Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Presented as a Promotional Theater at the 2016 ASHP Summer Meetings & Exhibition

Monday, June 13, 2016
Baltimore, Maryland

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Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Agenda

6:00-6:30 p.m.  Dinner

6:30-6:40 p.m.  Introductions and “Setting the Stage” for Breakout Sessions
Ryan A. Forrey, Pharm.D., M.S., FASHP, Activity Chair

6:40-7:00 p.m.  Leveraging Sterile Compounding Facility Design Standards to Change the Organization’s Compounding Landscape
Ryan A. Forrey, Pharm.D., M.S., FASHP

7:00-7:20 p.m.  Leveraging Sterile Compounding Standards to Expand Services Through Central Fill Operations
Katie McMillen, Pharm.D., M.P.H., M.H.A.

7:20-7:55 p.m.  Breakout Sessions

7:55-8:00 p.m.  Closing Thoughts and Comments
Ryan Forrey, Pharm.D., M.S., FASHP

Faculty & Facilitators

Ryan Forrey, Pharm.D., M.S., FASHP, Activity Chair
Director of Pharmaceutical Services
Emory University Hospital Midtown
Atlanta, Georgia

Katie McMillen, Pharm.D., M.P.H., M.H.A.
Director of Pharmacy
Oncology Service Line & ISC
Froedtert & The Medical College of Wisconsin
Milwaukee, Wisconsin

Todd Canada, Pharm.D., BCNSP, FASHP, FTSHP
Clinical Pharmacy Services Manager
Nutrition Support Team Coordinator
The University of Texas M.D. Anderson Cancer Center
Houston, Texas

Robert Eastin, Pharm.D.
Director
Central Pharmacy and Shared Services
Scripps Health
San Diego, California

Cindy Mitman, Pharm.D., M.B.A.
Assistant Director of Pharmacy
Lehigh Valley Health Network
Allentown, Pennsylvania

Richard Montgomery, B.S.Pharm, M.B.A.
Contracts and Operations Manager
Pharmacy Supply Chain
Adventist Health System
Orlando, Florida

Melissa Ortega, Pharm.D., M.S.
Director, Pediatrics and Inpatient Pharmacy Operations
Tufts Medical Center
Boston, Massachusetts
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Breakout Session Tables

To assist with selection of a breakout session table, below are the topics each facilitator is prepared to address. See page 17 for additional details on facilitators, their organizations, and their “insourcing” experience.

Table 1 – Todd Canada, Pharm.D., BCNSP, FASHP, FTSHP – The University of Texas M.D. Anderson Cancer Center
- Real estate and facility considerations for renovating an existing i.v. sterile compounding space
- Evaluating the business case of insourcing total parenteral nutrition
- Simplifying pharmacy parenteral nutrition workflow
- Developing pharmacist and technical staff parenteral nutrition competence
- Navigating the process of ending outsourcing contracts

Table 2 – Robert Eastin, Pharm.D. – Scripps Health
- Standardization of i.v. sterile compounding operations in a multi-hospital health system
- Environmental monitoring considerations of insourcing i.v. sterile compounding operations
- Determining the formulary for a centralized hospital packaging pharmacy in order to best support a 5 hospital health system
- Managing the process of assigning beyond-use-dates to compounded sterile preparations

Table 3 – Ryan Forrey, Pharm.D., M.S., FASHP – Emory University Hospital Midtown
- Real estate and facility considerations for renovating an existing i.v. sterile compounding space
- Using a decision matrix for modular walls and materials for building or renovating sterile compounding space
- Key design elements for a USP Chapter <797> and USP Chapter <800> compliant renovation
- Developing a program of requirements (POR) for your facility renovation
- Understanding “value engineering” and which compromises to make in design specifications

Table 4 – Katie McMillen, Pharm.D., M.P.H., M.H.A. – Froedtert & The Medical College of Wisconsin
- Metrics and the evaluation of those metrics in making the business case for insourcing CSPs using a “central fill” model
- Real estate and facility considerations for building or designing a “central fill” model for i.v. sterile compounding
- Regulatory considerations of insourcing i.v. sterile compounding operations
- Challenges of insourcing i.v. sterile compounding operations in a changing regulatory landscape
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Table 5 – Cindy Mitman, Pharm.D., M.B.A. – Lehigh Valley Health Network

- CSP waste metrics and the evaluation of these metrics to determining when to outsource for better dating
- Standardizing insourced compounded sterile preparations (CSPs) operations and training across multiple sites
- Overcoming CSP insourcing challenges in a small hospital
- Standardizing CSP concentrations within a multi-hospital formulary
- Conducting site visits for outsourcing vendors

Table 6 – Richard Montgomery, B.S.Pharm, M.B.A. – Adventist Health System

- Regulatory considerations of insourcing i.v. sterile compounding operations
- Metrics and the evaluation of those metrics to make the business case for insourcing compounded sterile preparations (CSPs) using a “central fill” model
- Real estate and facility considerations for building or designing a “central fill” model for CSPs

Table 7 – Melissa Ortega, Pharm.D., M.S. – Tufts Medical Center

- Metrics and the evaluation of those metrics in making the business case for insourcing compounded i.v. sterile preparations
- Regulatory considerations of insourcing i.v. sterile compounding operations
- Successes and challenges of insourcing i.v. sterile compounding within a stand-alone hospital
- Establishing risk mitigation procedures to meet high standards of practice to ensure patient safety for both internal and external sterile compounding facilities

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- Ryan Forrey, Pharm.D., M.S., declares that he is a consultant and/or member of an advisory board for Corvida, Amgen, and InfuSystem; and is a member of the USP Compounding Expert Committee.
- All other faculty and planners report no financial relationships relevant to this activity.

