

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



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Objectives

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

1. State common safety challenges faced by technicians using sterile compounding technology.
2. Explain the role of the technician in designing a safe workflow plan for sterile compounding technology.
3. Discuss best practices identified during ISMP's National Sterile Compounding Summit.



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CE Activity Information & Accreditation



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The speakers listed below have no relevant commercial and/or financial relationships to disclose:

Elham Amiri, CPhT, CSPT, BS, HRGC

Christina Michalek, BSc Pharm, RPh, FASHP

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**

Please note: The opinions expressed in this activity should not be construed as those of the CE provider. The information and views are those of the faculty through clinical practice and knowledge of the professional literature. Portions of this activity may include unlabeled indications. Use of drugs and devices outside of labeling should be considered experimental and participants are advised to consult prescribing information and professional literature.



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Polling Question 1

Which of the following best represents your role:

- a) Pharmacy Technician
- b) Pharmacist
- c) Director/Administrator/Manager
- d) Medication Safety/Risk/Quality Specialist
- e) Faculty or Student



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Polling Question 2

Does your institution currently use sterile compounding technology?

- a) Yes
- b) No
- c) Not applicable to my setting



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Over the past 10 years, we have seen increased growth and use of sterile compounding technology.

In order to support safe use of these technologies, it is essential that pharmacists and pharmacy technicians work together to address workflow challenges.

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Pharmacy Technicians – Your Secret Weapon!

Pharmacy Technicians are one of the most effective resources you have to ensure that your IV workflows make the best and safest use of IV compounding technologies.

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A network graphic background consisting of white and blue nodes connected by thin lines, set against a dark blue gradient. An orange horizontal bar is located in the top left corner.

IV Workflow Management Systems
IV Robots
Automated Compounding Devices

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A network graphic background consisting of white and blue nodes connected by thin lines, set against a dark blue gradient. An orange horizontal bar is located in the top left corner.

Common safety challenges
faced by technicians using
sterile compounding technology

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Safety Challenges

- Foundation system double checks
- Workflows and shortcuts
- USP compliance & automation reliance
- Training and competency
- Understanding the why

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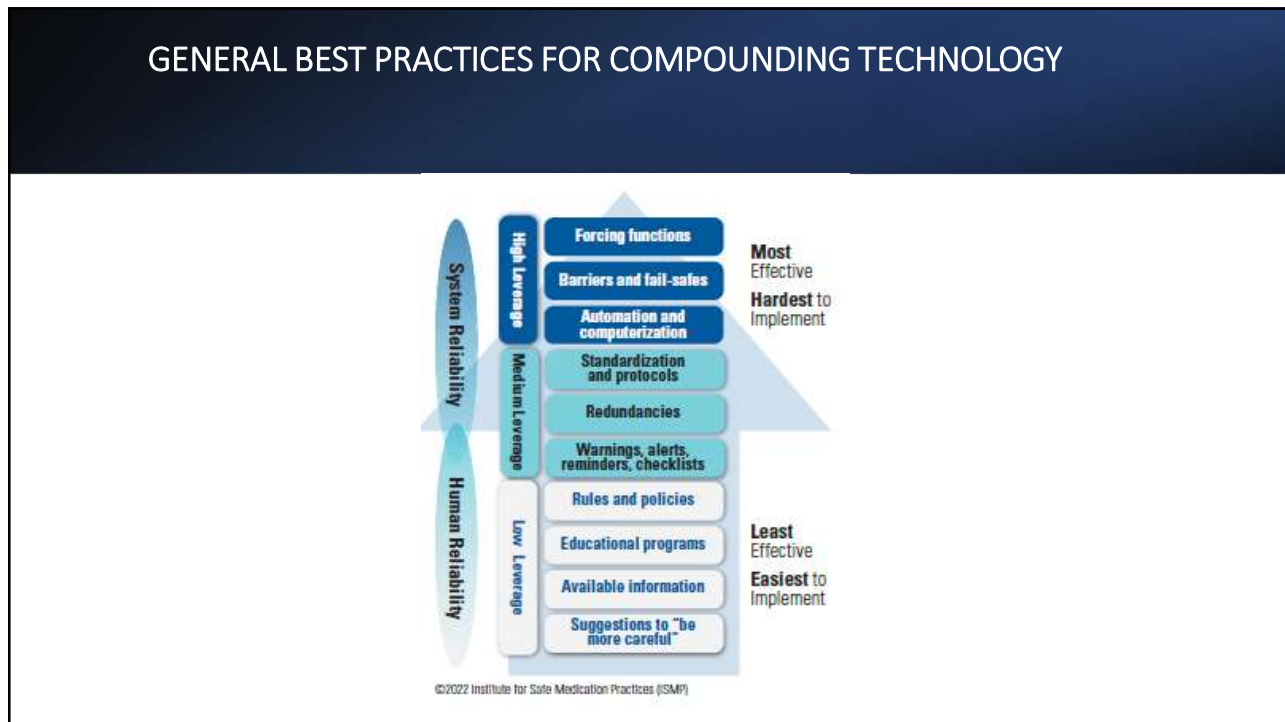
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Explaining the role of the technician in designing a safe workflow plan for sterile compounding technology

