Control
1C3	Specification of Compounding Equipment and Materials within Dynamic Conditions
1C4	Cleaning, Disinfection, Deactivation, and Decontamination of Environments and Equipment
1C5	Hygiene and Garbing (e.g., PPE, hand washing, personnel preparations)
1C6	Environmental Sampling, Monitoring, and Trending
1C7	Personnel Sampling, Monitoring, and Trending
1C8	Contingency Planning
1C9	Insanitary Conditions
2	**Therapeutics and Patient Management**
2A	Therapeutic Implementation
2A1	Patient-Specific Parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology)

2A2	Preparation-Specific Parameters (e.g., pharmaceutical chemistry, compatibility, chemical stability)
2A3	Medication Delivery and Administration (e.g., routes of administration, delivery devices, home infusion, patient education)
2A4	Interprofessional Care Coordination
2B	Therapeutic Outcomes and Monitoring
2B1	Therapeutic and Physiological Monitoring
2B2	Adverse Events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)
2B3	Medication Adherence
2B4	Infection Control
3	**Professional Practice**
3A	Quality Management
3A1	Safety Culture (e.g., error prevention, hazard communication, medical surveillance)
3A2	Professional Practice Requirements (e.g., personnel competency, media fill testing, gloved fingertip testing)
3A3	Quality Management and Process Improvement (e.g., root cause analysis, corrective and preventive action, continuous readiness)
3A4	Quality Control Programs
3A5	Inspection Methods
3A6	Product Recall Management
3B	Practice Management
3B1	Standard Operating Procedures
3B2	Literature Evaluation (e.g., research methods, statistics, applicability)
3B3	Regulations, Standards, and Guidelines related to Personnel and Patient Safety (e.g., OSHA, NIOSH, EPA, ISMP)
3B4	Regulations, Standards, and Guidelines related to Sterile Preparations (e.g., USP, FDA, CMMS, CDC, ASPEN, TJC)

The panel also helped create a definition of the compounded sterile preparations pharmacist, the target population for the BCSCP credential, and a statement describing the purpose of the BCSCP credentialing program.

The BPS Board-Certified Compounded Sterile Preparations Pharmacist (BCSCP) program is a credential for pharmacists who perform compounding of sterile preparations and oversee the compounding process in alignment with quality, safety, and environmental control requirements, regulations, and standards.
The purpose of the BPS Board-Certified Compounded Sterile Preparations Pharmacist (BCSCP) program is to validate that the pharmacist has the advanced knowledge, skills, and experience necessary to optimize the quality and safety of organizational processes and therapeutic outcomes related to medications that require sterile compounding.

The panel also refined a list of demographic questions to be provided to survey respondents which would help better understand the professional characteristics of the respondent sample, which is described in more detail in the next section.

Lastly, the panel engaged in a linkage analysis, which is an exercise to identify the inter-relationships among the knowledge areas and tasks. Each panelist was asked to individually develop a linkage matrix in which tasks are listed as columns and knowledge areas as rows, and an x-mark indicating that the knowledge area is required for performance of the task. Individual matrices were aggregated such that any proposed linkage (x-mark) by more than half of the panelists was counted in the final (consensus) linkage matrix.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1A1							X	X													
1A2	X		X	X		X	X														
1A3				X		X	X	X													
1A4							X	X													
1A5	X		X				X	X													
1A6	X		X				X	X													
1A7	X		X				X														
1A8	X		X	X		X	X														
1B1							X	X													
1B2	X						X		X	X		X					X				
1B3									X	X					X						
1B4	X								X	X					X						
1B5	X						X		X	X		X									
1B6	X								X	X					X						
1C1	X	X	X	X		X					X										
1C2	X	X	X	X							X										
1C3	X		X	X		X					X										
1C4	X	X	X	X		X															
1C5	X	X	X	X	X						X										
1C6	X	X	X	X							X						X				
1C7	X	X	X	X	X						X				X		X				
1C8			X								X			X							
1C9		X	X	X							X										
2A1													X								
2A2													X								X
2A3													X								X
2A4													X						X		X
2B1											X		X								
2B2											X		X	X							
2B3													X								
2B4				X							X										

3A1														X		X						X
3A2	X				X										X	X			X			
3A3	X	X									X	X		X	X	X	X					
3A4	X	X	X	X	X			X			X	X		X	X	X	X	X				
3A5	X	X		X							X	X		X		X						
3A6	X										X	X		X		X		X				
3B1	X	X	X	X	X	X		X	X	X		X		X	X	X	X					
3B2								X					X								X	
3B3	X	X	X						X	X	X					X	X	X				
3B4	X	X	X	X	X			X	X	X	X	X		X		X	X	X				

2. Survey Administration and Analysis

A survey was created for the purpose of soliciting ratings of endorsement from the larger practitioner population. Survey results are used to validate the appropriateness of the knowledge areas and tasks developed by the panelists and to inform content weighting decisions. The survey was developed with the following components:

- Description of the purpose of the survey
- Definition of the target population identified by the specialty practice area
- Respondent ratings of endorsement for the task statements
- Respondent ratings of endorsement for the knowledge areas
- Demographic questions that assess survey respondents' professional qualifications
- Open field for any additional comments

The ratings of endorsement from the survey respondents were solicited using two scales: Importance and Frequency. Each scale consists of a prompt for task statement, prompt for knowledge areas, and numerical responses with an associated text anchor (description).