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Activity Overview

Network with fellow pharmacists who have successfully modified the sterile i.v. compounding operations of their organization to meet contemporary safety and quality standards and patient needs. This program will feature the stories of two organizations that leveraged regulatory standards to expand and/or modernize i.v. sterile compounding facilities. The perspectives of two different facilities will be presented—a health-system that built a standalone central fill facility and another in which existing space in the hospital was modified. Following the presentations, participants will participate in two of seven breakout sessions, selecting those that align best with their organization’s needs. During these breakout sessions, participants will be able to seek answers to their tough questions about insourcing.

Learning Objectives

- Identify tools and resources available to assist in answering the “tough questions” related to insourcing sterile i.v. compounding services.
- Describe steps that must be taken to ensure thorough evaluation of sterile i.v. compounding financial and operational needs in a hospital or health-system setting.
- Outline steps that contribute to successful implementation of sterile i.v. compounding services in a hospital or health-system setting.

Featured on www.CSPInsourcing.org

- Toolkit for evaluating and implementing insourcing of CSPs includes sample documents, templates, and reference material
- Gap Analysis Tool to assist with the decision-making process

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Notes
Leveraging Sterile Compounding Facility Design Standards to Change the Organization's Compounding Landscape

Ryan A. Forrey, Pharm.D., M.S., FASHP
Director of Pharmacy
Emory University Hospital Midtown
Atlanta, Georgia

Disclosure

• I am a member of the USP Compounding Expert Committee.

• However, the views expressed today in this presentation are solely my own and not those of USP.

Objectives

• Identify tools and resources available to assist in answering the “tough questions” related to insourcing sterile i.v. compounding services.
• Describe steps that must be taken to ensure thorough evaluation of sterile i.v. compounding financial and operational needs in a hospital or health-system setting.
• Outline steps that contribute to successful implementation of sterile i.v. compounding services in a hospital or health-system setting.

Current State

• Sterile products area renovated in 2004, shortly after release of first version of USP Chapter <797>
• Uses the displacement airflow concept of facility design
  – No ability to compound high risk compounded sterile products (CSPs)
  – Hazardous drugs are compounded in a compounding aseptic containment isolator (CACI)

Changing Regulations

• USP Chapter <800>
  – Official, not yet enforceable
• Proposed Revision to USP Chapter <797>
  – Not official
• Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic (FD&C) Act FDA Draft Guidance
  – Not official
USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

• Hazardous Drugs—Handling in Healthcare settings
• Official draft released February 1, 2016 for publication in USP 39 NF 34, first supplement
  – Enforceable July 1, 2018
• Consolidates hazardous drug (HD) safe handling throughout the entire healthcare setting (entry to exit)
  – Includes HDs as CSPs

USP Chapter <800> Facility Requirements for CSPs

• Receiving/Unpacking
  – Negative/neutral pressure
• Storage
  – Negative pressure
  – Externally vented
  – At least 12 air changes per hour (ACPH)
• Compounding
  – Buffer room or containment segregated compounding area (C-SCA)

<800> Compounding Facilities

• C-SCA
  – Physically separated space
  – 12 ACPH
  – Unclassified air
  – Externally vented
  – Negative pressure (-0.01 to -0.03 inches of water column)
• HD Buffer Room
  – Physically separated space
  – 30 ACPH
  – ISO Class 7 air quality
  – Externally vented
  – Negative pressure (-0.01 to -0.03 inches of water column)

Proposed Revision to USP <797>

• Category 1 and 2 CSPs replace low, medium, and high-risk CSPs
• Beyond Use Dates (BUDs):
  – Category 1
    • ≤12 hours at room temperature (RT)
    • ≤24 hours refrigerated (RF)
  – Category 2
    • Determined based on a cascade of conditions
    • Maximum BUD:
      – RT 28 days
      – RF 42 days

Proposed Revision to USP <797>

• BUD changes could limit the use of outsourcing facilities
  – Maximum BUD of 28 days for CSPs without antimicrobial preservative and with sterility testing completed
  – Maximum BUD of 42 days if sterility tested and antimicrobial preservative added
• Practically, it may not allow for enough time to ship and use some outsourced CSPs
Proposed Revision to USP <797>

- Facility Design
  - Category 2 CSPs
    - Must be prepared in a physically separate room
    - Airflow displacement concept not allowed
  - Compounding aseptic isolators (CAIs) and compounding aseptic containment isolators (CACIs) must be placed in a room with ISO Class 7 or better air quality
    - Many currently use CAIs and CACIs in ISO Class 8 or unclassified spaces


Analysis of the Regulatory Trends

- HD compounding standards will require renovations in most cases due to increased environmental controls compared to USP <797>
- FDA may continue to drive toward greater regulatory control in the current 503A compounding space

Planning for Renovations

- A program of requirements (POR) should be developed in advance of any facility planning
  - Determines the services to be provided and identifies future needs
  - Allows standardized planning for adequate space
    - Does not assume that current space is sufficient
    - Can be reproduced for multiple sites

