From Diluting and Mixing to Monitoring and Compliance: The Evolving Role of Pharmacy Technicians in Sterile Compounding

Objectives

• Describe current landscape relative to the role of the pharmacy technician.

• Discuss specialized roles for pharmacy technicians within sterile compounding, i.e., environmental monitoring, regulatory compliance, and automation.

• Describe examples of pharmacy technicians positively impacting sterile compounding operations and workflow efficiency.

Expanding Technician Roles in Sterile Compounding:
Specialized Roles for Pharmacy Technicians in the Changing Sterile Compounding Landscape

Jason Tomichek, Pharm.D.
Manager, Sterile and Non-Sterile Products
Vanderbilt University Medical Center
Nashville, Tennessee

Agenda

• Outline the pharmacy enterprise for Vanderbilt University Medical Center

• Discuss the impact of the fungal meningitis outbreak from contaminated compounded sterile products on current regulations

• Describe how the roles of a designated sterile products team can have an impact on compounding oversight

Disclosures

The program chair and presenters for this continuing education activity have reported no relevant financial relationships.

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2015 Midyear Clinical Meeting & Exhibition

Pharmacy Enterprise

VUMC Pharmacy Enterprise
FY 2016 Budget

Facility
<table>
<thead>
<tr>
<th>Beds</th>
<th>Clinic Visits</th>
<th>Drug Expense</th>
<th>FTE's</th>
</tr>
</thead>
<tbody>
<tr>
<td>VUH Hospital Pharmacy</td>
<td>820</td>
<td>1.6 million</td>
<td>$253,000,000</td>
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<tr>
<td>VUH Children's Hospital</td>
<td>270</td>
<td>300,000</td>
<td>$24,000,000</td>
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<tr>
<td>VUH Psychiatric Hospital</td>
<td>88</td>
<td></td>
<td>$417,000</td>
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<tr>
<td>VUH Rehabilitation Hospital</td>
<td>80</td>
<td></td>
<td>$481,000</td>
</tr>
</tbody>
</table>

TOTAL: 8,000

Admit & Children's Admissions = 10,000
Admit CMI = 2.1
Children's CMI = 1.6

Pharmacy Staff

Vanderbilt University Hospital & Clinics
Monroe Carell Jr. Children's Hospital at Vanderbilt

Pharmacists: 13
Techs: 19
Other: 60

Annual Sterile Product Workload

Sterile Product Production

<table>
<thead>
<tr>
<th>Facility</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>VUH Hospital ( heroine)</td>
<td>785,785</td>
<td>1,881,881</td>
<td>1,828,828</td>
</tr>
<tr>
<td>VUH Clinic (non-chemo)</td>
<td>21,580</td>
<td>21,948</td>
<td>21,277</td>
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<tr>
<td>VUH Clinic (chemo)</td>
<td>8,080</td>
<td>8,080</td>
<td>8,080</td>
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<tr>
<td>Green Hills (non-chemo)</td>
<td>152</td>
<td>1,372</td>
<td>2,155</td>
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<tr>
<td>Cool Springs (non-chemo)</td>
<td>1,889</td>
<td>2,200</td>
<td>1,392</td>
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<tr>
<td>Oncology (chemo)</td>
<td>68,144</td>
<td>68,563</td>
<td>73,688</td>
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<td>TOTALS</td>
<td>1,180,868</td>
<td>1,286,944</td>
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</tbody>
</table>

*Correlation Total inhalation & clinic volume

2015 projected @ 1,286,944

Daily Workload Stats

Metric | Volume
---|---
Orders Processed | 6,000
Doses Dispensed | 20,000
Retail Prescriptions | 1,780
Sterile Products | 2,500
Hematology Inpatient | 1,600
TPN's | 30
AcuDose-Transaction | 15,000

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Sterile Product Production

- Admix Batch
- Premix Batch ↔ Hazardous

Sterile Product Production

- Anticipatory
  - OR Anesthesia Syringes
  - Oxytocin Infusions

- Blood Products
  - IVIG
  - Kcentra

- Pain Management
  - Epidurals
  - PCAs

Compounding Crisis

- Tuesday, September 18, 2012

- Email from Vanderbilt University Medical Center to Tennessee Department of Health reporting case of fungal meningitis

- Linked case to lumbar epidural steroid injections patient had received at outside facility

- Within 48 hours had confirmed exposure, contacted CDC, and identified 2 additional potential cases in TN

- Outside facility voluntarily closes and supplies of medications including methylprednisolone acetate (MPA) sequestered

Why?