Importance	How important is this task to compounded sterile preparations pharmacy practice? How important is this knowledge area to compounded sterile preparations pharmacy practice?
0	not at all / not applicable
1	of very little importance
2	somewhat important
3	moderately important
4	very important
5	critically important
Frequency	How frequently is this task performed in compounded sterile preparations pharmacy practice? How frequently is this knowledge used in compounded sterile preparations pharmacy practice?
0	not at all / not applicable
1	very rarely
2	rarely
3	occasionally
4	often
5	very often

The survey was pilot tested with a sample that consisted of the job analysis panelists, the specialty examination council, and BPS staff persons. The pilot test was conducted during the dates of 5-12 July 2024. Pilot testers did not identify any necessary changes. See Appendix C for a copy of the final survey text.

The survey was open and available from 23 July to 26 August 2024. All pharmacists who hold the BCIDP credential were directly invited via email to complete the online survey. The survey was also disseminated through the following affiliate organizations: American Society of Health-System Pharmacists and American College of Clinical Pharmacy.

The survey yielded 153 sable responses. Responses were not used if the survey was not completed or if the respondent indicated spending less than 50% of their pharmacy practice in compounded sterile preparations pharmacy.

Responses to Demographic Questions		
Percentage of Time in CSP Pharmacy	Mean = 79.0 | SD = 18.28	***n***
50		25
51 – 75		36
76 – 99		50
100		42
Post-Graduate Pharmacy Residency Programs		***n***
PGY1 Pharmacy		30
PGY1 Managed Care Pharmacy		6
PGY1 Community-Based Pharmacy		4
PGY2 Ambulatory Care Pharmacy		5
PGY2 Cardiology Pharmacy		7
PGY2 Clinical Pharmacogenomics		6
PGY2 Community-Based Pharmacy Administration and Leadership		7
PGY2 Corporate Pharmacy Administration and Leadership		5
PGY2 Critical Care Pharmacy		6
PGY2 Emergency Medicine Pharmacy		9
PGY2 Geriatric Pharmacy		2
PGY2 Health System Pharmacy Administration and Leadership		12
PGY2 Infectious Diseases Pharmacy		3
PGY2 Internal Medicine Pharmacy		4
PGY2 Investigational Drugs and Research		2
PGY2 Medication Use Safety and Policy		5
PGY2 Neurology		2
PGY2 Oncology Pharmacy		1
PGY2 Pain Management and Palliative Care Pharmacy		2
PGY2 Pediatric Pharmacy		2
PGY2 Pharmacotherapy		4
PGY2 Pharmacy Informatics		2
PGY2 Population Health Management and Data Analytics Pharmacy		3
PGY2 Psychiatric Pharmacy		2
PGY2 Solid Organ Transplant Pharmacy		3
PGY2 Specialty Pharmacy Administration and Leadership		2
Other: Drug Information Residency		1

BPS Certifications		*n*	
BCACP - Ambulatory Care		4	
BCCCP - Critical Care		7	
BCCP - Cardiology		3	
BCEMP - Emergency Medicine		8	
BCGP - Geriatric		5	
BCIDP - Infectious Diseases		9	
BCNP - Nuclear		7	
BCNSP - Nutrition Support		8	
BCOP - Oncology		6	
BCPP - Psychiatric		3	
BCPPS - Pediatric		5	
BCPS - Pharmacotherapy		6	
BCSCP - Compounded Sterile Preparations		117	
BCTXP - Solid Organ Transplantation		0	
Years of Experience as a Licensed Pharmacist	Mean = 15.71 | SD = 9.84	***n***	**%**
0-5		21	13.73%
6-10		38	24.84%
11-15		31	20.26%
16-20		25	16.34%
20+		38	24.84%
Years of Experience in CSP Pharmacy	Mean = 12.32 | SD = 9.28	***n***	**%**
0-5		38	24.84%
6-10		48	31.37%
11-15		27	17.65%
16-20		19	12.42%
20+		21	13.73%
Primary Practice Setting		***n***	**%**
Academic Institution / Educational Institution		7	4.58%
Academic Medical Center or Hospital		22	14.38%
Centralized Nuclear Pharmacy		3	1.96%
Children's Hospital		8	5.23%
Community Hospital		31	20.26%
Community Pharmacy		5	3.27%
Governmental Healthcare Facility / Veterans Affairs Hospital		13	8.50%
Home Infusion / Ambulatory Infusion		32	20.92%
Hospice		0	0.00%
Hybrid Academic-Community Hospital		0	0.00%
Integrated Health System / Accountable Care Organization		4	2.61%
Investigational Drug Service		1	0.65%
Long-Term Care Pharmacy		3	1.96%

Managed Care	3	1.96%
Outpatient Clinic / Ambulatory Clinic	6	3.92%
Outsourcing Facility (503b)	1	0.65%
Pharmaceutical Industry / Med Tech / Consulting	4	2.61%
Specialty Pharmacy	3	1.96%
Veterinary Medicine Facility	1	0.65%
Other	6	3.92%
Which FDA designation applies to your primary practice setting?	**n**	**%**
503a	96	62.75%
503b	13	8.50%
Both	14	9.15%
Neither	30	19.61%
Location of Primary Practice	***n***	**%**
AL	3	2.0%
AR	5	3.3%
AZ	4	2.6%
CA	11	7.2%
CO	4	2.6%
CT	1	0.7%
DE	1	0.7%
FL	9	5.9%
FM	1	0.7%
GA	6	3.9%
GU	1	0.7%
HI	2	1.3%
IA	1	0.7%
ID	3	2.0%
IL	7	4.6%
IN	3	2.0%
KS	1	0.7%
KY	2	1.3%
MA	4	2.6%
MD	2	1.3%
MI	4	2.6%
MN	2	1.3%
MO	4	2.6%
MT	1	0.7%
NC	7	4.6%
NE	1	0.7%
NJ	5	3.3%
NM	1	0.7%

