Achieving and Maintaining Excellence in Sterile Compounding: Innovative Techniques to Ensure Competency

Presented as a Midday Symposium and Live Webinar at the
49th ASHP Midyear Clinical Meeting and Exhibition

Tuesday, December 9, 2014
Anaheim, California

Action Reminder

Planned and conducted by ASHP Advantage and supported by an educational grant from Hospira, Inc.

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Agenda

11:30 a.m. – 11:35 a.m.	**Welcome and Introduction** John B. Hertig, Pharm.D., M.S., CPPS
11:35 a.m. – 12:00 p.m.	**A Novel Approach to Critical Elements of Aseptic Technique: A Matter of Safety** John B. Hertig, Pharm.D., M.S., CPPS
12:00 p.m. – 12:25 p.m.	**Strategies for Training Personnel to Assess Environmental Readiness: An Ongoing Process** Amy Benner, Pharm.D., BCPS
12:25 p.m. – 12:50 p.m.	**Case Study: Engagement of Staff to Ensure the Safe Preparation of Compounding Sterile Products** Cindy Chan, Pharm.D.
12:50 p.m. – 1:00 p.m.	**Faculty Discussion and Audience Questions** All Faculty

Food and beverage are no longer provided at Midday Symposia. This ASHP policy considers the varied internal policies of commercial supporters related to the Physician Payments Sunshine Act.

Faculty

John B. Hertig, Pharm.D., M.S., CPPS
Activity Chair
Associate Director, Center for Medication Safety Advancement
Clinical Assistant Professor of Pharmacy Practice
Purdue University College of Pharmacy
Indianapolis, Indiana

Amy Benner, Pharm.D., BCPS
Director, Central Pharmacy and Shared Services
Scripps Health
San Diego, California

Cindy Chan, Pharm.D.
Sterile Compounding Manager
Providence Infusion and Pharmacy Services
Tukwila, Washington

Disclosure Statement

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Activity Overview

This educational activity will provide examples of effective ways to engage staff and ensure competency in sterile compounding. Innovative ways to train the pharmacy workforce on topics from the basic tenets of aseptic technique to environmental monitoring and beyond will be described. The activity will conclude with a case study highlighting the impact of staff development on patient safety.

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Review basic components of aseptic technique and environmental monitoring and describe why ongoing training in these areas is critical for patient safety.
- Illustrate innovative training techniques that can be used with iv cleanroom staff.
- Describe ways to engage staff in the processes for maintaining, monitoring, and testing a clean room environment.
- Review quality assurance measures for a facility that complies with USP standards.

Your educational opportunities related to maintaining excellence in sterile compounding extend beyond today's symposium…

- **Available in 2015**
    - **On-demand activity** based on today's live symposium (1.5 hours of CPE, please note that individuals who claim CPE credit for the live symposium or webinar are ineligible to claim credit for the on-demand activity)

For more information and to sign up to receive e-mail updates about this educational series, visit

www.ashpadvantage.com/ivcompentency

Continuing Education Accreditation

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1.5 hours (0.15 CEUs – no partial credit) of continuing pharmacy education credit (ACPE activity #0204-0000-14-707-L05-P for the live activity and ACPE activity #0204-0000-14-707-H05-P for the on-demand activity).

Complete instructions for receiving your statement of continuing pharmacy education credit online are on the next page.

Webinar Information

Visit www.ashpadvantage.com/ivcompetency to find

- Webinar registration link
- Group viewing information and technical requirements

ACTION REMINDER EMAIL

Have ideas about what YOU want to remember to do as a result of what you are learning in this educational session? Use the Action Reminder tool via your smart device, and you will be sent an email reminder from YOURSELF next month.

If you do not have a smart device, access the Action Reminder for this activity at www.ashpadvantage.com/go/ivcompetency/remindme

CPE Instructions for Pharmacists and Technicians

Per ACPE, CPE credit must be claimed **no later than 60 days** from the date of the live activity or completion of a home study activity. All ACPE-accredited activities processed on the eLearning site will be reported directly to CPE Monitor. To claim pharmacy credit, you must have your NABP e-Profile ID, birth month, and birth day. If you do not have an NABP e-Profile ID, go to www.MyCPEMonitor.net for information and application. Follow these instructions to process your CPE credit for this activity.

1. Access the e-Learning site at **http://elearning.ashp.org/my-activities**

2. If you already have an ASHP account, log in using your username and password.

   If you do not have an ASHP account, click on the **Register** link and follow the registration instructions. You do not have to be a member to create an account.

For Midyear Attendees in Anaheim

- Once logged in, select "**Conferences"** and click on the conference name under **Your Conferences**.

- Under Add Sessions enter your attendance code announced during the activity, and click Submit.

  Helpful Tip: If your code is not redeeming successfully, verify that you have clicked on the title of your conference to access the Attendance Code field, not the Enrollment Code field.

- Each session will be listed under Your Sessions. Click Claim Credit for a particular session.

- Complete any requirements for each session by clicking on the name of the activity and following the instructions.

- Click Claim Credit. See steps 3-5 below.

For Offsite Webinar Attendees

- Once logged in, enter the enrollment code (announced during the webinar) into the "ENROLLMENT CODE" box for the activity and click Redeem.

- The title of this activity will appear in a pop-up box on your screen. Click on the **Go button or the activity title**.

- Complete all required elements. A green check should appear as each required element is completed. You can now claim your credit.

3. Available credit(s) will appear beneath the completed required activities. Look for your profession in the list of available credits and click the appropriate **Claim** button. You might have to click to see more credit options if you do not see your profession listed.

4. Review the information for the credit you are claiming. If all information appears to be correct, check the box at the bottom and click **Claim.** You will see a message if there are any problems claiming your credit.