POR Space Requirements

- Primary Engineering Control (PEC)
  - 50 - 100 square feet (SF) of clean room per PEC
- Anteroom (for garbing)
  - 100 SF of clean room per facility
- Workroom
  - 80 - 120 SF of “office space” per PEC

Budgeting Costs of Renovation

<table>
<thead>
<tr>
<th>Example 1,100 SF Renovation (2 HD PECs, 5 non-HD PECs)</th>
<th>Buffer Room Space (per SF)</th>
<th>Office Space (per SF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construction</td>
<td>$ 800</td>
<td>$ 108</td>
</tr>
<tr>
<td>Professional Services (11%)</td>
<td>$ 66</td>
<td>$ 11.88</td>
</tr>
<tr>
<td>Furniture, Fixtures &amp; Equipment (FF&amp;E) (18%)</td>
<td>$ 144</td>
<td>$ 19.44</td>
</tr>
<tr>
<td>Miscellaneous (3%)</td>
<td>$ 24</td>
<td>$ 3.24</td>
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<tr>
<td>Contingency (8%)</td>
<td>$ 64</td>
<td>$ 11.40</td>
</tr>
<tr>
<td>Total</td>
<td>$ 1120</td>
<td>$ 153.96</td>
</tr>
</tbody>
</table>

- Construction cost and FF&E per SF decrease with increasing size
  - Much of the cost is due to heating, ventilation, and air conditioning (HVAC) equipment

Example Renovation #1

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Space per Unit (in SF)</th>
<th>Total Space (in SF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD PEC</td>
<td>2</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Non-HD PEC</td>
<td>5</td>
<td>50</td>
<td>250</td>
</tr>
<tr>
<td>Anteroom</td>
<td>1</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Workroom</td>
<td>1</td>
<td>550</td>
<td>550</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>1100</td>
</tr>
</tbody>
</table>

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Example Renovation #1

- Clean room space = 550 SF
  - Budget is $616,000
- Office space = 550 SF
  - Budget is $84,678
- Total cost
  - Budget is $700,678

Example Renovation #2

- Clean room space = 420 SF
  - Budget is $470,400
- Office space = 420 SF
  - Budget is $64,663
- Total cost
  - Budget is $535,063

**Example Renovation #2**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Space per Unit (in SF)</th>
<th>Total Space (in SF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD PEC</td>
<td>1</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>Non-HD PEC</td>
<td>2</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Anteroom</td>
<td>1</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Workroom</td>
<td>1</td>
<td>420</td>
<td>420</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>840</strong></td>
</tr>
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<table>
<thead>
<tr>
<th>Example 840 SF Renovation (1 HD PEC, 2 non-HD PECs)</th>
<th>Buffer Room Space (per SF)</th>
<th>Office Space (per SF)</th>
</tr>
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<tr>
<td>Construction</td>
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Comparison of Examples

- **Example #1**
  - 5 non-HD PECs
    - Adds capacity for OR syringe preparation (operational savings of $34,000 annually)
  - 2 HD PECs
    - Allows for growth in HD compounding capacity (e.g., oncolytic viruses, gene therapy)
  - Cost premium 30%
  - ROI: 4.85 years for additional investment

- **Example #2**
  - 2 non-HD PECs
    - No additional capacity for on-site compounding of OR syringes
  - 1 HD PEC
    - Does not allow for new therapies, expansion of services, or redundancy in case of failure
  - Cost premium 0%
  - ROI: None

Future State

- Total project budget initially came in at nearly $1 million
  - Additional scope creep within pharmacy
- Only $650,000 plus $80,000 in equipment had been budgeted
- Reclassified the workroom air from ISO Class 7 to ISO Class 8 or even clean, not classified (CNC)
  - Reduced the HVAC supply air requirements
- Single exhaust for all HD PECs
Conclusions

• Regulatory changes related to HD compounding will likely require renovations
• Expanded compounding capacity can be created with limited incremental cost to allow insourcing of CSPs
• Depending on current outsourcing volumes, insourcing may provide an ROI for the incremental costs

Leveraging Sterile Compounding Standards to Expand Services Through Central Fill Operations

Katie McMillen, Pharm.D., M.P.H., M.H.A.
Director of Pharmacy, Oncology Service Line & Integrated Service Center (ISC)
Froedtert & The Medical College of Wisconsin
Milwaukee, Wisconsin

Healthcare Delivery Platform – Acute Care

Decision to Centralize

• External compounding environment – Quality and safety concerns
• Drug shortages & inflated prices
• Reduction of waste
• System support

ISC Exterior - 2016

What are the Benefits of Integration at One Location?

Expected go-live July 2016

• Centralized IV Compounding
  – Reduces the impact of drug shortages
  – Reduces the need to outsource purchases from vendors
  – Leads to lower drug costs

• Specialty Pharmacy
  – Improves our access to limited distribution medications
  – Expands access to prescribers and patients across the region
  – Increases our ability to care for patients receiving complex specialty medications.

