

Ensuring Sterile Compounding Safety: A Leading Role for Pharmacy Technicians



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Rita K. Jew, PharmD, MBA, BCPPS, FASHP
President
Institute for Safe Medication Practices

Angelica Henson-Ervin, CPhT
Sterile Compounding Quality Improvement Specialist
Dept. of Pharmaceutical Services, UCSF Medical Center

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Objectives

Following completion of this activity, participants will be able to:

1. Describe the most common error types associated with the preparation of compounded sterile preparations in the pharmacy.
2. Identify key safety practices for the reduction of risk during sterile compounding.
3. Describe the leadership role pharmacy technicians can play in ensuring medication safety and regulatory compliance for sterile compounding.



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CE Activity Information & Accreditation



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Susan Paparella MSN, RN

Angelic Henson-Ervin, CPhT

The speakers listed below disclosed potential conflicts of interest*:

Rita K. Jew, PharmD, MBA, BCPPS, FASHP

***Conflicts identified were resolved with a peer review process**

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Program Faculty



Susan Paparella, RN
Vice President, Services
ISMP



Rita K. Jew, PharmD, MBA,
BCPPS, FASHP
President
ISMP



Angelic Henson-Ervin, CPhT
Sterile Compounding Quality
Improvement Specialist
Dept. of Pharmaceutical
Services, UCSF Medical
Center



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Sterile Compounding Safe Practices

Rita K. Jew, PharmD, MBA, BCPPS, FASHP
President
Institute for Safe Medication Practices

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Evolution of CSPs Preparation

- Nurses prepared on counter-top in medication room
- Pharmacy prepared in laminar flow hood/biological cabinets
- USP 797 2004, 2008, latest revision pending
- State BOP regulations
- FDA designation of 503A & 503B compounding pharmacies



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Why all these changes?

Sterile compounding is a high-risk process!!



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Common Sterile Compounding Errors

- Wrong drug
- Wrong dose
- Wrong diluent
- Wrong concentration
- Mislabeling
- Contamination

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, December 17, 2014

14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak

Two Pharmacists Charged with 25 Murders in 7 States 12 Others Charged with Multiple Criminal Acts

ISMP SafetyAlert! Acute Care 1

April 23, 2009 • Volume 14 Issue 8

KCl concentrations need improved visibility. The potassium chloride 10 mEq containers from Hospira (pictured below) were placed in the vials.

Failed check system for chemotherapy leads to pharmacist's no contest plea for involuntary manslaughter

The April 19, 2009, Cleveland Plain Dealer covered another disconcerting report about a healthcare professional who is facing criminal charges for his role in a fatal

they start with an empty bag and follow a similar process. Compounding the solution from scratch is error-prone. Such exactness of base solutions is most often unnecessary from a clinical standpoint. Communication

ISMP SafetyAlert! Acute Care 1

September 15, 2007 • Volume 12 Issue 18

Your Reports at Work

packaging change. Thanks to your reports about look-alike packaging confusion between DAPTACEL (digifera and intranasal tonsils and axillary pertussis vaccine adjuvanted) and ADACEL (intranasal tonsils, reduced digifera tonsils, and axillary pertussis vaccine adjuvanted), small poster has changed the carton

Fatal 1,000-fold overdoses can occur, particularly to neonates, by transposing mcg and mg

In October 2006, an infant received a lethal dose of zinc stemming from an error that occurred during the order entry and compounding of a TPN solution. While not privy to a full root cause analysis, ISMP has learned details about the event^{1,2}

technician, noting the unusual preparation of the TPN that required numerous replenishments of the zinc syringe. The oncoming technician checked the order, discovered the error, and alerted a pharmacist, who immediately called the unit to stop the

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General Sterile Compounding Safe Practices