5. After successfully claiming credit, you may print your statement of credit by clicking on **Print**. If you require a reprint of a statement of credit, you can return at any time to print a duplicate. For CPE credit for pharmacists and technicians, printed statements may not be necessary because your credit is reported directly to CPE Monitor.

NEED HELP? Contact eLearning@ashp.org

Date of Activity:	Tuesday December 9, 2014	**Code:**	_ _ _ _ _	**CPE Hours:**	1.5

John B. Hertig, Pharm.D., M.S., CPPS
Activity Chair
Associate Director
Center for Medication Safety Advancement
Clinical Assistant Professor of Pharmacy Practice
Purdue University College of Pharmacy
Indianapolis, Indiana

John B. Hertig, Pharm.D., M.S., CPPS, currently serves as Associate Director and Director of Education for the Purdue University College of Pharmacy Center for Medication Safety Advancement (CMSA). In addition, Dr. Hertig has an appointment as Clinical Assistant Professor of Pharmacy Practice at Purdue University College of Pharmacy.
Dr. Hertig received his Bachelor of Science in Pharmaceutical Sciences and Doctor of Pharmacy degrees from Purdue University and completed a combined PGY1/PGY2 Masters in Health-System Pharmacy Administration residency at The Ohio State University Medical Center in Columbus. As part of this program, he received a Masters in Health-System Pharmacy Administration degree.

Since returning to his alma mater in this capacity, he has led multiple state-wide medication safety initiatives with Indiana hospitals, worked closely with health professionals as a member of various Indiana patient safety coalitions, launched a residency and fellowship program in medication safety, and expanded didactic and experiential training opportunities in medication safety, leadership, and management. Dr. Hertig has been involved in various state and national organizations, and has served on several ASHP advisory groups including the Executive Committees for Student and New Practitioners Forum and the Commission on Affiliate Relations. Currently, he serves as a member of the ASHP Section of Pharmacy Practice Managers Leadership and Career Development Advisory Group and on the ASHP Council on Public Policy. In Indiana, Dr. Hertig is Chair of the Indiana Pharmacy Practice Model Initiative Taskforce, an elected delegate for the ASHP House of Delegates, and President-elect of the Indiana Society of Health-System Pharmacists.

Amy Benner, Pharm.D., BCPS
Director, Central Pharmacy and Shared Services
Scripps Health
San Diego, California

Amy Benner, Pharm.D., BCPS, is Director of Central Pharmacy and Shared Services for Scripps Health in San Diego, California. Dr. Benner earned her Doctor of Pharmacy degree at the University of Sciences in Philadelphia, Philadelphia College of Pharmacy. After graduation, she was commissioned by the United States Navy and completed four years on active duty in various leadership and clinical roles at Naval Medical Center San Diego. She also completed a PGY1 residency at Naval Medical Center San Diego.
Dr. Benner has served in a number of different roles, including Clinical Pharmacist and Clinical Coordinator at Naval Medical Center San Diego and Assistant Director of Pharmacy at Scripps Green Hospital in San Diego. Most recently, Dr. Benner opened the first licensed Central Pharmacy facility in the state of California to serve the five Scripps Health acute care facilities with non-patient specific sterile compounded and repackaged oral medications.

Dr. Benner currently serves on the CPTA (California Pharmacy Technician Association) Board of Directors and is an active member of CSHP (California Society of Health-System Pharmacists).

Achieving and Maintaining Excellence in Sterile Compounding: Innovative Techniques to Ensure Competency

Cindy Chan, Pharm.D.
Sterile Compounding Manager
Providence Infusion and Pharmacy Services
Providence Infusion Hospital Services
Tukwila, Washington

Cindy Chan, Pharm.D. is Sterile Compounding Manager at Providence Infusion and Pharmacy Services. Dr. Chan earned her Doctor of Pharmacy degree and Certificate in Geriatric Pharmacy at the University of Washington School of Pharmacy.

Dr. Chan has extensive experience in home infusion and long term care pharmacy. She has worked for Providence Infusion and Pharmacy services for the last 7 years and currently manages the Home Infusion and Manufacturing business lines. She has responsibility for USP Chapter <797> compliance, hazardous drug safe handling, and meeting Joint Commission Standards in their home infusion service line. Dr. Chan also recently obtained a state pharmaceutical manufacturing license for their manufacturing service line and has been successful in implementing Current Good Manufacturing Practices (CGMP).

Dr. Chan has mentored pharmacy technician and Pharm.D. students sharing her passion for high quality standards and exceptional patient care.

Achieving and Maintaining Excellence in STERILE COMPOUNDING:

Innovative Techniques to Ensure Competency

John B. Hertig, Pharm.D., M.S., CPPS, *Activity Chair*
Purdue University College of Pharmacy
Amy Benner, **Pharm.D., BCPS**
Scripps Health
Cindy Chan, Pharm.D.
Providence Infusion and Pharmacy Services

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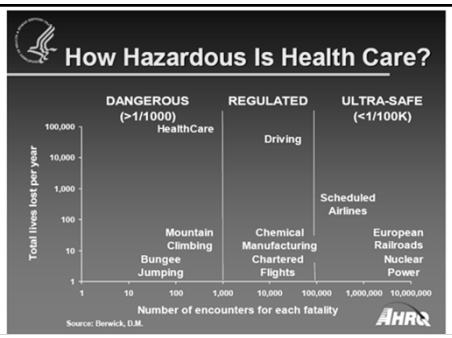
Learning Objectives

- Review basic components of aseptic technique and environmental monitoring and describe why ongoing training in these areas is critical for patient safety
- Illustrate innovative training techniques that can be used with iv cleanroom staff
- Describe ways to engage staff in the processes for maintaining, monitoring, and testing a clean room environment
- Review quality assurance measures for a facility that complies with USP standards