• Supply Chain Distribution Center, Print Shop and Courier
  – Increased ability to control the entire supply chain process
  – Enhances supply chain services provided to end-users
  – Ultimate, more efficient and cost effective supply chain processes

• Data Center
  – Replaces the outdated data center with a world-class facility
  – Provides redundancy and reliability to support our health care enterprise
  – Gives flexibility to support future growth
  – Seamlessly handle future growth of the enterprise, while managing costs more effectively

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F& MCW ISC Compounding Center

- Operational Plan & Design
  - 2200 square feet
    - Cost of equipment: $113,000
    - Cost to build out space: $460,000
  - Fully USP 797/800 compliant
  - M-F 7:00 – 15:30 initial hours of operation
  - 3.5 FTEs
    - 1.5 Pharmacists
    - 2.0 Pharmacy technicians
  - Limited production to start
    - Priority to show cost savings

Year 1 Projected Savings

*Table reflects products identified to compound during initial start-up

Insourcing Readiness and Feasibility

- Strategic Planning and Business Cases
  - Stakeholders
  - Assessment of product and volumes
  - Staffing considerations
  - Space & clean room design considerations

- Basic Considerations
  - Compliance with USP & State regulations
  - Internal Preparation of CSPs
  - Commercial alternatives
  - Compounding scope

- Quality elements & risk
  - End product testing
  - Stability testing
  - Sterility testing
  - Risk analysis
Insourcing Readiness and Feasibility

• Implementation & Operational Considerations
  – Policies, procedures and training
  – Standard operating procedures
  – Workflow management
  – Product and/or staffing shortages
  – Downtime/Disaster

http://www.cspinsourcing.org

503A vs 503B

503A
• Describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FD&C Act requiring:
  – FDA approval prior to marketing (section 505)
  – Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); and
  – Labeling with adequate directions for use (section 502(f)(1))
• States primarily regulate pharmacies that qualify for the exemptions

503B
• Must comply with CGMP requirements and subject to FDA inspections
• Must report which products they are compounding and any adverse events
• Must pay establishment, annual fees, and reinspection fee if applicable

FDA Draft Guidance

• Hospital and Health System Compounding Under the Federal FD&C Act
  – Published in the Federal Register April 18, 2016
• Would require a patient-specific prescription in advance of 503A compounding unless 3 conditions are met

FDA Draft Guidance

• Requisite conditions for 503A non-patient specific compounding:
  – The drug products are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy;
  – The drug products are only administered within the healthcare facilities to patients within the healthcare facilities, pursuant to a patient specific prescription or order; and
  – The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions (section 501(a)(2)(A)) or misbranded (e.g., section 502(g))

Key Takeaways

• Readiness assessment
  – Intent of service
  – Reduce number of surprises during planning
  – Site visits to learn through your peers
• Building the business case
• Utilize experts
  – Avoid costly mistakes
  – Meet regulatory requirements
### Year 1 Projected Savings

<table>
<thead>
<tr>
<th>Product</th>
<th>Total Cost of Dose</th>
<th>Total</th>
<th>Total Annualized Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product 1</td>
<td>$5,000</td>
<td>100</td>
<td>$500</td>
</tr>
<tr>
<td>Product 2</td>
<td>$3,500</td>
<td>50</td>
<td>$175</td>
</tr>
<tr>
<td>Product 3</td>
<td>$2,000</td>
<td>25</td>
<td>$50</td>
</tr>
</tbody>
</table>

*Table reflects products identified to compound during initial start-up.*
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### Breakout Table 1 – Todd Canada

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### Todd W. Canada, Pharm.D., BCNSP, FASHP, FTSHP

Todd W. Canada, Pharm.D., BCNSP, FASHP, FTSHP, is both Clinical Pharmacy Services Manager and a clinical pharmacy specialist in nutrition support for the University of Texas MD Anderson Cancer Center in Houston. He earned a B.S. in pharmacy from the University of Oklahoma Health Sciences Center and a Pharm.D. from the University of Texas Health Science Center at San Antonio. He completed a specialized residency in Critical Care /Nutrition Support at the University of Tennessee—Memphis and is board certified in nutrition support.

Dr. Canada’s current responsibilities include providing direct patient care, managing and mentoring his group of 15 non-oncology clinical pharmacy specialists, and serving as a pharmacy educator and preceptor. He serves as the University of Texas at Austin College of Pharmacy regional internship institutional and clinical coordinator for the Galveston/Houston area and is Adjunct Assistant Professor. He also holds an appointment as Adjunct Clinical Assistant Professor at the University of Houston College of Pharmacy since MD Anderson Cancer Center serves as a teaching site for both colleges.

Dr. Canada has previously served on the Board of Pharmaceutical Specialties – Nutrition Support Specialty Council, the Texas Society of Health-Systems Pharmacists Board of Directors and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. He has held elected offices for several pharmacy- and nutrition-related organizations over the past 28 years. Dr. Canada was the recipient of the A.S.P.E.N. Distinguished Nutrition Support Pharmacist Service Award in 2011. He has presented and published in a variety of areas including safe practices for parenteral nutrition, critical care pharmacy practice and pharmacy mentoring.
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**Breakout Table 1 – Todd Canada**

### The University of Texas M.D. Anderson Cancer Center
- One of only 45 comprehensive cancer centers designated by the National Cancer Institute
- Eight different Houston-area locations for M.D. Anderson and one main campus located in the Texas Medical Center with a 667-bed hospital
- Main campus hospital dispenses annually from central pharmacy and three separate pharmacy satellite locations within the building:
  - 261,000 intravenous sterile preparations
  - 9400 parenteral nutrition formulations