NV	1	0.7%
NY	12	7.8%
OH	7	4.6%
PA	6	3.9%
RI	1	0.7%
SC	2	1.3%
TN	5	3.3%
TX	10	6.5%
VA	5	3.3%
WA	1	0.7%
WI	2	1.3%
WV	1	0.7%
Other	4	2.6%
Time Spent in Professional Role	***n*** **(>50%)**	**Average %**
Direct Patient Care	0	7.86%
Compounding of Sterile Preparations (e.g., activities in clean room)	18	22.42%
Operations Related to Compounding Process (e.g., verification, auditing)	11	23.47%
Administration / Management	25	26.54%
Consulting	2	6.21%
Sales / Commercial Activity	0	2.35%
Teaching / Precepting	3	7.95%
Research / Scholarship	0	2.56%

	Mean Ratings for Task Statements	Importance	Frequency
1	Evaluate, establish, and/or align policies and procedures according to practice standards and regulatory and accreditation requirements	4.37	3.99
2	Evaluate and/or address inspection, survey, certification, and other assessment reports and findings	4.39	3.67
3	Participate in the design and evaluation of the facility layout and engineering controls	4.05	2.86
4	Ensure proper cleaning, disinfection, deactivation, and decontamination of engineering controls, equipment, materials, and compounding environments is completed	4.56	4.54
5	Ensure proper personal hygiene and garbing procedures are performed	4.50	4.41
6	Ensure usage and maintenance of compounding equipment is in accordance with manufacturer specifications and other standards	3.90	3.63
7	Specify requirements for equipment, supplies, active pharmaceutical ingredients, and other ingredients	3.73	3.28
8	Evaluate compounding components and consumables in accordance with manufacturer specifications and other requirements	3.76	3.45
9	Perform compounding and/or repackaging of sterile preparations in accordance with regulations, standards, and best practices	4.29	4.08
10	Ensure compounding and/or repackaging of sterile preparations is performed in accordance with regulations, standards, and best practices	4.43	4.34
11	Evaluate and remediate conditions that may present a risk to compounded sterile preparations and/or patients	4.29	3.66
12	Ensure proper quality checks and quarantine of compounded sterile preparations are performed before release or rejection of final product	4.22	4.05
13	Educate patients and healthcare professionals on compounded sterile preparations, including their administration and use	3.48	3.09
14	Evaluate, report, and/or address adverse events and out-of-specification events	3.95	2.96
15	Ensure competency of staff persons through training, assessment, and/or remediation of knowledge and skills	4.41	3.99
16	Participate in the design, implementation, evaluation, and maintenance of quality control, quality assurance, and process improvement programs	3.84	3.27
17	Ensure documentation and document retention is performed for all aspects of the compounding and quality control process	4.04	3.97
18	Ensure outsourced products and services comply with established process, standards, and regulatory requirements	3.67	2.97
19	Engage in professional development in compounded sterile preparations practice, such as professional advocacy, committee involvement, scholarly activities, and continuing education	3.39	3.04
20	Evaluate research literature and other published information to determine the quality and applicability to compounded sterile preparations	3.50	3.13
21	Collaborate with interdisciplinary professional teams to promote and optimize workplace and medication safety	3.65	3.28

Mean Ratings for Knowledge Areas		Importance	Frequency
1	**Compounded Sterile Preparations**		
1A	Materials and Equipment		
1A1	Source Components (e.g., quality, storage, acceptance criteria, certificate of analysis, safety data sheet, visual inspection)	3.88	3.44
1A2	Compounding Equipment and Technology (e.g., robotic technology, automated compounding devices, balances)	3.50	3.30
1A3	Compounding Supplies	3.80	3.76
1A4	Containers and Closures	3.73	3.52
1A5	Handling Procedures for Components (e.g., receiving, material transfer, storage, transport)	3.85	3.71
1A6	Disposal Procedures	3.78	3.65
1A7	Sterilization Methods	3.00	2.41
1A8	Calibration, Verification, Validation, and Maintenance of Equipment	3.75	3.38
1B	Compounding Process and Release		
1B1	Physicochemical Characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)	3.67	3.27
1B2	Compounding Documentation and Reproducibility (e.g., master formulation records, compounding logs, beyond-use dating)	4.15	3.97
1B3	Compounding Workflow (e.g., SOPs, workflow software, production queues)	3.95	3.80
1B4	Aseptic Technique and Appropriate Manipulations	4.59	4.38
1B5	Release Inspection and Testing	3.57	3.24
1B6	Handling Procedures for Compounded Sterile Preparations (e.g., receiving, material transfer, storage, transport, disposal)	3.84	3.74
1C	Facilities and Environmental Control		
1C1	Primary and Secondary Engineering Controls	4.39	4.29
1C2	Particle Generation and Control	4.24	3.98
1C3	Specification of Compounding Equipment and Materials within Dynamic Conditions	3.95	3.61
1C4	Cleaning, Disinfection, Deactivation, and Decontamination of Environments and Equipment	4.45	4.35
1C5	Hygiene and Garbing (e.g., PPE, hand washing, personnel preparations)	4.53	4.50
1C6	Environmental Sampling, Monitoring, and Trending	4.17	3.97
1C7	Personnel Sampling, Monitoring, and Trending	4.19	3.90
1C8	Contingency Planning	3.73	2.90
1C9	Insanitary Conditions	4.24	3.30
2	**Therapeutics and Patient Management**		
2A	Therapeutic Implementation		
2A1	Patient-Specific Parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology)	3.29	3.24
2A2	Preparation-Specific Parameters (e.g., pharmaceutical chemistry, compatibility, chemical stability)	3.73	3.46