A Novel Approach to Critical Elements of Aseptic Technique:
A Matter of Safety

John B. Hertig, Pharm.D., M.S., CPPS *Activity Chair*
Associate Director and Assistant Clinical Professor
Center for Medication Safety Advancement
Purdue University College of Pharmacy
Indianapolis, Indiana



October 2012: New England Compounding Center (NECC)
- Fungal contamination of preservative-free MPA epidural steroid injections
- Nearly 14,000 people in 23 states exposed
- **64 deaths** and greater than **751 sick** due to fungal meningitis

www.ahrq.gov; www.cdc.gov

Background: A Need for Safety

- Compounding parenteral products is "high risk"
  - Mean error rate of 9%; 1 in 10 products prepared incorrectly prior to dispensing
  - Complex solutions (i.e., parenteral nutrition
    - 37% for manual preparation
    - 22% for partly automated preparation
- 30% of hospitals experienced a patient event involving a compounding error in the past 5 years

Flynn EA, Pearson RE, Barker K. *Am J Health-Syst Pharm*. 1997;54(8):904-12.
Pharmacy Purchasing & Products. *Pharmacy Purchasing & Products.* April 2009

Safe Compounding: USP <797>

- United States Pharmacopeia (USP)
  - Non-governmental organization
  - Creates standards for patient safety, healthcare information, and product verification
- Chapter <797> specifically refers to safe sterile compounding of pharmaceuticals (i.e. IV admixtures)
  - Chapter <1> to <999> are required
    - Subject to inspection for compliance with required standards
  - Chapter <1000> to <1999> are informational

Selected Chapter <797> Sections

- Personnel cleansing and gowning
- Risk level classification of Compounded Sterile Products (CSP) and quality assurance
- Verification of accuracy and sterilization of CSP
- Personnel training and assessment
- Environmental quality and control
- Storage and beyond-use dating

Chapter USP <797> Training

- "Personnel who prepare compounded sterile products or parenteral preparations must be provided with appropriate training in the theoretical principals and practical skills of aseptic manipulations"
- Annually for low and medium-risk level products
  - Low: manually compounding no more than three products
  - Medium: complex aseptic manipulations (other than a single volume transfer)
- Semi-annually for high-risk level products
  - Combining sterile ingredients in non-sterile devices before sterilized
  - Dissolving non-sterile bulk ingredients to make solutions, which then will be sterilized

USP Chapter <797>.The United States Pharmacopeial Convention.

What is your primary job position?

a. Director or Assistant Director of Pharmacy
b. Clinical Coordinator or Other Supervisory Role
c. Clinical or Staff Pharmacist
d. Medication Safety or IT Specialist
e. Faculty

Just-In-Time (JIT) Training

- "Training provided to individuals or units just before the skills or function will be used in a practical application"
  - Learn
  - Apply
  - Feedback
- Initially designed for production, inventory, and customer response
  - Used to increase productivity and eliminate waste
- Day-to-day use of JIT:
  - "How to . . . " videos
  - GPS directions
  - Google search

Lannarelli B. www.fas.org; accessed Sep 2014.

Just-In-Time Training in Health Care

- Focus on web and simulation-based application
- Example: Neil and Elise Wallace Simulation Training, Research, and Technology Utilization System Center (Stratus)
  - Brigham and Women's Hospital
  - Talking, Breathing, Blinking Mannequins
  - "Arcade" area for endoscopic, laparoscopic, and endovascular simulated procedures
  - Virtual patients to practice care giving techniques

Lannarelli B. www.fas.org; accessed Sep 2014.

Simulation-Based Training

- "It is a technique to replace and amplify real experiences with guided ones, often "immersive" in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion."

www.ncbi.nlm.nih.gov

Simulation-Based Training

- The educational benefits of simulation in medical education include the following:
  - Deliberate practice with feedback
  - Exposure to uncommon events
  - Reproducibility
  - Opportunity for assessment of learners
  - The absence of risks to patients
- Safe environment to make and learn from errors
  - Anesthesiology
  - Nursing
  - Etc…

Wendling, AL, Halan, S, Tighe P, et al. *Academic Medicine* 2011. 86 (3): 384-388.
Lateef F. *J Emerg Trauma Shock*. 2010; 3(4): 348-352

How do you currently assess competency at your organization?

a. Written assessment only
b. Hands on assessment only
c. Simulation based assessment
d. Combination of 2 or more of the above
e. We do not assess competency

"Tell me and I forget. Show me and I remember. Let me do and I understand"

- *Confucius*

Why a Virtual Cleanroom?

- Need to train students in safe sterile compounding
- Space
- Cost
  - $1 million to create a functional live unit
  - $260 - $520 per sqft
- USP <797>
  - Introduced in 2004
  - Often revised
  - Modifications to a physical space are expensive

Purdue Pharmacy Virtual Cleanroom

- Developed as an immersive environment simulated experience
- Envision Center (Purdue)
- Simulated experience grounded in reality

Images Courtesy of J. Hertig

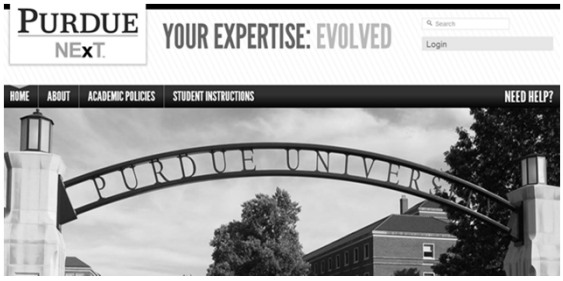
2,160 student experiences

- Orientation to the cleanroom environment
- Modeling safe practices
- Order processing and preparation