### I.V. Sterile Compounding Timeline
The Division of Pharmacy developed a 5-year implementation plan in 2010 to totally insource ALL i.v. sterile preparations. The final insourced compounded sterile products were parenteral nutrition (PN). By 2014, all of the pharmacy i.v. compounding areas were USP Chapter <797> compliant within the main campus hospital and the majority of i.v. sterile products were insourced except PN. Final sterile products satellite renovation was completed in 2015 for the PN compounding area, which allowed the division of pharmacy to end the outsourcing agreement in December 2015 to be completely self-sufficient.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 2 – Robert Eastin

Topics

- **Standardization of i.v. sterile compounding operations in a multi-hospital health system**
- **Environmental monitoring considerations of insourcing i.v. sterile compounding operations**
- **Determining the formulary for a centralized hospital packaging pharmacy in order to best support a 5 hospital health system**
- **Managing the process of assigning beyond-use-dates to compounded sterile preparations**

Robert J. Eastin, Pharm.D.

Robert J. Eastin, Pharm.D., is Director of Central Pharmacy and Shared Services at Scripps Health in San Diego, California. He was previously the manager of pharmacy operations for the Scripps Mercy, San Diego campus, the largest teaching hospital of the Scripps Health system.

Dr. Eastin received his Bachelor of Science degree in biology from Duke University. Prior to earning his doctor of pharmacy degree and graduating summa cum laude from the University of the Pacific, he served four years as a surface warfare officer in the United States Navy and worked as a pharmaceutical sales representative for Eli Lilly & Company. He completed his PGY-1 Pharmacy Practice Residency at Scripps Mercy Hospital and worked as a clinical pharmacist at two of the Scripps Health hospital locations.

As the pharmacy operations manager at Scripps Mercy, Dr. Eastin was primarily responsible for the training and quality assurance associated with sterile compounding. He also co-chaired the health system’s “Beyond-Use-Dating” Committee which formalized the process for reviewing, establishing and maintaining the beyond-use-dates for compounded sterile preparations.

Dr. Eastin is currently the pharmacist-in-charge of Scripps Central Pharmacy Production Center (CPPC), a centralized hospital packaging pharmacy. CPPC provides sterile injectable preparations, produces repackaged oral solids and solutions, and administers the environmental sampling program for the five hospital system. He also oversees Scripps telepharmacy service and the System Resource Services for pharmacy which provides workforce staffing support to the hospital and clinics in the system. As the chair of the Pharmacy Operations Standardization Committee for the system, he leads the group tasked with implementing system-wide standards related to medication preparation, dispensing, and administration.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 2 – Robert Eastin

Scripps Health

- Scripps Encinitas
  - 158 bed community hospital
  - Outpatient physical rehabilitation center
- Scripps Green
  - 173 bed teaching hospital
  - Bone marrow and organ transplantation
- Scripps La Jolla
  - 312 bed community hospital
  - Prebys Cardiovascular Institute
- Scripps Mercy San Diego and Chula Vista
  - 700 bed teaching hospital
  - Level 1 trauma center

- Scripps Central Pharmacy Production Center
  - Sterile compounding formulary contains 18 CSPs, including 12 with extended BUDs
  - 398,486 IV doses produced in 2015
- Standardized system-wide sterile compounding policy and training programs
- Environmental sampling program conducting testing at all hospitals monthly
  - Media results read in-house by staff
  - Growth sent to lab for speciation

I.V. Sterile Compounding Timeline

Prior to Fall 2012
- All Scripps hospitals operated semi-independently in the administration of the sterile compounding programs.
- Out-sourced CSP utilization varied from hospital to hospital. Some sites requested quality assurance reporting from the vendors, others did not. Outsourced products included
  - TPN
  - Antibiotic syringes (cefazolin)
  - Vasopressors
  - Controlled substances (PCA)

January 2014- Scripps Health implemented a system-wide environmental sampling program. Initially, all sampling at the hospitals conducted by the pharmacy technicians of central pharmacy.

February 2014- Scripps central pharmacy licensed as a centralized hospital packaging pharmacy

February 2014- Central pharmacy began production of antibiotic syringes

March 2014- Pharmacy leadership (directors, operations managers, medication safety officers) received formal sterile compounding training

March 2014- Central pharmacy began production of vasopressors and other selected IVPBs

May 2014- Scripps Health approved system-wide sterile compounding policy which includes:
  - Education and competency requirements for all personnel who perform or oversee sterile compounding
  - Standardization of training for environmental services technicians who clean pharmacy areas, including i.v. buffer rooms and ante-areas
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 3 – Ryan Forrey

Topics

- Real estate and facility considerations for renovating an existing i.v. sterile compounding space
- Using a decision matrix for modular walls and materials for building or renovating sterile compounding space
- Key design elements for a USP Chapter <797> and USP Chapter <800> compliant renovation
- Developing a program of requirements (POR) for your facility renovation
- Understanding “value engineering” and which compromises to make in design specifications

Ryan A. Forrey, Pharm.D., M.S., FASHP

Ryan A. Forrey, Pharm.D., M.S., FASHP, is Director of Pharmaceutical Services, at Emory University Hospital Midtown in Atlanta, Georgia, and Clinical Assistant Professor at The Ohio State University (OSU) College of Pharmacy, Columbus, Ohio.