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How to prepare for technology implementation – Pre, Post & Beyond

The diagram illustrates the PDCA cycle (Plan, Do, Check, Act) and the preparation steps for technology implementation, categorized into three phases:

- PRE:**
 - FMEA
 - Human factors
 - Workflows created by your expert technician SME's
- POST:**
 - Stay updated
 - Maintenance
 - Safety – Sampling
- PDCA:**
 - Ongoing

PDCA Cycle Diagram:

- Plan:** Plan
- Do:** Perform
- Check:** Monitor
- Act:** Improve

FMEA: failure mode and effects analysis
SME: subject matter expert
PDCA: plan do check act

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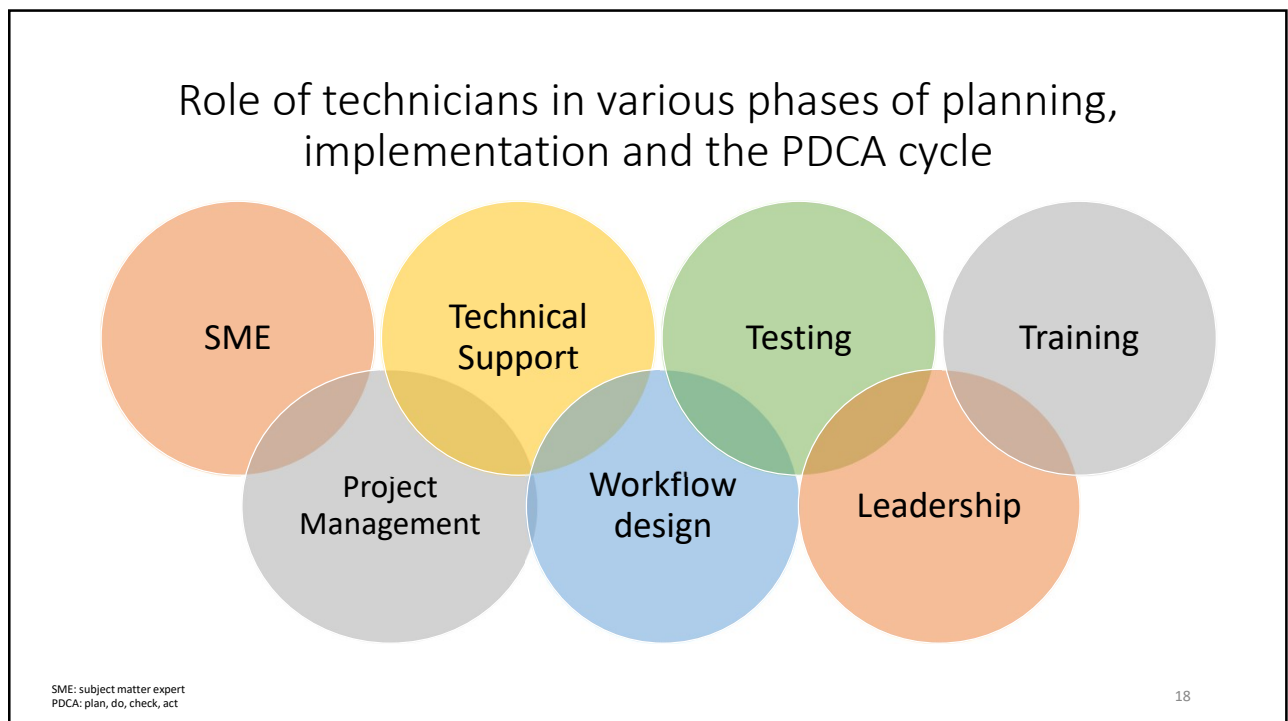
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Advance your technician staff to work at the top of their licenses