Innovative Education

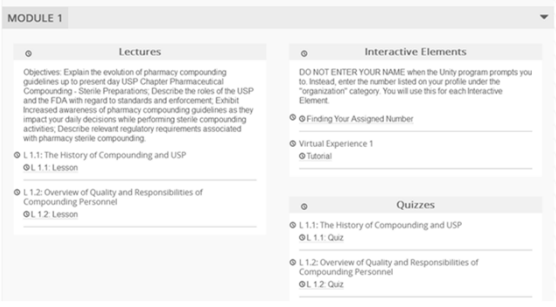
- Combine didactic material with simulated "hands-on" training
  - Gowning
  - Calculations
  - Product manipulation with reviewer observation
- Simulate impact of errors
  - Review common failure modes
  - Emphasize the possible outcomes that result from sterile product errors

Worldwide Online Platform



Used with permission from Purdue University

Training Interface



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Virtual Cleanroom Simulation

Image Courtesy of J. Hertig

Virtual Cleanroom Simulation

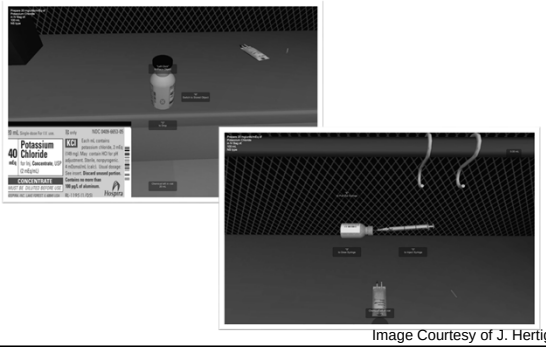


Image Courtesy of J. Hertig

Testimonial Results

- "You can work at your own pace; immediate feedback"
- "New, innovative idea"
- "Hands on experience"
- "Like a video game, interactive, visual"
- "Practice without causing harm"
- "Different from a classroom, better than boring paper slides"

Image Courtesy of J. Hertig

Learning: Results

Outcome	*Improvement
Comfort using cleanroom terminology	34 %
Comfort explaining compounding procedures to others	49 %
Knowledge of proper IV product precautions	54 %
Knowledge of available resources	50 %
Improved knowledge of IV Compounding	39 %

*Statistically significant: p-value < 0.05

Summary

- Sterile compounding is “high risk”
  - Complying with USP Chapter <797> will help ensure personnel and patient safety
- Competency and JIT training is key to compliance
- Simulation training is a novel approach
  - Seek opportunities to implement unique educational techniques
  - Further research should be completed

Strategies for Training Personnel to Assess Environmental Readiness:
An Ongoing Process

Amy Benner, Pharm.D., BCPS
Director, Central Pharmacy and Shared Services
Scripps Health
San Diego, California

Clinical Pharmacy vs. Compounding Pharmacy

It's just not that sexy……

Images www.danoah.com
www.crazyscrubs.com

Which of the following describes your organization's EM program (i.e., air/surface sampling)?

a. Completed by one dedicated person
b. Completed by an outsourced certifier
c. Taught to a few staff who rotate duties
d. Taught to all staff and duties rotate
e. EM is not completed

Scripps Health System

- Pharmacy Sterile Compounding Services
  - Five Acute Care Hospitals
    - Licensed bed size range 154-517
    - Main pharmacy and compounding satellites
  - Oncology/Infusion Centers
    - 4 infusion centers
  - Central Pharmacy
    - Provides non-patient specific compounded sterile and non-sterile medications to five acute care facilities

Sterile Compounding Excellence- Employee Engagement

- Identify a formal or informal leader (pharmacist or technician)
- Provide training to ensure their success
  - In person/live training course preferable
- Provide the TIME, resources and support (pharmacy department AND executive leadership)
- Involvement in policy/procedure review and development
- Set the example
  - Department focus on compounding quality should not be inferior to clinical quality

This is who you want in charge of your program

Keeping in mind……

Perfection is not attainable. But if we chase perfection, we can catch excellence. ~Vince Lombardi

Image www.domorebemore.org

Scripps EM (Environmental Monitoring) Training-Central Pharmacy

- Pharmacists and Leadership
  - Attended in person week long training course
  - Utilized learned knowledge in Policy/Procedure development
- Technician staff
  - Online sterile compounding training modules (30 CEUs)
  - Policy/Procedure review
  - Equipment training
  - Handling of media
  - Return demonstration of correct aseptic and environmental monitoring technique

EM Competency Checklist

SKILL	P= Pass F= Fail N/O	COMMENTS
1. Describes the difference between viable and non-viable contamination and the role of each in an Environmental Sampling Plan.		
2. Articulates the purpose of an Environmental Sampling Plan and what the data generated can be used to determine.		
3. States the location of the facility Environmental Sampling Plan and data forms.		
4. Describes the procedure for air, surface and personnel sampling.		
5. Describes the actions to take in the event that any of the environmental monitoring plates exceed established action limits.		
6. Describes the process for particle control and particulate counts at their pharmacy and when particle counts must occur.		
7. Describes pressure differential/velocity measurements at their facility and correctly states established limits.		
8. Gathers all supplies needed for environmental sampling including correct media, volumetric air sampler, tape, black "sharpie" pen, pen, documentation forms, gloves, lint free wipes.		
9. Checks all media for packaging integrity and expiration dates. Note lot # and expiration dates as well as manufacturer and type on documentation forms.		
10. Inspects each media unit to ascertain that there is no growth on the plate prior to beginning sampling.		
11. Cleans the outside of all containers and supplies before bringing into the clean room or anteroom.		
12. Labels each media unit using a "sharpie" identifying sample location (per environmental monitoring plan), date and time taken, sampler's initials.		
13. Resanitizes gloves and allow to dry. Resanitizes gloves after every 5 plates.		
14. Discards plates if during transport or placement, the media unit is exposed or contaminated prior to or during sampling.		
15. Places media units and accompanying documentation into a cleaned tote to go in to cleanroom.		