Dr. Forrey has published articles in the field of medication errors and prevention, operational efficiency and productivity measurement, and hazardous drug safe handling. He has presented on numerous topics, USP Chapter <797>, USP Chapter <800>, hazardous medication handling and preparation, and pharmaceutical waste management. In his role at Emory, he leads and directs the Department of Pharmacy for Emory University Hospital Midtown, which includes the outpatient infusion pharmacy areas for the Emory Winship Cancer Institute.

Dr. Forrey currently serves on the United States Pharmacopeial Convention (USP) Compounding Expert Committee for 2015-2020. He is also an active member of the Hematology/Oncology Pharmacists Association (HOPA), ASHP, and the International Pharmaceutical Federation (FIP). He currently represents HOPA on the Oncology Nursing Society (ONS) Safe-Handling Taskforce.
Emory Healthcare

Emory Healthcare is the largest, most comprehensive health system in Georgia
- Seven hospitals and more than 1,800 hospital beds
- Includes Emory University Hospital, Emory University Hospital Midtown, Emory Saint Joseph’s Hospital, Emory Johns Creek Hospital, Emory University Orthopaedics & Spine Hospital, Emory University Hospital at Wesley Woods, and the Emory Rehabilitation Hospital, which is in partnership with Select Medical

Emory University Hospital Midtown
- 511-bed community-based, acute care teaching facility and full-service hospital in Midtown Atlanta
- Offers a full range of services, which include general medicine, maternal and infant care, orthopaedics and surgery
- Includes 56 ICU beds and level III neonatal intensive care unit
- Staffed by 600 Emory medical faculty and 800 community physicians
- More than 23,205 inpatients and 143,961 outpatients come to Emory University Hospital Midtown each year
- Sterile preparations area utilizes the airflow displacement “open” concept for maintaining the ISO 7 buffer area
  - Prepares an average of 1500 non-hazardous CSPs daily, includes a mixture of traditional patient specific admixtures, batched compounding, and proprietary bag/vial systems
  - The Department of Pharmacy also operates an operating room satellite pharmacy 16 hours per day and an outpatient oncology satellite pharmacy that opened January 2016 and is both USP Chapter <797> and <800> compliant.

I.V. Sterile Compounding Timeline

At Emory University Hospital Midtown (EUHM) the current i.v. sterile compounding area was renovated most recently in 2004, shortly after the release of the first version of USP 797. At that time, it was compliant with both hazardous drug requirements as well as low and medium-risk compounding. The space utilizes the airflow displacement concept for maintaining the required ISO 7 air classification.

Prior to 2012 the department outsourced some sterile preparations to a variety of compounding pharmacies, but since the NECC tragedy, the outsourcing has been limited and now is exclusively limited to 503B registered facilities, and annual inspections of these facilities are conducted. Total Parenteral Nutrition admixtures (TPNs) were previously compounded in a central location for all of Emory Healthcare, but with changes in state regulations, EUHM began compounding TPNs on-site.

In late 2015, with the discontinuation of Baxter RAPIDFILL™ system after a class 1 recall of the proprietary syringe strips, anesthesia syringes for the ORs were outsourced to a 503B registered compounding pharmacy. Renovations of the sterile compounding area began in May 2016, and when completed, OR syringe batch preparation as well as high-risk compounding will be supported.
Engaging Colleagues: Making Connections to Answer the
Insourcing “Tough Questions”

Breakout Table 4 – Katie McMillen

Topics

- Metrics and the evaluation of those metrics in making the business case for insourcing CSPs using a “central fill” model
- Real estate and facility considerations for building or designing a “central fill” model for i.v. sterile compounding
- Regulatory considerations of insourcing i.v. sterile compounding operations
- Challenges of insourcing i.v. sterile compounding operations in a changing regulatory landscape

Katie McMillen, Pharm.D., M.P.H., M.H.A.

Katie McMillen, Pharm.D., M.P.H., M.H.A., is Director of Pharmacy for the Oncology Service Line and Specialty Pharmacy Services at Froedtert and Medical College of Wisconsin. She is responsible for the development and management of the recently accredited URAC Specialty Pharmacy Program for the health system. This includes a newly-constructed dedicated off-site Integrated Service Center that will serve as the clinical and operational hub for specialty services and centralized sterile products compounding for patients across the system.

During her time at Froedtert, Dr. McMillen has been the project lead for the planning and design of four new clean rooms and one clean room renovation. Prior to Froedtert, Dr. McMillen worked as an Operations Manager at the University of Pittsburgh Medical Center where she also completed a two-year health care administration residency.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 4 – Katie McMillen

Froedtert & Medical College of Wisconsin

- Three hospital health system
  - Three hospital cleans room
  - Three cancer center cleans rooms (Note- prepare all hazardous medications for each respective campus)
  - One dedicated infusion center clean room
  - 120,000 compounded sterile preparations (CSPs) dispensed system wide per year
- Integrated Service Center that will serve as centralized i.v. compounding site for system
  - Under construction with expected completion July 2016
- Seven on-site retail pharmacies
- Integrated, decentralized practice model
  - 7/70 staff
  - 8 hour, rotating staff
- OR pharmacy satellite
- Hematology/oncology pharmacy satellite
- ED pharmacy services
- Ambulatory care pharmacy services

I.V. Sterile Compounding Timeline

Sterile compounding has been an evolution. As organizations struggle with space and financial constraints, prioritizing much needed but costly updates to institution clean rooms tends to fall below threshold approval. Without the ability to make structural changes Froedtert & MCW continued to implement operational and product changes that would allow standards within the department of pharmacy to be met. Unable to fully meet USP Chapter <797> regulations and drug product shortages have resulted in many organizations, such as Froedtert & MCW, outsourcing a portion of their compounded sterile products.