Critical ingredient to maximize safety and compliance

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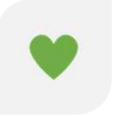
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Workflow Management Standard Work Documents & Workflows



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Soft skills to develop & embrace in your future technician leaders

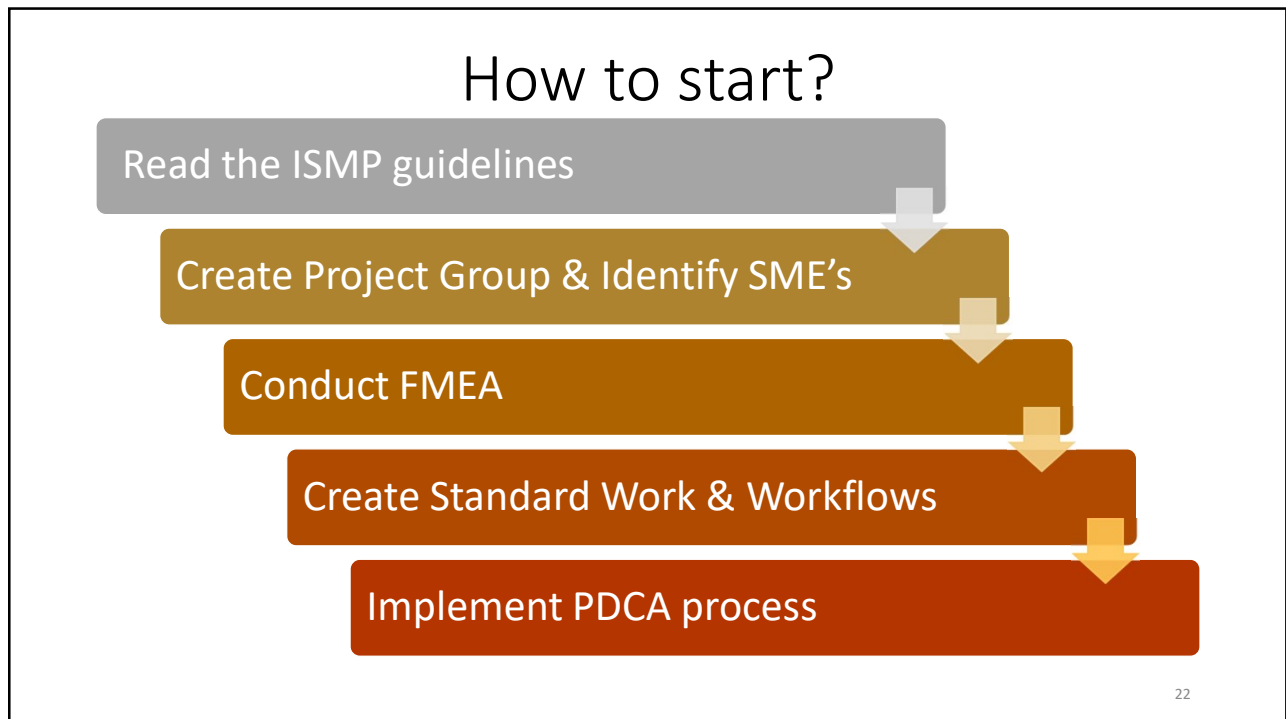
-  EMBRACES INNOVATION
-  OPEN MINDED
-  APPROACHABLE
-  ANALYTICAL
-  EMPATHETIC