- Minimize sterile compounding outside the pharmacy
- Use commercially manufactured parenteral products when available
- Utilize technology for sterile compounding when possible
- Consider outsourcing based on organizational assessment
- Follow USP standards, other regulations & guidelines
- SOPs for sterile compounding
- Specific SOPs for labeling of CSP
- Specific SOPs for verification of CSP
- Pharmacist verify all transcribed orders



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General Sterile Compounding Safe Practices

- Additional training & competency assessment for preparing
 - Chemotherapy & hazardous drugs
 - Parenteral nutrition
 - Neonatal & pediatric preparations
 - High-risk compounding
- IDC master formulations
- Separation of products & supplies for each CSP or batch
- Dose volume available to avoid manual calculations
- DO NOT use production labels as final dispensing labels
- All containers are presented for final verification
- Clearly defined area for product verification



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General Sterile Compounding Safe Practices

- Separate preparation of pediatric/neonatal CSPs from adult CSPs
- Batch preparations include theoretical vs actual yield
- Drug conservation policy maintain integrity & sterility of drugs
- Machine-readable coding verification used for replenishment & removal of medications from inventory
- Advanced training & certification for pharmacists & technicians
- Document & analyze errors & close calls
- Report errors & close calls to ISMP MERP



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Sterile Compounding Safe Practices - Manual

- Maximize use of manufacturer-prepared products
- Purchase ready to administer products when available
- Consider outsourcing based on organizational assessment
- CSPs prepared in pharmacy
 - May compound same drug, dose & route for multiple patients at the same time
 - CSPs IDC by a pharmacist
- CSPs prepared outside pharmacy, SOPs in place for
 - Compounding (aseptic technique, BUD, etc.)
 - Labeling
 - Training
 - IDC by a 2nd practitioner
- Document & analyze errors & close calls
- Report errors & close calls to ISMP MERP



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Ensuring Safety and Compliance During Sterile Compounding: Sterile Compounding Program and The Role of the Technician

Angelica M. Henson-Ervin

Quality Improvement Health Care Specialist – Compliance
UCSF Medical Center



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Sterile Compounding Program – Nine Key Safety Practices

Policies and procedures/standard operating procedures

Sterile compounding training, competency validation and documentation

Environmental cleaning, maintenance, documentation and monitoring

Sterile compounding facility design

Equipment/room certification and calibration, and viable/non-viable sampling

Collaboration with other departments

Strategic operations planning

Quality assurance

Site-specific leader oversight



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Policies and procedures/standard operating procedures

- Follow USP guidelines and regulatory requirements
- Include all aspects of the Compounded Sterile Preparation(CSP) process
 - Master formula content and step-by-step preparation guide
 - CSP verification and validation
 - Beyond use dating (BUD) and rationale
 - CSP label criteria
 - Documentation process and record keeping
 - Training process and qualification to prepare and handle CSPs
 - Maintenance and monitoring of environmental controls and devices pivotal to CSPs
 - Storage, receiving, transport, and recall process



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Sterile compounding training, competency validation and documentation

All sterile compounding staff must go through a qualification process

- Policy/Standard operation procedure review and acknowledgment
- Didactic course work tailored to all sterile compounding safety and processes
- Hands-on demonstration and training
- Written exam encompassing sterile compounding knowledge and comprehension
- Direct observation of aseptic technique and safe handling proficiency
- Media validation of most complex CSP procedures and aseptic processes



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Environmental cleaning, maintenance, documentation and monitoring

Quality control in locations where CSPs are being prepared and stored

- Exceptional cleaning program for environmental controls, compounding devices, and facilities
 - Identification of party responsible for cleaning all environmental items
 - Products being used to clean the environment
 - Tools and equipment
 - Germicidal and sporicidal agents used and their contact/dwell time and BUD (as applicable)
 - How and where the tools and equipment are stored/disposed of
- Documentation of cleaning and record keeping of associated logs
- Monitoring of engineered controls uniquely designed to manage airflow mechanics
 - Documentation of the monitoring process
 - Adequate maintenance process in place as defined by policy