- Lack of compliance with regulations
- Inadequate and ineffective oversight
- Lack of competency and proficiency
- Inadequate policies and procedures
- Hand hygiene and grooming
- Preventive maintenance

Exposure

Persons with Fungal Infections Linked to Steroid Injections, by State

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Regulatory Response

- Compounding Quality Act
- November 2013
- Outsourcing Facilities
- Traditional Compounders
- FDA Regulation
- State Board of Pharmacy

USP Chapter <797>
- Tennessee Board of Pharmacy
  - January 2014
  - Sterile compounding now mandated by USP Chapter <797>

- Minimum practice and quality standards for compounding sterile preparations
- Mission of chapter is to prevent harm
  - Microbial contamination
  - Excessive bacterial endotoxins
  - Unintended chemical and physical contaminants

A Wake Up Call
- Decision made to gain more control of CSP production within institution
  - Risk management: Insourcing

Vanderbilt & USP Chapter <797>
- Oversight of internal procedures
  - Sterile Products Policy Subcommittee
  - Sterile Products Oversight Committee

- Standards of practice for high reliability in sterile product compounding
  - Automation

- Increased compounding oversight
  - Quality control
  - Regulatory compliance
  - Inventory management

Sterile Product Oversight Committee
- Charter
  - Provide oversight and support for maintaining compliance with regulatory standards and safe practice guidelines

- Responsibilities
  - Set general direction and policy
  - Establish a quality assurance and control plan
  - Review reports, trends, and audit results
  - Provide compliance and oversight direction
  - Provide appropriate resources
  - Determine needed modifications or expansion
  - Correct and/or report deficiencies within expected timeframes

Sterile Product Oversight Committee
- Activities to date
  - Southeastern Certification Review
    - Cleanroom compliance (hoods and rooms)
    - Environmental sampling for viable organisms
  - Review of personnel training, competencies, and media challenge
  - Dashboard review
  - Robot Progress
  - ISMP Recommendations
  - DoseEdge Implementation

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Automation

- Rapid-Fill Automated Syringe Filler
  - Variety of products
  - Anesthesia syringes
  - Dialysis antibiotic locks
  - OR antibiotic syringes

- TPN Compounder
  - Streamlined for parenteral nutrition
  - Compliance with detailed reporting

Pharmacy Workflow Manager

- Promotes Dose Preparation Safety
  - Automatic calculations
  - Barcode verification

- Reduce Waste
  - Identifies errors prior to admixture
  - Unexpired returned doses can be used

- Enhances Pharmacy Productivity
  - Remote dose inspection

I.V. Robotics

- In-process barcode scanning and image recognition
- Gravimetric controls for accuracy
- Automated final product labeling
- Remote verification

Sterile Products Team

Provides oversight for sterile products at VUMC
- USP <797> compliance
- Training
- Anticipatory batching
- Adult and pediatric PNs
- Informatics
- Committee participation

Sterile Products Team

- Sterile Product Manager
- Sterile Product Technician Coordinator
- Pharmacists (7)
- Tech III (16)
Key Takeaways

• Outbreaks such as the contaminated MPA from NECC have shifted the regulatory focus to compounding of sterile products

• The Compounding Quality Act of 2013 has increased the amount of oversight required to remain compliant in compounding and has created unique opportunities for technicians

Expanding Technician Roles in Sterile Compounding:
Training, Competency, and Certification
Driving Quality and Efficiency