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Sterile Compounding



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ISMP's Historical Triggers

- Series of compounding-related events reported to ***ISMP National Medication Errors Reporting Program*** (ISMP MERP)
- Risks identified by ISMP team members while working with healthcare providers
- Eighteen serious events; half resulting in the death of a patient
- Acknowledgement of adverse events occurring in hospital settings



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Original Guidelines

— Focused on

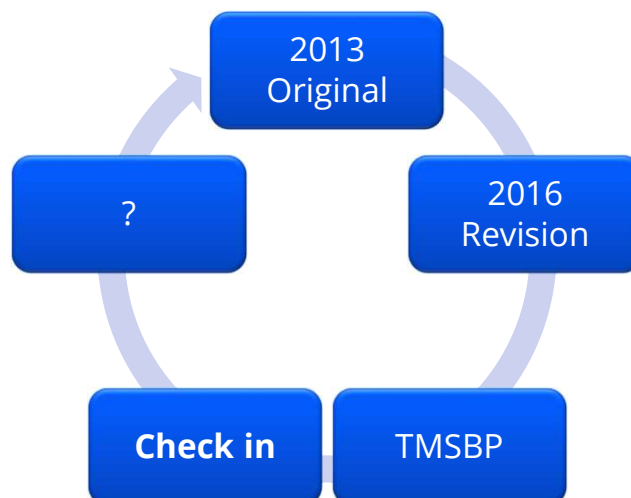
- Policies and procedures for compounding sterile preparations
- Order entry and verification processes
- Inventory and storage practices
- Compounding process, including verification and labeling
- Drug conservation
- Technology use
- Staff competency



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Trigger for Revised Guidelines