2A3	Medication Delivery and Administration (e.g., routes of administration, delivery devices, home infusion, patient education)	3.68	3.41
2A4	Interprofessional Care Coordination	3.12	3.03
2B	Therapeutic Outcomes and Monitoring		
2B1	Therapeutic and Physiological Monitoring	3.09	2.88
2B2	Adverse Events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)	3.52	3.07
2B3	Medication Adherence	2.94	2.61
2B4	Infection Control	3.77	3.35
3	**Professional Practice**		
3A	Quality Management		
3A1	Safety Culture (e.g., error prevention, hazard communication, medical surveillance)	3.96	3.74
3A2	Professional Practice Requirements (e.g., personnel competency, media fill testing, gloved fingertip testing)	4.31	4.12
3A3	Quality Management and Process Improvement (e.g., root cause analysis, corrective and preventive action, continuous readiness)	3.86	3.37
3A4	Quality Control Programs	3.81	3.50
3A5	Inspection Methods	3.68	3.36
3A6	Product Recall Management	3.65	2.81
3B	Practice Management		
3B1	Standard Operating Procedures	4.10	3.93
3B2	Literature Evaluation (e.g., research methods, statistics, applicability)	3.35	3.05
3B3	Regulations, Standards, and Guidelines related to Personnel and Patient Safety (e.g., OSHA, NIOSH, EPA, ISMP)	3.98	3.69
3B4	Regulations, Standards, and Guidelines related to Sterile Preparations (e.g., USP, FDA, CMMS, CDC, ASPEN, TJC)	4.14	3.92

An exploratory factor analysis[7] using maximum likelihood extraction and varimax rotation[8] was performed on the importance ratings provided for the knowledge areas. One primary factor emerged, with an eigenvalue of 18.09, that explained 44.12% of the variability in importance ratings. A second factor emerged, with an eigenvalue of 4.40, that explained 10.73% of the variability in importance ratings. The primary factor appeared had strong factor loadings with all the knowledge areas, whereas the secondary factor had strong factor loadings with the knowledge areas in content domain two; this suggests that the primary factor represents the total scope of CSP pharmacy while the second factor represents a focus on the patient care component exclusively. All subsequent factors had eigenvalues of 1.90 or less and each explained less than 4.64% of the variability in importance ratings. This provides additional evidence for the consistency of the knowledge areas developed and their applicability to the intended measurement construct.

[7] Thompson, B. (2004). Exploratory and confirmatory factor analysis: Understanding concepts and applications. American Psychological Association: Washington DC.
[8] Kaiser, H. (1958). The varimax criterion for analytic rotation in factor analysis. Psychometrika, 23(3).

3. Finalization of Exam Content Outline

The job analysis panel reconvened on 4 September 2024 via teleconference to review the results of the survey and to finalize the exam content outline.

The panelists reviewed the results of the survey demographic questions and deemed the respondent sample to be representative of the target population, which are pharmacists specializing in compounded sterile preparations pharmacy.

The panelists agreed to retain all the task statements developed as is. The panelists agreed to retain all the knowledge statements developed and made only one edit: The examples in the parenthesis for 1A2 were amended to exclude “robotic technology” and to include “IV workflow technology” and “repeater pumps.” The panelists discussed any tasks or knowledge areas with somewhat lower ratings and explained that some of the lower ratings may be due to the variability within the scope of practice (e.g., may be more applicable to home infusion than 503a) rather than indicating that a given task or knowledge area is not within scope.

Lastly, the panelists were tasked with determining the content weighting, the proportion of examination content to be distributed to each content domain and sub-domain. The sum of the mean criticality ratings for the knowledge areas in each domain was tabulated and compared against the sum of the mean criticality ratings for all knowledge areas.

	Content Domains and Subdomains of ECO	Criticality	Final Weight
1	**Compounded Sterile Preparations**		**60%**
1A	Materials and Equipment	100.27	18%
1B	Compounding Process and Release	89.47	16%
1C	Facilities and Environmental Control	147.32	26%
2	**Therapeutics and Patient Management**		**15%**
2A	Therapeutic Implementation	45.55	8%
2B	Therapeutic Outcomes and Monitoring	40.02	7%
3	Professional Practice		**25%**
3A	Quality Management	81.53	15%
3B	Practice Management	57.26	10%

See Appendix D for the final Examination Content Outline.

Appendix A – Subject Matter Experts

Name	Credentials	Years Post-Licensure Experience	Job Title	Employer/ Affiliation	Location	Practice Setting
Terrence Adams	PharmD, BCSCP	11	Pharmacist	US Marine Corps	FL	Community Hospital
Paul Baker	PharmD, BCSCP	17	Assistant Director, Quality Compliance and Regulatory Affairs	Mass. General Hospital	MA	Academic Medical Center/Hospital
Mallory Barron	PharmD, BCSCP	10	Pharmacist	Baptist Health Louisville	KY	Community Hospital
Charles Bovell	PharmD, MPH, BCSCP	4	Sterile Compound-ing Pharmacist	Ascension St. Vincent's Birmingham	AL	Community Hospital
Tamara Drahman	BS Pharmacy, BCSCP	39	Pharmacy Quality Assurance Manager	Option Care Health	IN	Infusion Pharmacy
Erica Garris	PharmD, BCSCP	20	CSP Program Manager	VA Nebraska-Western IA Health Care System	NE	Govern-mental Healthcare Facility
Kimberly Haverstick	PharmD, MBA, BCSCP	16	Director of Pharmacy	CARTI Cancer Center	AR	Community Hospital
Bryan Kudlawiec	PharmD, MBA, BCSCP	14	Director of Pharmacy	UPMC Chartwell	PA	Academic Medical Center/ Hospital
Savannah Mancuso	PharmD, BCSCP	5	Consultant Pharmacist	Prisma Health	SC	Academic Medical Center/ Hospital