Used with permission from Scripps Pharmacy

EM Competency Checklist

Viable Volumetric Air Sampling		
16. Electronic Air Samples are taken at locations that are consistent with the established Environmental Monitoring Plan.		
17. Samples are taken using a procedure that is consistent with policy and procedure.		
18. Air volume sampled is consistent with amounts specified in the policy and procedure.		
Surface Sampling		
19. Contact plates are applied at locations that are consistent with the established Environmental Sampling Plan.		
20. Samples are taken using a procedure that is consistent with policy and procedure.		
21. Cleans the area where the sample was taken to remove media residue per established policy and procedure.		
Incubation and Post Sampling Procedures		
22. Samples are handled in an aseptic manner which prevents accidental exposure outside of the selected sampling location.		
23. Exposed samples are closed aseptically with tops secured to bottom with tape.		
24. All closed samples are placed in a bin and removed from the controlled environment.		
25. Documentation is completed immediately prior to placing the samples in the incubator.		
26. TSA samples are placed into the incubator in an inverted position. Fungal plates are placed right side up.		

Used with permission from Scripps Pharmacy

EM Competency Checklist

Reading Environmental Monitoring Samples		
16. Selects the correct Environmental Sampling Form that corresponds with the samples being read.		
17. Removes samples from the incubator in the time frame specified in established policy and procedure (TSA incubation should be not less than 48 but not greater than 72 hours). Fungal plate incubation should occur for a period of 5-7 days.		
18. Documents the date and time that samples are removed from the incubator to be read.		
19. Reads the plates one at a time counting the number of discrete colony forming units (CFUs) on each plate.		
20. Documents the number of CFUs on each plate in the correct corresponding location on the Environmental Sampling Data collection form.		
21. After all the results for each plate are read and documented, compares the result to the established Action Limit value for each location.		
22. If any sample/s fails, the failing plate is marked "fail" with a black "sharpie".		
23. Immediately reports any out of limit results (CFU # that exceed established Action limits) to the Pharmacy Manager and saves that plate/s to be sent for speciation if applicable.		
24. Reviews documentation form for those samples and once complete, files Environmental Monitoring Data Collection form per established policy and procedure.		
25. Properly disposes of plates (except failed plates) according to established policy and procedure.		

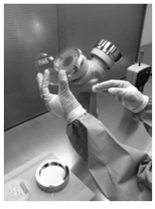
Used with permission from Scripps Pharmacy

How often do you conduct environmental sampling?

a. Monthly
b. Quarterly
c. Biannually
d. Annually
e. We do not conduct environmental sampling

Scripps EM Program

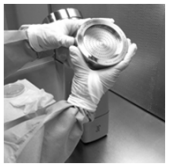
- Monthly at all sterile compounding locations:
  - Viable Air Sampling-Volumetric
  - Surface Sampling-Contact Plates
  - Non-Viable Air Sampling (quality check)



Images courtesy of A Benner

Viable and Non-Viable Sampling

- Viable surface and volumetric air sampling
  - Use of two growth media
    - TSA (trypticase soy agar)-supports the growth of bacteria and some fungi
    - MEA (Malt extract agar)-supports the growth of fungi
  - Surface sampling
    - Media plates with convex surface plus lecithin and polysorbate 80
  - Volumetric air sampling equipment
    - Volume sampled in each location (400-1000 L of air)
- Non-Viable air (total particle counts)
  - Used as a quality check
    - Not for certification purposes



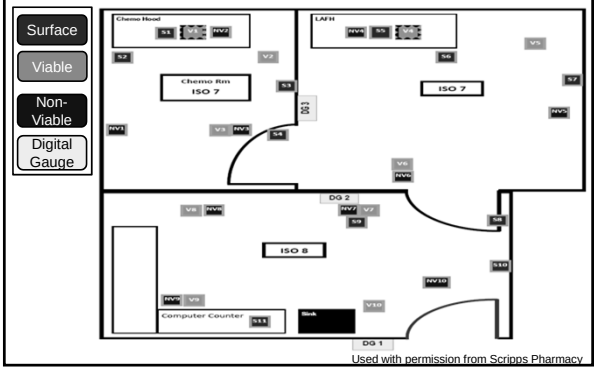
Images courtesy of A Benner

Determining Sampling Locations

- Map clean room workflow
  - Involvement of staff who do the work every day
    - Follow both people and product to determine sampling locations
    - Focus on locations prone to contamination during staging, gowning, labeling, compounding etc.

Images courtesy of A Benner

EM Map-Hospital Pharmacy



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Enlarged on page 38

EM Map Key

(S) Surface Samplings (TSA & MEA)	(V) Viable Samplings
S1-Chemo Hood	V1-Chemo Hood
S2-DoseEdge screen Chemo Hood	V2-Right side of Chemo Hood
S3-Wall surface (chemo rm)	V3-After entrance into chemo rm
S4-PUSH door handle into chemo rm	V4-LAFH
S5-LAFH	V5-Around rack (right side of LAFH)
S6-DoseEdge screen LAFH	V6-After entrance into cmpd rm
S7-Wall surface (cmpd rm)	V7-Around gowning supply rack
S8-PUSH door handle into cmpd rm	V8-Around large supply rack
S9-Around gowning supply rack	V9-Around computer counter
S10-Wall surface (ante ISO 8 rm)	V10-Around sink
S11-Computer counter (near sink)	