Ashley Smith, CPhT
Sterile Products Technician Coordinator
Vanderbilt University Medical Center
Nashville, Tennessee

Agenda

❖ Describe the current landscape of the role of the pharmacy technician at Vanderbilt University Medical Center

❖ Discuss specialized roles for pharmacy technicians within sterile compounding
Career Ladder 2015

- Mentoring and Training Opportunities
  - Enhance on-the-job performance
  - Future marketability

- Increased knowledge
  - Customer service
  - Leadership and problem solving
  - Information technology
  - Computer applications
  - Process improvement

Verifier

- Technician Check Technician (TCT)
  - Programs have been in existence for over 20 years
  - Adopted into Tennessee law in 2010
  - Studies show comparable accuracy for medication verification as pharmacists

- Provision of TCT State Law
  - Verify contents of unit dose cart prepared by other technicians
  - Must have other verification means such as bar code or registered health care professional prior to administration

Requirements & Training

- Required experience
  - 24 months of general pharmacy experience
  - 12 months of Vanderbilt Pharmacy experience
  - Completion of IV training

- Didactic work
  - Hospital order fundamentals
  - Pharmacy law, topics of regulatory compliance
  - Medication safety (look-alike, sound-alike and high alert medications)
  - Basic clinical pharmacy principles

Expectations & Interventions

- Expectations
  - 99% accuracy rate on 1500 items prior to independent checking
  - Follow up audits monthly, quarterly, and annually
  - Random audits

- Interventions
  - Greater than 100 per month
    - Decrease tablet burden with dose strength changes
    - Written dose directions clarified
    - MD order revisions
    - Warfarin order clarification
Verifier Exam

Technician I

Experience
- 6 months pharmacy

Knowledge & Skills
- CPhT Certification
- Fundamental proficiency in dispensing medications under pharmacist supervision
- Awareness of appropriate inventory levels
- Effective use of pharmacy computer systems
- General problem recognition and solving

Technician II

Experience
- 6 months VUMC pharmacy
- 6 months Technician I

Knowledge & Skills
- Mentors and trains entry-level technicians
- Identifies errors and effectively communicates them to pharmacist
- Working knowledge of inventory procurement and management
- Demonstrates ability to be team leader
- Advanced customer service skills

Technician III

Experience
- 15 months VUMC pharmacy
- 9 months Technician II

Knowledge & Skills
- Manage & lead technicians
- Mitigate staff conflict
- Identifies & pursues areas of improvement
- Assists in the on-boarding, mentoring, and training of new hires
- Lead technician in specific area
- Procurement & supply process problem resolution

Advancement Review Board
- Appointed representatives from each of the major divisions of the pharmacy
- Coordinators present technicians for advancement to the board
- Each division receives one vote
- Board votes on advancement of technician
  - Technician I ➔ Technician II
  - Technician II ➔ Technician III
Sterile Products Training Overview

Welcome to sterile products training. Over the course of the next four weeks (10 days), you will be trained in the proper way to prepare sterile products here at Vanderbilt. You will be assigned a trainer, and upon successful completion of the training, you will be checked off and be allowed to work on the unit independently.

Sterile Product Training: Didactic

- Videos
- ASHP
- DoseEdge
- Aseptic Technique
  - Cleanroom Airflow (Positive vs. Negative)
  - Hood Airflow (Vertical vs. Horizontal)
  - Critical Site
  - Garbing Technique
- Equipment & Math
  - IV Automation
  - Equipment (Bag Adapters, Needles, Syringes, etc.)
  - Dose Calculations

Sterile Product Training: Active Participation/Observation

- Cleansing/Garbing
- Media/Fingertip Challenge
- Product Preparation

Sterile Product Training: Check-Off

- Observation of Product Preparation
  - Technician III Trainer
  - Sterile Product Coordinator
- Scoring of technique and math
  - Positives/deficiencies reviewed
  - Score of 80% to pass
- I failed, now what?
  - 4 more days of intense training
  - Check-off retake