Pamela Mathis	PharmD, BCSCP	18	Staff Pharmacist	Crisp Regional Hospital	GA	Community Hospital
Mary McGarry	PharmD, MS, BCSCP	30	Compliance Officer	US FDA	NH	Other
Andrew Meyer	PharmD, BCPS, BCSCP	11	Pharmacy Supervisor	OSF HealthCare	IL	Academic Medical Center/ Hospital
Cindy Mitman	PharmD, MBA, BCSCP	20	Pharmacist in Charge	Leiters Health	NJ	Pharma-ceutical Industry
Kembral Nelson	PharmD, MS, BSCSP	5	Pharmacy Medication Safety and Compliance Adminis-trator	Nationwide Children's Hospital	OH	Children's Hospital
Darren Stevens	PharmD, MBA, BCSCP, BPLA	16	Executive Pharmacist	Equashield	VA	Pharma-ceutical Industry
Tyler Vest	PharmD, MS, BCPS, BCSCP	8	Network Director of Pharmacy, Pharmacy Supply Chain	University of Vermont Health Network	VT	Academic Institution
Matt Wolf	PharmD, MS, BCSCP	12	Pharmacy Director	Atrium Health Wake Forest Baptist Medical Center	NC	Academic Medical Center/ Hospital
Nancy Woo	PharmD, BCSCP	16	Pharmacy Operations Manager	Children's Hospital of Orange County	CA	Academic Medical Center/ Hospital
Celeste Zizzamia	PharmD, BCSCP	20	Clinical Compound-ing Pharmacist	PCCA	CT	Consulting

Appendix B – Orientation Presentation

Job Analysis

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Job Analysis

A job analysis is often called a role delineation study or practice analysis in healthcare certification settings

The key points of inquiry in a Job Analysis are:

- ✓ **Definition of Target Population**
- ✓ **Tasks Performed**
- ✓ **Competencies Required**

The outcome is an exam content outline, which is used for creation of exams that reflect current practice and to identify to other stakeholders the scope of the exam

bps

Multi-Method Approach

Both quantitative and qualitative methods are used in an RDS, which helps bolster the defensibility of the process and outcomes

Qualitative
- Interviews with Practitioners
- Focus Group with Practitioners

Quantitative
- Survey Administration and Analysis

Here is what the process looks like in sequence

bps

Multiple Levels of Analysis

Consider how you would describe a job role to someone

All three levels help define the scope

But only the outer layer is the level at which an examinee is assessed

bps

Exam Content Outline

An ECO is a grouping of examination content areas in a hierarchical list

Exam Content Outline Structure and Components		(Somewhat Silly) Example
1	Content Domain	Chocolate
1A	Content Subdomain	History
1A1	Knowledge Area	Mesoamerican Usage
1A2	Knowledge Area	European Adaptation
1A3	Knowledge Area	Modern Production
1B	Content Subdomain	Types
1B1	Knowledge Area	Milk Chocolate
1B2	Knowledge Area	Dark Chocolate
1B3	Knowledge Area	White Chocolate

Domains:

The Major Aspects of Practice Area

Meaningful Divisions within the Domain

The Knowledge Assessed by Exam Items

Each of these should be written such that they can be preceded by the phrase "Knowledge of"

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Context Is Key

In addition to creation of an ECO, we will develop an inventory of task statements.

- These tasks identify the objectives and responsibilities of the role.
- These tasks provide the context in which the knowledge is applied.
- Tasks need not be grouped into content domains.
- Tasks will not be used to classify exam items nor determine what is tested.

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Linkage Analysis

A linkage matrix looks something like this

	1	2	3	4	5	6	7	8	9
1A1						x		x	
1A2					x				
1A3				x					x
1B1			x	x					
1B2			x				x		
1C1	x	x							
1C2		x					x		x

Purpose of the Linkage Matrix

- demonstrate which knowledge areas are required for each task
- demonstrate that the knowledge areas are indeed practice-based
- help identify gaps in either inventory
- help identify tasks or knowledge that are superfluous or out-of-scope

Helpful Hints

- An x-mark means that the specific knowledge is needed to perform that specific task.
- For example, knowledge of different types of chocolate is needed to *Develop Chocolate Recipes* but history of chocolate is not needed for that same task.

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Confidentiality

Although the outcomes of the Job Analysis will eventually be summarized in a public-facing document, please do not disclose information about our deliberations or work in progress

Any information other than that provided by BPS can give an unfair advantage or disadvantage to examinees, thereby threatening the validity of the exam

When asked about your involvement, simply direct prospective examinees and other stakeholders to official channels (BPS website) for information about the certification program