(NV) Non-Viable Samplings	Digital gauges
NV1-Around supply rack (chemo rm)	DG1-By the main entrance
NV2-Inside Chemo Hood	DG2-By the sliding door in cmpd rm
NV3-After entrance into chemo rm	DG3-By the door in the chemo rm
NV4-Inside LAFH	
NV5-Around supply rack (cmpd rm)	V Both TSA & MEA
NV6-After entrance into cmpd rm	
NV7-Around gowning supply rack	
NV8-Around large supply rack	
NV9-Around computer counter	
NV10-After entrance into ante ISO 8 rm	

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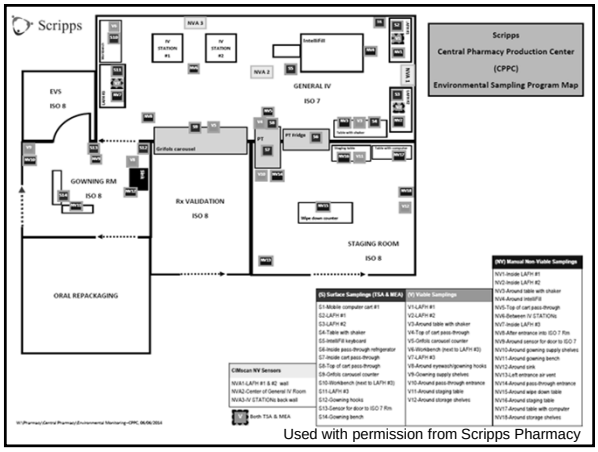

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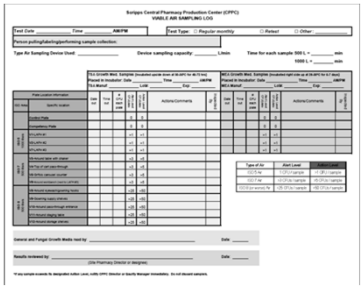
Enlarged on page 38

EM Results/Incubation



TSA incubation: 30-35 C 2-3 days
MEA incubation: 26-30 C 5-7 days

Images courtesy of A Benner

Action Level Determination

- Surface

Table 4. Recommended Action Levels for Microbial Contamination*

Classification	Fingertip Sample	Surface Sample (Contact Plate) (cfu per plate)
ISO Class 5	> 3	> 3
ISO Class 7	N/A	> 5
ISO Class 8 or worse	N/A	> 100

* Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-8 (3) April 2007.

- Viable Air
  - Based on ISO classification and **volume of air sampled**

Table 2. Recommended Action Levels for Microbial Contamination*
†(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample†
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

* Guidance for Industry–Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice–US HHS, FDA September 2004.

USP Chapter <797>.The United States Pharmacopeial Convention.

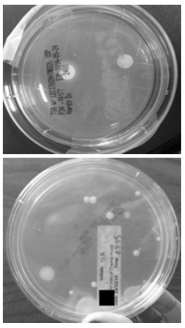
Action Levels Exceeded-Plan Development

- Contamination Sources
  - **People**
  - Supply Air/Engineering Controls
  - Adjacent Areas
  - Water sources
  - Equipment
  - Materials (IV bags, etc.)
- Action plan development based on:
  - Type of sample (surface, viable air)
    - Micro-organism identification to genus level

Action Plans-Gram Positive Rods/Cocci

- Common organisms
  - Staphlococcus
  - Micrococcus
  - Bacillus
- Assessment
  - Requires gowning/garbing evaluation and re-training
  - Review dust/dirt, floor traffic in and out of classified areas

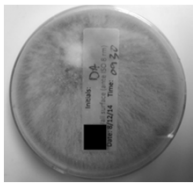
Gram Stain	Macroscopic Observation	Microscopic Observation	Organism
Positive	Glossy, beige colonies	Rods	*Bacillus sphaericus*
Positive	Small, beige colonies	Rods	*Bacillus lentus*
Positive	Small, round off-white colonies	Cocci	*Staph epidermidis*



Images courtesy of A Benner

Action Plans-Molds

- Assessment
  - Damaged HEPA filters
  - Pre-filters
  - HVAC/duct work
  - Staging/wiping practices (cardboard)
  - Mold contaminated clothing
- Organism examples



Gram Stain	Macroscopic Observation	Microscopic Observation	Organism
N/A	Green with white margins, velvety texture, folded, light reverse	Conidia in chains, septate condiphore, flask-shaped phialides	Genus *Penicillium*
N/A	Greenish colonies with light brown center, powdery/granular texture, white margins, light reverse	Non-septate conidiophore	Genus *Aspergillus*

Images courtesy of A Benner

Action Plans-Surface Samples

- Evaluation of cleaning agents
  - Germicidal detergent
  - Disinfectant (ex. Sterile IPA)
  - Sporicidal rotation
- Assessment of cleaning and disinfecting practices
  - Employee competency in performing work practices
    - Pharmacy AND janitorial staff
  - Dwell time
  - Dilution of cleaning agents
  - Cleaning equipment (mops, buckets)
  - Cleaning process
    - Cleanest to dirtiest and top to bottom

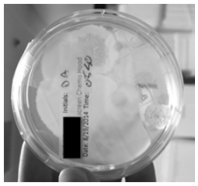


Image courtesy of A Benner

Staff Engagement in Continuous Improvement

- Show and Tell
  - Share plate results (visual learning)
- Narrow down contamination source based on micro-organism identification
  - Involve compounding staff in action plans
- Monitor progress monthly to assess impact of changes
- Track and trend results
  - Communicate back to compounding staff

Summary

- Environmental Monitoring is a core component of sterile compounding and requires the same attention level/training as aseptic technique
- A comprehensive EM program requires identification of key personnel to execute
  - To ensure success ALL should know the importance of the process
- Engagement of staff can be obtained in a variety of ways and impacts the success of any program

Case Study:
Engagement of Staff to Ensure the Safe Preparation of Compounded Sterile Products