Future of Sterile Products Training

- Supervisor
  - Coordinate training enterprise wide
- Enterprise Goal:
  - To provide consistent training to every employee in every pharmacy division
  - More Didactic Training
    - Airflow and Particle Studies
    - Non-Viable, Viable, and Environmental Sampling
  - Training on multiple shifts
    - Customized to employee’s shift
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Inventory Management

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Description</th>
<th>Shelf Life</th>
<th>Batch Number</th>
<th>Expiration Date</th>
<th>Lot Number</th>
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<tr>
<td>Example</td>
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<td>XX1234</td>
<td>04/2022</td>
<td>5678</td>
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Software Maintenance

Cleaning & Disinfection

USP Chapter <797>

<table>
<thead>
<tr>
<th>Area</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td>Handling</td>
<td>Daily</td>
</tr>
<tr>
<td>Countertops</td>
<td>Weekly</td>
</tr>
<tr>
<td>Equipment</td>
<td>Monthly</td>
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</tbody>
</table>

VUMC

<table>
<thead>
<tr>
<th>Area</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>Daily</td>
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<td>Weekly</td>
</tr>
<tr>
<td>Equipment</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

Table 3: Minimum Frequency of Cleaning and Disinfecting Compounding Areas

- **ISO Class 1 (See Title 3):** Primary Engineering Control (e.g., UVF, UV, O2, O3)  
  - At the beginning of each shift, before and after each change in demonstrated surface disinfection, and during nonstop cleaning areas, sterile products, and equipment.  
  - To be used in the sterile area, sterile products, sterile equipment, and equipment nonsterile area.

- **Countertops and utility carts:**  
  - Daily

- **Equipment:**  
  - Monthly

- **Storage:**  
  - Monthly

PN Order Entry

Adult and Pediatric PN

Primary order entry

<table>
<thead>
<tr>
<th>Order Type</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Adult</td>
<td>Adult orders</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Pediatric orders</td>
</tr>
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</table>

PN 3rd Check

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Environmental Monitoring
- Pressure Differential
- Temperature & Humidity
- Monthly Pre-Filter Check

Media Challenges

Documentation

Future Opportunity

Career Ladder - Future
(True or False) The Compounding Quality Act of 2013 gave authority to the FDA to regulate outsourcing facilities and gave state specific boards of pharmacy regulation over traditional compounders.

- True
- False

Which of the following roles can technicians establish to help increase compounding oversight?

- Cleaning and Disinfection
- Training and Competency
- Policy and SOP creation
- All the above

Case Study: Pharmacy Technicians Positively Impacting Workflow and Quality

Cindy Chan, Pharm.D.
Pharmacy Operations Manager
Providence Infusion and Pharmacy Services
Tukwila, WA

Agenda

- Background of Providence Infusion and Pharmacy Services
- Role of Lead Technician
- Role of Quality Control Unit
- Pharmacy Technician Training Program
- Staff Engagement with USP 797
- Case Study #1- Environmental Sampling Results
- Case Study #2- Compounding Error

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

- Home Infusion Business Line
  - Serves 1100 patients across Washington State
  - Therapies
    - Antibiotics
    - TPN
    - PCA
    - Hydration
    - Chemotherapy
    - Miscellaneous (Inotropic agents, IVIG, SQIG)
Providence Infusion and Pharmacy Services
- Manufacturing Business Line
  - Serves 12 Providence hospitals in Washington State under state pharmaceutical manufacturing license
  - Product formulary
    - Antibiotics (~12,000 doses/month)
    - Oxytocin (~1,600 doses per month)
    - Buffered Lidocaine (~5000 doses/month)
  - Goal for FDA 503B registration in 2016

Home Infusion Cleanroom
- Environmental Testing
  - Viable air/surface sampling performed monthly by trained Providence staff
  - Non-viable sampling performed semi-annually by certified vendor
  - Results meet or exceed USP 797 standards
    - Buffer Room ISO 6 (min = ISO 7)
    - Ante Room ISO 7 (min = ISO 8)
    - LAFW’s ISO 3 or 4 (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 7 (min = ISO 7)
    - Ante Room ISO 6 (min = ISO 8)
    - LAFW’s ISO 3 or 4 (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