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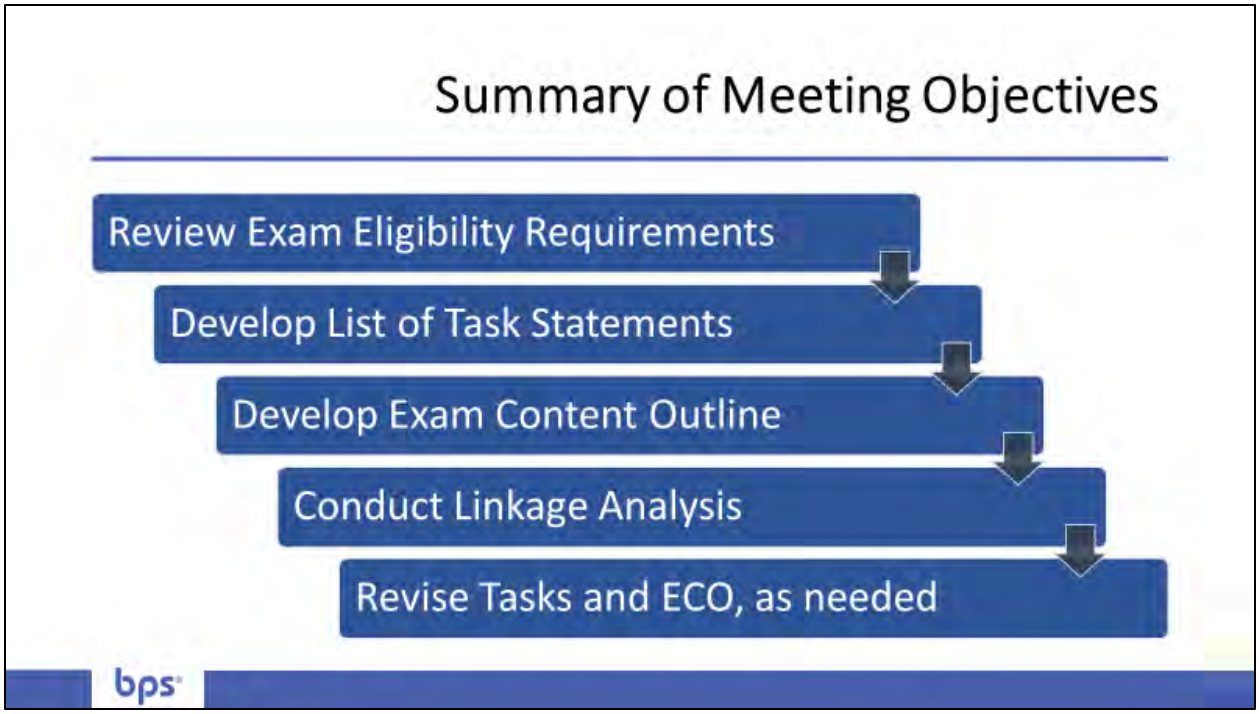

Appendix C – Survey Text

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BPS 2024 Compounded Sterile Preparations Pharmacy (BCSCP) Job Analysis Survey

Survey Introduction

The Board of Pharmacy Specialties (BPS) is conducting a Job Analysis for the Board-Certified Compounded Sterile Preparations Pharmacy (BCSCP) certification program to develop an updated examination content outline, which serves as a blueprint for the certification exam and the scope for recertification and eligibility purposes.

As part of this Job Analysis, we request your participation in this survey to provide ratings and feedback for the tasks and knowledge areas identified as representing current pharmacy practice in Compounded Sterile Preparations pharmacy.

Survey respondents will be prompted to rate each task and knowledge area on its importance to Compounded Sterile Preparations pharmacy practice and its frequency of use.

Additionally, respondents will be asked a few demographic questions to better understand the respondent sample's professional qualifications - but no personally identifiable information will be solicited.

Responses will only be reviewed in aggregate and will not be used for any other purpose than the Job Analysis.

Your participation is expected to take 15 to 30 minutes in total.

Those who complete the survey are eligible for entry into a raffle for one of ten $25 Amazon gift cards.

If you have any questions about this survey, please feel free to contact ja@aphanet.org.

Are you willing to participate in this survey and provide your responses to BPS?

◯ Yes

◯ No

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BPS 2024 Compounded Sterile Preparations Pharmacy (BCSCP) Job Analysis Survey

Task Statements

Please rate each task statement according to its importance to compounded sterile preparations pharmacy practice and the frequency of its performance in Compounded Sterile Preparations pharmacy practice.

	Importance	Frequency
Evaluate, establish, and/or align policies and procedures according to practice standards and regulatory and accreditation requirements		
Evaluate and/or address inspection, survey, certification, and other assessment reports and findings		
Participate in the design and evaluation of the facility layout and engineering controls		
Ensure proper cleaning, disinfection, deactivation, and decontamination of engineering controls, equipment, materials, and compounding		

environments is completed		
Ensure proper personal hygiene and garbing procedures are performed		
Ensure usage and maintenance of compounding equipment is in accordance with manufacturer specifications and other standards		
Specify requirements for equipment, supplies, active pharmaceutical ingredients, and other ingredients		
Evaluate compounding components and consumables in accordance with manufacturer specifications and other requirements		
Perform compounding and/or repackaging of sterile preparations in accordance with regulations, standards, and best practices		
Ensure compounding and/or repackaging of sterile preparations is performed in accordance with regulations, standards, and best practices		
Evaluate and remediate conditions that may present a risk to compounded		

sterile preparations and/or patients		
Ensure proper quality checks and quarantine of compounded sterile preparations are performed before release or rejection of final product		
Educate patients and healthcare professionals on compounded sterile preparations, including their administration and use		
Evaluate, report, and/or address adverse events and out-of-specification events		
Ensure competency of staff persons through training, assessment, and/or remediation of knowledge and skills		
Participate in the design, implementation, evaluation, and maintenance of quality control, quality assurance, and process improvement programs		
Ensure documentation and document retention is perfomed for all aspects of the compounding and quality control process		
Ensure		

outsourced products and services comply with established process, standards, and regulatory requirements		
Engage in professional development in compounded sterile preparations practice, such as professional advocacy, committee involvement, scholarly activities, and continuing education		
Evaluate research literature and other published information to determine the quality and applicability to compounded sterile preparations		
Collaborate with interdisciplinary professional teams to promote and optimize workplace and medication safety		

What task associated with compounded sterile preparations pharmacy is missing from this list, if any?