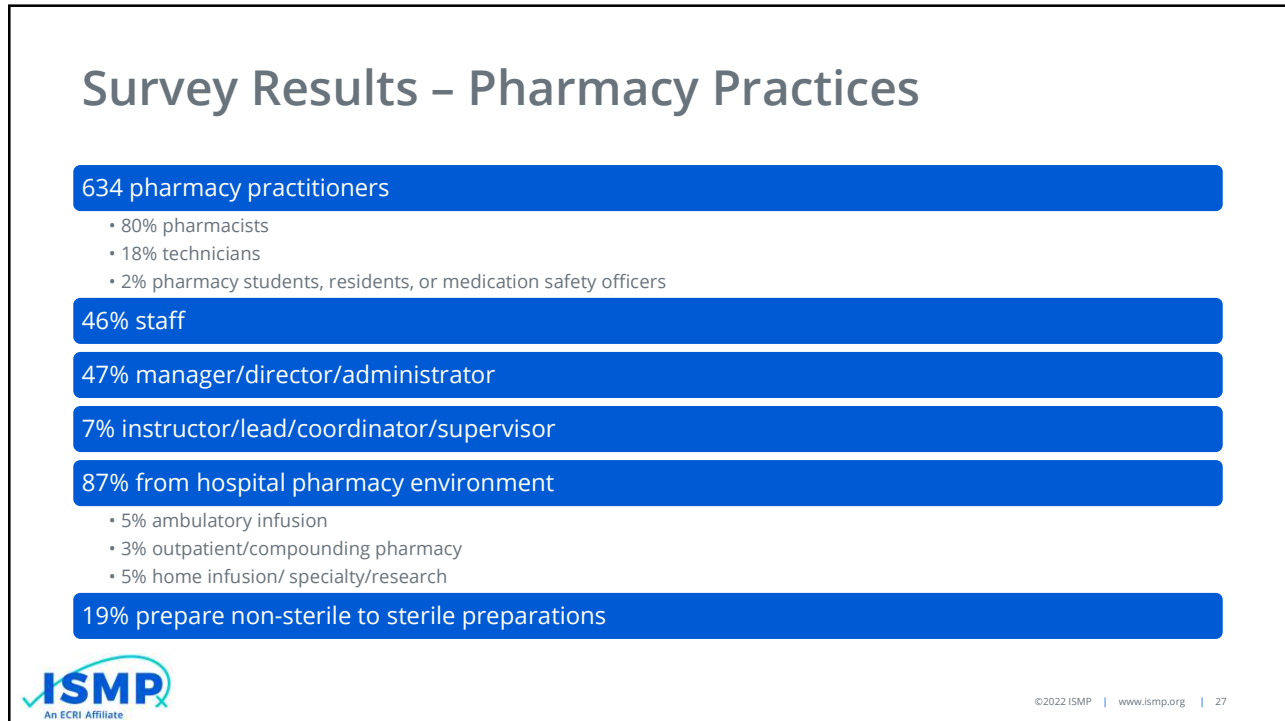


TMSBP: ISMP's Targeted Medication Safety Best Practices