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

How often do you conduct environmental sampling?
- Monthly
- Semi-annually
- Annually
- I’ve never conducted environmental sampling
Lead Technician
- Conducts/oversees training, ongoing competencies, processes related to USP 797
- Directs workflow
- Contributes to departmental goals, objectives, P&P’s
- Participates in QA/QI process
- Resolves equipment malfunctions in IV room

Lead Technician (cont.)
- Tracks tech productivity
- Participates in software upgrades & maintain product formulary for pharmacy applications
- Conducts monthly environmental sampling

Quality Control Unit
- Conducts/oversees training, ongoing competencies, processes in compliance with cGMP’s
- Approves/rejects all components, finished product related to manufacturing
- Performs method suitability & sterility testing of all manufactured finished product

Quality Control Unit (cont.)
- Conducts monthly environmental sampling
- Maintains established quality management system
- Creates batch records/labels
- Establishes procedures facilitating cGMP-compliant workflows

Pharmacy Technician Training Program
Upon hire and annually thereafter:
- Media Fills, Gloved Fingertip Sampling
- Review of P&P’s, USP 797
- Observed Competencies, Written Exams
- Online competencies

Photos provided by Providence Infusion and Pharmacy Services

Photos provided by Providence Infusion Hospital Services

Photos provided by Providence Infusion Hospital Services

Photos provided by Providence Infusion Hospital Services
Pharmacy Technician Training Program

- Total average initial training time per pharmacy technician: (without batching): 640 HOURS
- Total average initial training time per pharmacy technician: (with batching): 720 HOURS
- Annual Training per Pharmacy Technician: 55 HOURS

What does your pharmacy technician training program include?

- Media fills
- Observed competencies
- Written exams
- One or more of the above

Staff Engagement with Practice Standards

- Structured interview process - establish expectations
- Expectations reinforced on Day 1
- 30-day, 60-day, 90-day, 6-month annual review
- Monthly review of environmental sampling results
- Quarterly Quality Meetings to discuss events, errors, near-misses, process improvement

Staff Engagement with Practice Standards

- Weekly stand-up meeting
- Annual online training related to USP <797>/cGMPs
- Individual employee goals
- Peer-to-peer audits of standardized processes

Case Study #1

- Air sample near staging cart grew 12 colony forming units (cfu) (10 cfu = action level)
- Surface sample on staging cart within normal limits (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 misted with sterile isopropyl alcohol (IPA) 70% prior to entering room
Case Study Action Steps

- Cart removed from buffer room and cleaned in ante room 3 times with the following protocol:
  - Lysol IC
  - Sterile IPA 70%
  - Sporicidin
  - Sterile IPA 70%

Microbiology Results

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

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 continues to be informed of environmental test results
**Case Study #2**

- Premature infant in NICU infused incorrect TPN formula
- Infant experienced hyperglycemia
- Insulin drip initiated
- Infant developed sepsis
- Existing comorbidities

**Case #2 Contributing Factors to Compounding Error**

- Lack of standardization in staging, compounding, and checking process
- Distractions
- Lack of focus

**Case #2 Action Plan**

- Correct formula compounded and immediately delivered to hospital
- Staff informed immediately after event reported.
- Staff met next day to brainstorm process changes to ensure safety
- New processes initiated

**Case #2 Action Plan (cont.)**

- Root cause analysis completed
- Competency created; Sign-offs completed by Lead Tech & Supervisor
- Peer-to-peer audits
- Continuous process improvement

**Key Takeaways**

- **Key Takeaway #1**
  - Strong infrastructure is critical to quality
- **Key Takeaway #2**
  - Pharmacy Technicians are key contributors to quality outcomes
- **Key Takeaway #3**
  - Staff and management partnership in process improvement is vital to meeting practice standards

**Questions**