However, recent well-documented problems with compounding service provider is what led Froedtert & MCW to support the renovation of all existing clean rooms across the system. Additionally, the business plan to construct a newly centralized remote compounding center as part of the Integrated Service Center (ISC) was supported. The intent is to slowly bring back outsourced medications in-house starting with a small library of approximately 8 products. A secondary goal includes a shift in batch preparation (including OR syringes, TPNs, antiemetic premedication) to the ISC to allow the on-site hospital clean rooms to focus on patient specific medications.
## Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

### Breakout Table 5 – Cindy Mitman

### Topics

- **CSP waste metrics and the evaluation of these metrics to determining when to outsource for better dating**
- **Standardizing insourced compounded sterile preparations (CSPs) operations and training across multiple sites**
- **Overcoming CSP insourcing challenges in a small hospital**
- **Standardizing CSP concentrations within a multi-hospital formulary**
- **Conducting site visits for outsourcing vendors**

### Cindy L. Mitman, Pharm.D., M.B.A.

Cindy L. Mitman, Pharm.D., M.B.A., is Assistant Director of Pharmacy, at Lehigh Valley Health Network (LVHN), Cedar Crest and 17th Street sites in Allentown, Pennsylvania. Dr. Mitman has published articles in the fields of sterile compounding and clinical pharmacology. She has presented on numerous topics, USP Chapter <71>, USP Chapter <797>, and outsourcing compounded sterile preparations. In her role at LVHN, she leads and directs the operations of pharmacy at two of the network’s sites, including direct oversight of the sterile compounding areas. At the Cedar Crest site, she has direct oversight of the operations of the pharmacy for a 750+ bed hospital, which includes the children’s hospital. At the 17th Street site, she has direct oversight of the operations of the pharmacy for a 100-bed hospital.

### Lehigh Valley Health Network

5 campus hospital system
- Children’s hospital
- Over 1100 total beds
- 95 clinical specialties (burn center, level I trauma center, level III NICU, comprehensive stroke center, oncology)
- Dispense > 400,000 CSPs at Cedar Crest site
- Compound stats, fill list batches and anticipatory CSPs on 2 shifts, only stats overnight
I.V. Sterile Compounding Timeline

Cedar Crest adopted USP Chapter <797> standards just prior to the 2008 update. The first optimization of processes involved garbing practices. In 2007, a new pharmacy was planned and designs were under way. However, once the 2008 update was published, the designs for i.v. sterile compounding were quickly changed before the late 2008 move to the new pharmacy. Prior to 2008, the existing pharmacy compounded hazardous drugs in the same cleanroom as the non-hazardous drugs. The new design incorporated the change to having a separate negative pressure room for hazardous drug compounding.

Since the 2008 move, the commitment to achieving 100% USP Chapter <797> compliance continued. Education on USP <71> and USP <797> was provided to the compounding staff, standard operating procedures were developed and training was improved. After the Fall of 2012, environmental monitoring improved at LVHN, while education on the guidelines continued to be a focus.

Prior to the NECC tragedy, many CSPs were outsourced. Once the primary outsourcer closed, LVHN insourced almost everything, except TPNs and oxytocin. LVHN has slowly started outsourcing, but not without conducting site visits to every prospective vendor. LVHN has begun working on insourcing everything again through a central i.v site, but has most recently been affected by the latest FDA guidance documents on hospitals and health systems.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 6 – Richard Montgomery

Topics

- Regulatory considerations of insourcing i.v. sterile compounding operations
- Metrics and the evaluation of those metrics to make the business case for insourcing compounded sterile preparations (CSPs) using a “central fill” model
- Real estate and facility considerations for building or designing a “central fill” model for CSPs

Richard Montgomery, B.S.Pharm., M.B.A.

Richard Montgomery, B.S.Pharm., M.B.A., is the pharmacy contracts and operations manager for Adventist Health System, a 46 hospital, 8300-bed health system headquartered in Altamonte Springs, Florida. Prior to moving to Adventist Health, Mr. Montgomery was the system director of pharmacy for Florida Hospital Orlando division, an Adventist hospital system.

Mr. Montgomery earned his B. S. degree in pharmacy from the University of Pittsburgh and a Master of Business Administration from the University of Central Florida.

Within the Adventist Health system, Mr. Montgomery has been involved in multiple committees and project leads including serving as the lead in the development of the central distribution pharmacy. He is an active member in ASHP, serving as a delegate for the state of Florida at the House of Delegates and a member of the ASHP council on Education and Workforce Development in 2015. He is a member of Florida Society of Health System Pharmacists, serving as President in 2008-2009.