Cindy Chan, Pharm.D.
Sterile Compounding Manager
Providence Infusion and Pharmacy Services
Providence Infusion Hospital Services
Tukwila, Washington

Agenda

- Background of Providence Infusion and Pharmacy Services
- Environmental testing
- Certification report review
- Case study

Providence Infusion and Pharmacy Services

- Established in 1993
- Four business lines
  - Home Infusion
  - Manufacturing
  - Long-term Care Pharmacy
  - Enteral
- Four separate cleanrooms
- Joint Commission Accreditation since 1995

PROVIDENCE Infusion and Pharmacy Services

Providence Infusion and Pharmacy Services

- Home Infusion Business Line
  - Serves 1100 patients across Washington State
  - Therapies
    - Antibiotics
    - TPN
    - PCA
    - Hydration
    - Chemotherapy
    - Miscellaneous (Inotropic agents, IVIG, Heparin)

Providence Infusion and Pharmacy Services

- Manufacturing Business Line
  - Serves five Providence hospitals in Washington State under state pharmaceutical manufacturing license
  - Product formulary
    - Antibiotics (~5000 doses/month)
    - Oxytocin (~700 doses per month)
    - Buffered Lidocaine (~4000 doses/month)
  - Goal for FDA 503B registration in 2015

Home Infusion Cleanroom

- Environmental Testing
  - Performed monthly by trained Providence staff
  - Performed semi-annually by certified vendor
  - Results meet or exceed USP 797 standards
    - Buffer Room ISO 6 (min = ISO 7)
    - Ante Room ISO 6 (min = ISO 8)
    - LAFW's ISO 3 (min = ISO 5)

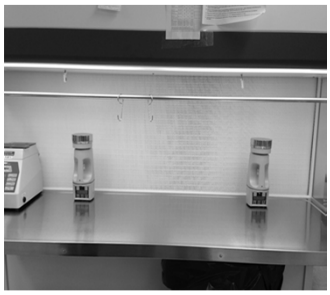
Manufacturing Cleanroom

- Environmental Testing
  - Performed monthly by trained Providence staff
  - Performed semi-annually by certified vendor
  - Results meet or exceed USP 797 standards
    - Buffer Room ISO 5 (min = ISO 7)
    - Ante Room ISO 6 (min = ISO 8)
    - LAFW's ISO 3 (min = ISO 5)

Monthly Environmental Testing

- Viable particle testing program
  - Air and surface sampling
  - TSA plates for bacteria & SDA plates for fungus
  - Volumetric air sampling with an impaction device
- Action plans implemented when action levels exceeded per USP 797 standards

Viable Air Sampling



Images courtesy of C. Chan

What method do you use to conduct environmental sampling?

a. Volumetric air sampling with impaction device
b. Qualitative air sampling with settling plate
c. I don't know, whatever the certifier uses

Semi-Annual Environmental Testing

- Vendor testing:
  - Terminal Air Filter (TAF) Airflow Measurements
  - Room Air Exchange Rates
  - Room Pressure Differentials
  - TAF Installation Leak Tests
  - Airborne and surface nonviable/viable particle counts
  - Hood certification

Vendor Selection for Environmental Testing

- National Environmental Balancing Bureau (NEBB) Certification
- Accreditation to ISO 3199 and 17025 for performance of calibration
- Field Service Technicians are accredited by the National Sanitation Foundation to NSF-49

Cleanroom Diagram

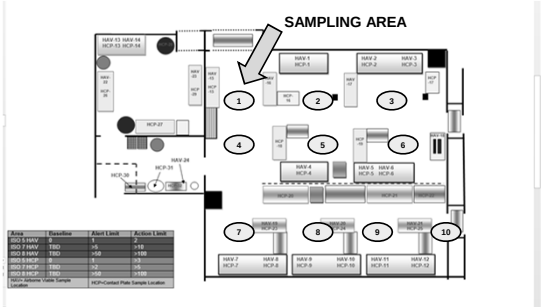


Image used with permission from Providence Infusion

Case Study

- Air sample near staging cart grew 12 cfu (10 cfu = action level)
- Surface sample on staging cart WNL
- All other areas in buffer room WNL

Staging Cart

- 60 to 80 order baskets are staged on cart in the buffer area per day
- Baskets are sprayed with sterile IPA 70% prior to entering room

Image courtesy of C. Chan

Case Study Action Steps

- Cart removed from buffer room and cleaned in ante room 3 times with the following protocol:
  - Lysol IC
  - Sterile Isopropyl Alcohol
  - Sporicidin
  - Sterile Isopropyl Alcohol

Case Study Action Steps

- Area resampled after cleaning
  - (showed 0 cfu)
- Notification to staff and administration
- Sample sent to lab for bacterial identification

Microbiology Results

- Microbiology Report Results
  - *Acinetobacter gemonospecies 9*
  - *Corynebacterium imitans*
  - *Corynebacterium tuberculostearicum*
  - *Janibacter melonis*
  - *Micrococcus luteus*
  - *Staphylcoccus epidermidis*
  - *Staphylcoccus haemolyticus*
  - *Staphylcoccus hominis*

Additional Action Steps

- Staff engagement (*essential for optimal results)
  - Food prohibited in checking/staging area (non-ISO classified room)
  - Hand washing requirement prior to entry of room when returning from lunch/breaks
  - Designated baskets for cleanroom/staging room and warehouse use
  - Monthly cleaning of order baskets
  - Clean, dry clothes prior to entering SVR