BPS 2024 Compounded Sterile Preparations Pharmacy (BCSCP) Job Analysis Survey

Knowledge Areas

Please rate each knowledge area in the Compounded Sterile Preparations: Materials and Equipment content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Source Components (e.g., quality, storage, acceptance criteria, certificate of analysis, safety data sheet, visual inspection)		
Compounding Equipment and Technology (e.g., robotic technology, automated compounding devices, balances)		
Compounding Supplies		
Containers and Closures		
Handling Procedures for Components (e.g., receiving, material transfer, storage, transport)		
Disposal Procedures		
Sterilization Methods		
Calibration, Verification, Validation, and Maintenance of Equipment		

Please rate each knowledge area in the Compounded Sterile Preparations: Compounding Process and Release content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Physicochemical Characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)		
Compounding Documentation and Reproducibility (e.g., master formulation records, compounding logs, beyond-use dating)		
Compounding Workflow (e.g., SOPs, workflow software, production queues)		
Aseptic Technique and Appropriate Manipulations		
Release Inspection and Testing		
Handling Procedures for Compounded Sterile Preparations (e.g., receiving, material transfer, storage, transport, disposal)		

Please rate each knowledge area in the Compounded Sterile Preparations: Facilities and Environmental Control content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Primary and Secondary Engineering Controls		
Particle Generation and Control		
Specification of Compounding Equipment and Materials within Dynamic Conditions		
Cleaning, Disinfection, Deactivation, and Decontamination of Environments and Equipment		
Hygiene and Garbing (e.g., PPE, hand washing, personnel preparations)		
Environmental Sampling, Monitoring, and Trending		
Personnel Sampling, Monitoring, and Trending		
Contingency Planning		
Insanitary Conditions		

Please rate each knowledge area in the Therapeutics and Patient Management: Therapeutic Implementation content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Patient-Specific Parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology)		
Preparation-Specific Parameters (e.g., pharmaceutical chemistry, compatibility, chemical stability)		
Medication Delivery and Administration (e.g., routes of administration, delivery devices, home infusion, patient education)		
Interprofessional Care Coordination		

Please rate each knowledge area in the Therapeutics and Patient Management: Therapeutic Outcomes and Monitoring content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Therapeutic and Physiological Monitoring		
Adverse Events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)		
Medication Adherence		
Infection Control		

Please rate each knowledge area in the Professional Practice: Quality Management content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Safety Culture (e.g., error prevention, hazard communication, medical surveillance)		
Professional Practice Requirements (e.g., personnel competency, media fill testing, gloved fingertip testing)		
Quality Management and Process Improvement (e.g., root cause analysis, corrective and preventive action, continuous readiness)		
Quality Control Programs		
Inspection Methods		
Product Recall Management		

Please rate each knowledge area in the Professional Practice: Practice Management content domain according to its importance to compounded sterile preparations pharmacy practice and the frequency of its use in compounded sterile preparations pharmacy practice.

	Importance	Frequency
Standard Operating Procedures		
Literature Evaluation (e.g., research methods, statistics, applicability)		
Regulations, Standards, and Guidelines related to Personnel and Patient Safety (e.g., OSHA, NIOSH, EPA, ISMP)		
Regulations, Standards, and Guidelines related to Sterile Preparations (e.g., USP, FDA, CMMS, CDC, ASPEN, TJC)		

What knowledge area associated with compounded sterile preparations pharmacy is missing from this list, if any?

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BPS 2024 Compounded Sterile Preparations Pharmacy (BCSCP) Job Analysis Survey

Survey Respondent Demographics

What percentage of your professional practice is spent in compounded sterile preparations pharmacy?

Which post-graduate pharmacy residency programs have you completed? Select all that apply and leave blank if none.

- [ ] PGY1 Pharmacy
- [ ] PGY1 Managed Care Pharmacy
- [ ] PGY1 Community-Based Pharmacy
- [ ] PGY2 Ambulatory Care Pharmacy
- [ ] PGY2 Cardiology Pharmacy
- [ ] PGY2 Clinical Pharmacogenomics
- [ ] PGY2 Community-Based Pharmacy Administration and Leadership
- [ ] PGY2 Corporate Pharmacy Administration and Leadership
- [ ] PGY2 Critical Care Pharmacy
- [ ] PGY2 Emergency Medicine Pharmacy
- [ ] PGY2 Geriatric Pharmacy
- [ ] PGY2 Health System Pharmacy Administration and Leadership
- [ ] PGY2 Infectious Diseases Pharmacy
- [ ] PGY2 Internal Medicine Pharmacy

- [ ] PGY2 Investigational Drugs and Research
- [ ] PGY2 Medication Use Safety and Policy
- [ ] PGY2 Neurology
- [ ] PGY2 Oncology Pharmacy
- [ ] PGY2 Palliative Care / Pain Management Pharmacy
- [ ] PGY2 Pediatric Pharmacy
- [ ] PGY2 Pharmacotherapy
- [ ] PGY2 Pharmacy Informatics
- [ ] PGY2 Population Health Management and Data Analytics Pharmacy
- [ ] PGY2 Psychiatric Pharmacy
- [ ] PGY2 Solid Organ Transplant Pharmacy
- [ ] PGY2 Specialty Pharmacy Administration and Leadership
- [ ] Other: please specify

Which BPS certifications do you currently hold? Select all that apply and leave blank if none.