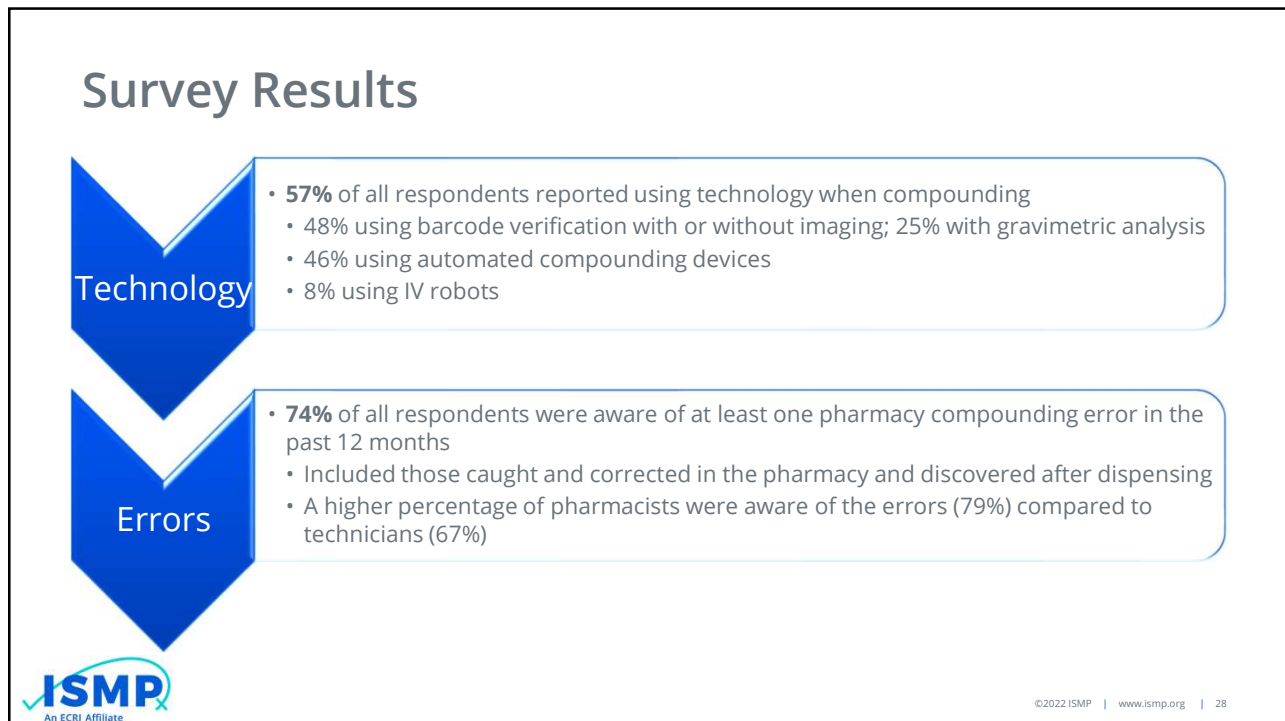
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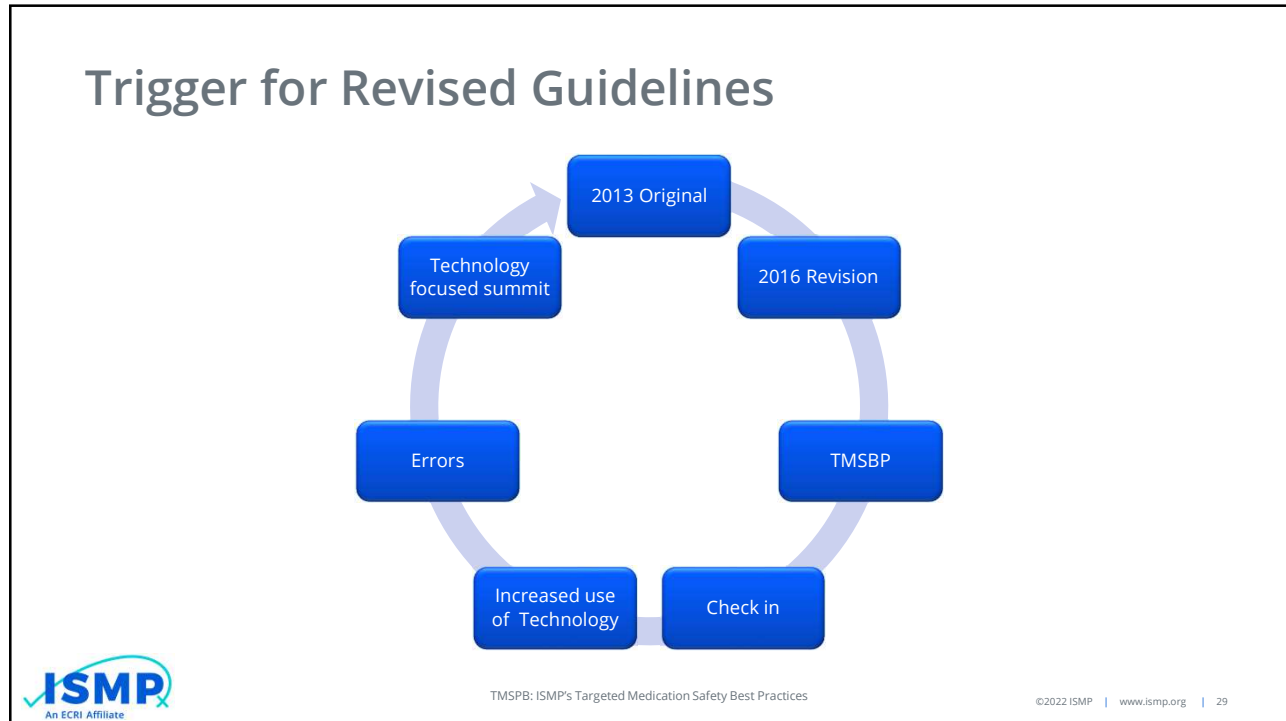