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Sterile Compounding Facility Design

- **Room surfaces** – smooth, cleaning agent compatible, and free from crevices and pores
- **Air quality** – flow, pressure differential, particle counts, and exchange rates
- **Equipment placement** – away from doorways/unsealed windows/high traffic areas, not blocking air returns, at least six inches from surrounding walls and other large equipment to allow for adequate cleaning and airflow
- **Line of demarcation** – placed to mitigate bioburden and support a dirty to clean protective equipment garbing process
- **Supply storage plan** – streamline medication and compounding supply to reduce particulate accumulation



Goal = Minimization of microorganism contamination



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Equipment/room certification and calibration, and viable/non-viable sampling

Assuring equipment safety and establishing a state of control

- HEPA filtered mechanics certified and/or calibrated by a well qualified vendor
- Balance/incubators/automatic compounding devices
- High touch and high traffic area sampling (air and surface)
 - Sampling map planning
 - Action level and limit workflow
 - Corrective action (and) preventative action (CAPA) plan
- Contracted well qualified certification and environmental sampling vendor



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Collaboration with other departments

Successful sterile compounding programs involve more than just the department of pharmaceutical services

- Building Facilities
 - HVAC, walls, floors, building structures
- Hospitality/Environmental Services
 - Cleaning program
- Infection Prevention
 - Viable sampling result analysis
 - Sampling site map collaboration
- Environmental Health and Safety
 - Consultation on environmental concerns
 - Medication waste oversight
 - Security measure program
- Regulatory Affairs
 - Legal collaboration
 - Federal regulatory liaison
- Material Procurement Services
 - Intravenous supplies
 - Waste containers
 - Various compounding related items



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Strategic operations planning

As regulations evolve, incorporating required changes into current workflows or redesigning workflows are necessary

- Elect a designated strategist or frontline staff to help evaluate the changes/requirements and how they can incorporate into workflows
- Form a work group panel to assess the strategist recommendations and provide constructive input
- Trial the revised/new workflow before full implementation



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Quality assurance

A successful sterile compounding program should include a proactive process in place to assure its integrity

Continuous system checks

- Policy adherence/compliance
- Qualitative/quantitative analysis
- Equipment functionality
- Software optimization
- Site audits (work practices and structural)

Regular team meetings

- Feedback
- Strategizing
- Check-in
- Project collaboration

Industry awareness

- Latest in best practice
- Upcoming regulation changes
- Innovative concepts



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Site-specific leader oversight

End-users execute the work practices designed to establish a state of control in the production of CSPs

- Identify frontline leaders in the sterile compounding areas
 - Foster an environment of inclusion – boost morale and aid ownership/accountability
 - Offer a designated position to garner insight, feedback, and assure expected execution of requirements
 - Conduct workflow training
 - Facilitate certification and environmental monitoring activities



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Pharmacy Technicians – Sterile Compounding Leaders

There are plenty of leadership positions within a comprehensive sterile compounding program that can be occupied by a pharmacy technician

- Potential sterile compounding program technician duties:
 - Developing sterile compounding policies and standard operation procedures
 - Develop and conduct sterile compounding program training
 - Outer department and committee liaison
 - Medication and CSP safety
 - Sterile compounding regulatory compliance
 - Sterile compounding research and development
 - Sterile compounding site leader
 - Competency and media validation facilitator



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Conclusion

- A well-run sterile compounding program is key to patient safety and regulatory compliance.
- Being proactive in assuring quality and utilizing the expert skill set of frontline work practice leaders will further optimize the sterile compounding program.
- The pharmacy technician has the dynamic insight that could help fuse the regulatory expectancy to the workflow while providing the needed safety measures.



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Questions?

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Sterile Compounding Technology: Pharmacy Technicians Lead the Adoption of Best Practices

June 7th, 2022 3-4 pm ET

www.ismp.org/events/sterile-compounding-technology-pharmacy-technicians-lead-adoption-best-practices



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