- [ ] BCACP - Ambulatory Care
- [ ] BCCCP - Critical Care
- [ ] BCCP - Cardiology
- [ ] BCEMP - Emergency Medicine
- [ ] BCGP - Geriatric
- [ ] BCIDP - Infectious Diseases
- [ ] BCNP - Nuclear
- [ ] BCNSP- Nutrition Support
- [ ] BCOP - Oncology
- [ ] BCPP - Psychiatric
- [ ] BCPPS - Pediatric
- [ ] BCPS - Pharmacotherapy
- [ ] BCSCP - Compounded Sterile Preparations
- [ ] BCTXP - Solid Organ Transplantation

How many years of experience do you have as a pharmacist?

How many years of experience do you have in compounded sterile preparations pharmacy?

What is your primary practice setting?

- ◯ Academic Institution / Educational Institution
- ◯ Academic Medical Center or Hospital
- ◯ Centralized Nuclear Pharmacy
- ◯ Children's Hospital
- ◯ Community Hospital
- ◯ Community Pharmacy
- ◯ Governmental Healthcare Facility / Veterans Affairs Hospital
- ◯ Home Infusion / Ambulatory Infusion
- ◯ Hospice
- ◯ Hybrid Academic-Community Hospital
- ◯ Integrated Health System / Accountable Care Organization
- ◯ Investigational Drug Service
- ◯ Long-Term Care Pharmacy
- ◯ Managed Care
- ◯ Outpatient Clinic / Ambulatory Clinic
- ◯ Outsourcing Facility (503b)
- ◯ Pharmaceutical Industry / Med Tech / Consulting
- ◯ Specialty Pharmacy
- ◯ Veterinary Medicine Facility
- ◯ Other (please specify)

Which FDA designation applies to your primary practice setting?

- ◯ 503a
- ◯ 503b
- ◯ Both
- ◯ Neither

Where is your primary practice located?

State or Territory (if in United States)	-- select state --
Nation/Country	

What percentage of your time do you spend in each area?

Direct Patient Care	
Compounding of Sterile Preparations (e.g., activities in clean room)	
Operations Related to Compounding Process (e.g., verification, auditing)	
Administration / Management	
Consulting	
Sales / Commercial Activity	
Teaching / Precepting	
Research / Scholarship	

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BPS 2024 Compounded Sterile Preparations Pharmacy (BCSCP) Job Analysis Survey

Thank You

Please provide any feedback or comments about the survey here.

Those who complete the survey are eligible for entry into a raffle for one of ten $25 Amazon gift cards. If you would like to be entered into the raffle, please enter your email address below. Your email address will be used for the sole purpose of sending your gift card if you win.

Thank you very much for your interest and participation!

Appendix D – Exam Content Outline

1	**Compounded Sterile Preparations**	60%
1A	Materials and Equipment	18%
1A1	Source Components (e.g., quality, storage, acceptance criteria, certificate of analysis, safety data sheet, visual inspection)	
1A2	Compounding Equipment and Technology (e.g., IV workflow technology, automated compounding devices, balances, repeater pumps)	
1A3	Compounding Supplies	
1A4	Containers and Closures	
1A5	Handling Procedures for Components (e.g., receiving, material transfer, storage, transport)	
1A6	Disposal Procedures	
1A7	Sterilization Methods	
1A8	Calibration, Verification, Validation, and Maintenance of Equipment	
1B	Compounding Process and Release	16%
1B1	Physicochemical Characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)	
1B2	Compounding Documentation and Reproducibility (e.g., master formulation records, compounding logs, beyond-use dating)	
1B3	Compounding Workflow (e.g., SOPs, workflow software, production queues)	
1B4	Aseptic Technique and Appropriate Manipulations	
1B5	Release Inspection and Testing	
1B6	Handling Procedures for Compounded Sterile Preparations (e.g., receiving, material transfer, storage, transport, disposal)	
1C	Facilities and Environmental Control	26%
1C1	Primary and Secondary Engineering Controls	
1C2	Particle Generation and Control	
1C3	Specification of Compounding Equipment and Materials within Dynamic Conditions	
1C4	Cleaning, Disinfection, Deactivation, and Decontamination of Environments and Equipment	
1C5	Hygiene and Garbing (e.g., PPE, hand washing, personnel preparations)	
1C6	Environmental Sampling, Monitoring, and Trending	
1C7	Personnel Sampling, Monitoring, and Trending	
1C8	Contingency Planning	
1C9	Insanitary Conditions	
2	**Therapeutics and Patient Management**	15%
2A	Therapeutic Implementation	8%
2A1	Patient-Specific Parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology)	
2A2	Preparation-Specific Parameters (e.g., pharmaceutical chemistry, compatibility, chemical stability)	

2A3	Medication Delivery and Administration (e.g., routes of administration, delivery devices, home infusion, patient education)	
2A4	Interprofessional Care Coordination	
2B	Therapeutic Outcomes and Monitoring	7%
2B1	Therapeutic and Physiological Monitoring	
2B2	Adverse Events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)	
2B3	Medication Adherence	
2B4	Infection Control	
3	**Professional Practice**	25%
3A	Quality Management	15%
3A1	Safety Culture (e.g., error prevention, hazard communication, medical surveillance)	
3A2	Professional Practice Requirements (e.g., personnel competency, media fill testing, gloved fingertip testing)	
3A3	Quality Management and Process Improvement (e.g., root cause analysis, corrective and preventive action, continuous readiness)	
3A4	Quality Control Programs	
3A5	Inspection Methods	
3A6	Product Recall Management	
3B	Practice Management	10%
3B1	Standard Operating Procedures	
3B2	Literature Evaluation (e.g., research methods, statistics, applicability)	
3B3	Regulations, Standards, and Guidelines related to Personnel and Patient Safety (e.g., OSHA, NIOSH, EPA, ISMP)	
3B4	Regulations, Standards, and Guidelines related to Sterile Preparations (e.g., USP, FDA, CMMS, CDC, ASPEN, TJC)	