Florida Hospital – Orlando

Seven campuses in Orlando, Florida, area

- System has 2300 licensed beds
- Specialty areas: Pediatrics, cardiology, oncology, transplant and gastroenterology
- Central pharmacy currently compounding 11,000 bags of various medications monthly
  - Primary medications: vancomycin, cefazolin, insulin, oxytocin, and nicardipine
  - OR syringes and vasopressor i.v. bags are next products to go into production
- Narcotic medications are obtained from a 503B outsourcing company
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 6 – Richard Montgomery

I.V. Sterile Compounding Timeline

Prior to the central pharmacy program, each hospital was responsible for IV compounding. Florida Hospital was slow to adopt USP Chapter <797>. The company chose to move to an isolator model in the mid 2000’s. During the drug shortage peak and the NECC tragedy, a decision was made to build a central i.v. compounding center. In the interim, FH reduced the number of outsourcing vendors to two. In 2013 the central pharmacy was built and started production. The ramp up period was extended due to some legislative changes in Florida. Currently the central pharmacy is producing select i.v. compounds and select OR syringes. Central pharmacy is not currently insourcing TPN’s nor doing any high risk compounding.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 7 – Melissa Ortega

Topics

• **Metrics and the evaluation of those metrics in making the business case for insourcing compounded i.v. sterile preparations**
• **Regulatory considerations of insourcing i.v. sterile compounding operations**
• **Successes and challenges of insourcing i.v. sterile compounding within a stand-alone hospital**
• **Establishing risk mitigation procedures to meet high standards of practice to ensure patient safety for both internal and external sterile compounding facilities**

Melissa Ortega, Pharm.D., M.S.

Melissa Ortega, Pharm.D., M.S., is Director, Pediatrics and Inpatient Pharmacy Operations at Tufts Medical Center in Boston. As a member of the Pharmacy Department’s leadership team, she oversees a combination of clinical and operational pharmacy services which includes central operations, the sterile products area, pediatrics and the emergency department. Additionally, she serves as preceptor for the PGY1 practice management rotation and oversees the Northeastern University’s Bouve’ College of Health Sciences School of Pharmacy cooperative education (Co-op) program.

Melissa has contributed to several key initiatives within her department including her involvement in the implementation of our Carousel technology, facilitating the Pharmacy Council for Technician Advancement, the design and deployment of our Team-Based Technicians, enhancing sterile compounding services to medium risk capability, increasing the amount of ready to administer doses dispensed form pharmacy, and the formalization of the Sterile Products Oversight Committee.

Melissa received her doctorate of pharmacy degree from Nova Southeastern University in Fort Lauderdale, Florida and completed her pharmacy practice and health-system pharmacy administration residencies at the University of Wisconsin Hospital and Clinics. Melissa remains active in the Massachusetts Society of Health-System Pharmacists and the ASHP Section for Pharmacy Practice Managers on Leadership Development.
Engaging Colleagues: Making Connections to Answer the Insourcing “Tough Questions”

Breakout Table 7 – Melissa Ortega

Tufts Medical Center
- Not-for-profit, 415-bed academic medical center subdivided into a full-service adult hospital and the Floating Hospital for Children.
- Located in downtown Boston, the Tufts Medical Center (TMC) is a regional referral center for complex and high-risk care, and the principal teaching hospital for Tufts University School of Medicine.
- Approximately 20,000 admissions and 40,000 emergency room visits.
- TMC contains one i.v. sterile compounding clean room in which the scope of i.v. sterile compounding is limited to low/medium risk capability and one infusion center that compounds hazardous medications.
- Department of pharmacy dispenses 2.3 million doses of medication annually
  - 350,000 compounded sterile products (CSPs) prepared annually
  - Reduced reliance on outside compounding services, limited to high-risk and complex admixtures (e.g. TPNs, anesthesia syringes, dialysate, and controlled substances)

I.V. Sterile Compounding Timeline
Historically, 7-10 years ago the Department of Nursing and Anesthesiology prepared thousands of sterile compounds of medications within the patient care areas. In the early 2000s the Department of Pharmacy began contracting with outside vendors who could not only prepare the sterile compounds our patients needed, but also do so in a manufacturing environment where the preparations are assigned extended dating that would reduce drug wastage. At that time, anesthesia preparations, TPNs, and high risk/complex compounds were prepared by outside vendors. The Department of Pharmacy was able to continue operations and USP Chapter <797> compliance for low risk compounds with existing FTEs and limited operations during the day.

In 2012, TMC was highly reliant on outside compounding pharmacies (80,000 CSPs annually) for the production of sterile compounds. Since the abrupt closure of these outside vendors, TMC began preparing approximately 200 additional doses of CSPs per day equating to a 30% increase in workload. CSPs previously outsourced were now prepared for specific patients or in batches or vials loaded in automated dispensing cabinets (ADCs) for providers/ nurses to prepare in patient care areas.

As TMC reviewed options, the following were specific elements evaluated: Necessary sterility testing needed for extended “beyond use dating” within i.v. room operations, storage at room temperature, and additional FTEs to account for the expansion of hours of operations and increased workload. Sterility testing for extended “beyond use dating” was determined to be cost-prohibitive and insourcing was only found to be feasible for non-controlled medications. Additional resources and refrigeration were justified to support the insourcing of non-controlled medications (45,000 CSPs annually). As a result, TMC is no longer outsourcing the majority of i.v. sterile compounding production and was able to successfully decrease annual operating expense while reducing overall risk exposure associated with outsourcing the majority of i.v. sterile compounding services.