Order Baskets

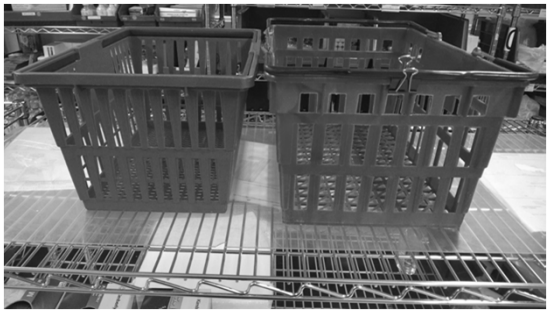


Image courtesy of C. Chan

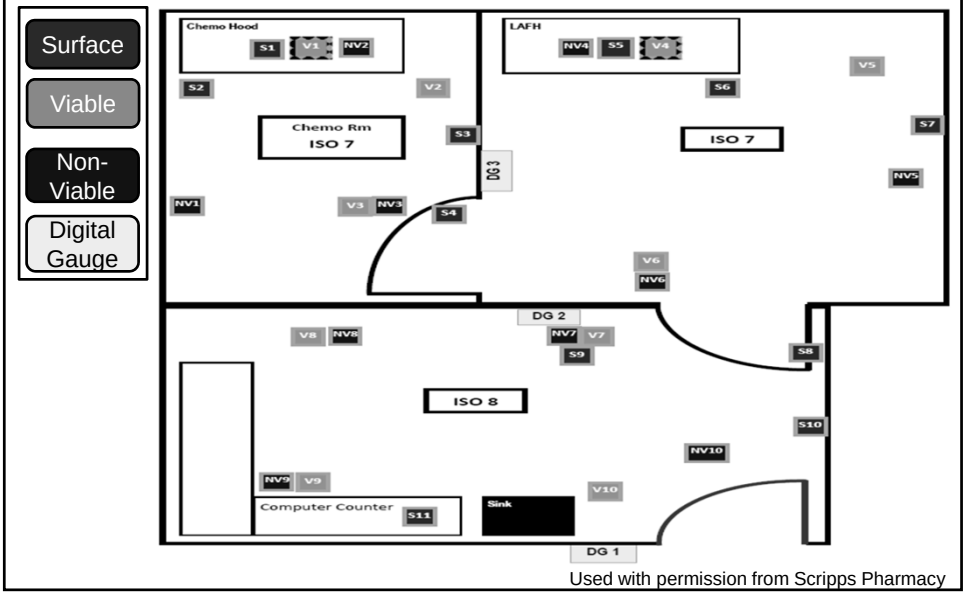
Results of Action Steps

- Air and surface sampling have remained WNL since action steps taken
- Staff continue to be engaged in processes to maintain a safe and clean environment
- Administration continue to be informed of environmental test results

Summary

- Environmental testing
- Certification report review and vendor selection
- Case study lessons learned

EM Map-Hospital Pharmacy



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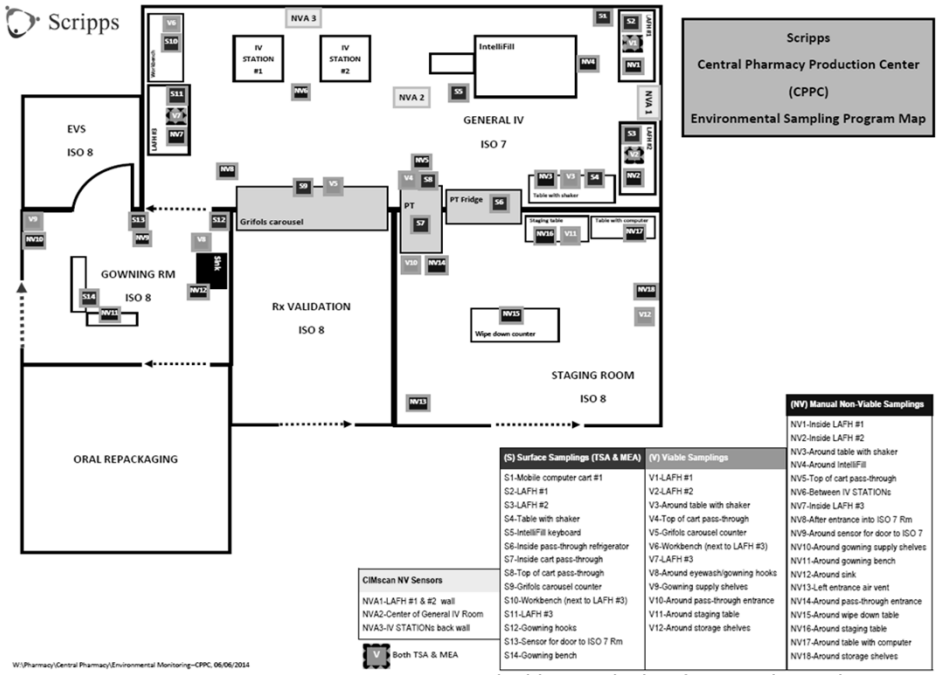

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Self–Assessment Questions

1. USP Chapter <797> includes all the following sections, EXCEPT:
    a. Personnel cleansing and gowning
    b. Risk level classification of Compounded Sterile Products (CSP) and quality assurance
    c. Personnel training and assessment
    d. All of the above

2. All of the following are benefits of simulation-based education and training, EXCEPT:
    a. Deliberate practice with feedback
    b. Risk potentially resulting in patient harm
    c. Exposure to uncommon events
    d. Opportunity for assessment of learners

3. The viable air action levels published in USP Chapter 797 are based on both ISO classification and volume of air sampled.
    a. True
    b. False

4. A comprehensive viable particle testing program should include:
    a. Air sampling
    b. Surface sampling
    c. Both A & B
    d. None of the above

5. The following tests should be included in your environmental testing program:
    a. Room pressure differentials
    b. Airborne and surface non-viable sampling
    c. Airborne and surface viable sampling
    d. All of the above

Answers

1. d
2. b
3. a
4. c
5. d