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Summit Target

- Target
- Address safe practices related to use of:
 - Sterile compounding workflow management systems
 - Automated compounding devices
 - Robotic compounding automation

- Goals
 - Review current state
 - Examine events and literature
 - Identify best practices for technology use
 - Recommend best practices when technology is not available

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Summit Process

Assembled a multi-stakeholder group

- Expert advisory panel
- Informed users
- Technology vendors
- Professional healthcare organizations
- Experts in medication safety and regulations

Three-phase approach

Pre-summit:

- Gather and analyze event data
- Literature review
- Survey

Summit:

- Essential attributes
- Safe pharmacy processes
- Safety gaps

Post-summit:

- Consensus statements
- Public comment



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Automated Compounding Devices

Essential Technology Attributes (15)

- Automated compounding devices are interfaced with the electronic health record
- Clinical decision support is available
 - Dose limits; specific to patient population; incompatibility or unstable; osmolarity
- Devices track beyond-use dates and lot numbers & expiration dates
- Process for calibration
 - Standard operating procedures define how often and who performs the calibration; calibration is verified by an independent double check



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Automated Compounding Devices

Safe Pharmacy Processes (13)

- Used for all compounded parenteral nutrition infusions
- Before entering a new drug (or new manufacturer) to the database, an assessment of information to ensure safe use is completed
- Number of staff with access to change database is limited
 - Staff are trained and competency is assessed
 - Second check occurs when a change is made
 - Each staff member has own unique login and password



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Automated Compounding Devices

Safety Gaps and Associated Best Practices

- Connecting tubing to source products
- Compounded stock solutions
- Adding products without use of the automated compounder
- Overriding notification alerts



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IV Workflow Management Systems

Essential Technology Attributes (19)

- Workflow management systems are interfaced with the electronic health record and queue updates if a preparation is discontinued
- Allows for a variety of master formulation records
 - Prompts for a double check
 - Changes are timestamped and logged
 - Prevents users from creating records for preparations that are outside limits
- Allow for customization of labels and prevents printing of the dispensing label until the compounding process is complete



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IV Workflow Management Systems

Safe Pharmacy Processes (19)

- Use of an IV workflow management system is the minimum safety standard for preparing compounded sterile preparations
- Master formulation records include specific directions for each process step
- Staff prepare and label one patient-specific product at a time
- The final label applied is a dispensing label intended for the practitioner or patient who will administer the medication
- System set up is in a manner that facilitates compounding without increasing the potential for frequent sterility breaches
- Planned workflow process changes are evaluated using simulation



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IV Workflow Management Systems

Safety Gaps and Associated Best Practices

- Multiple vials or bags required for preparation
- Tolerance limits when using gravimetric analysis
- Overriding notification alerts
- Label swapping
- Incomplete auxiliary product information



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IV Robots

Essential Technology Attributes (12)

- IV robots are interfaced with the electronic health record and workflow management systems, as appropriate
- Master formulation records include set up and programming
- IV robot applies a dispensing label to completed preparations
- IV robot prompts when maintenance is needed
- Service agreements address at a minimum, service expectations, hardware and software maintenance, training, and retraining



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IV Robots

Safe Pharmacy Processes (19)

- IV robots considered for high volume of use and/or large batch productions
- Annual vendor-supported training is offered to all operators
- A change control process including assessing information required to ensure safe use is followed when making modifications to the database
- Attempts are made to secure a large volume of products from the same manufacturer lot when preparing large batches



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IV Robots

Safety Gaps and Associated Best Practices

- Machine-readable codes that are not readable
- Label swapping
- Incomplete auxiliary product information



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Common to all Technologies

- Close call events are captured in a useful format and used to facilitate analysis and process improvement
- Vendors ensure customers receive and install system updates
- Vendor-suggested preventative maintenance is followed
- Downtime procedures
- Human factors engineering principles are used when designing workflow processes
- Before implementing, a failure mode and effect analysis (FMEA) is performed

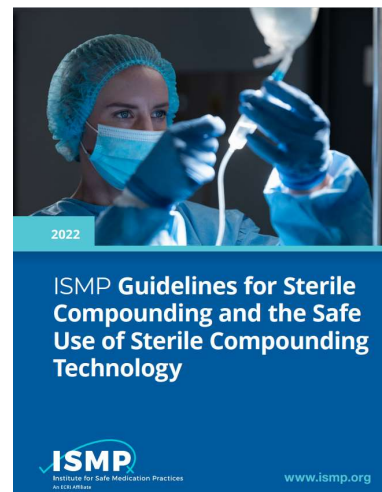


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Key Take Aways

- New ISMP best practice guidelines are available
- Created with input from a multi-stakeholder group of users and vendors as well as public comment
- Address safe pharmacy processes, practices to mitigate harm from safety gaps, and technology attributes for:
 - Automated compounding devices
 - IV Workflow management systems
 - IV Robots



<https://www.ismp.org/resources/guidelines-sterile-compounding-and-safe-use-sterile-compounding-technology>

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Next Steps

- Share the Webinar
- Meet with your teams – get them excited!
- If you already use your technicians in advanced roles, see how you can incorporate this approach
- If you are looking to implement advanced roles – here is the perfect start
- Take the technology dialogue and see where you can start, even if that start is just talking about the options



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Questions?
