

# Raising the Bar on Sterile Compounding Safety

A midday symposium conducted at the 2021 ASHP Midyear Clinical Meeting and Exhibition

Tuesday, December 8, 2021 - 1:00pm to 2:30pm

AGENDA	
1:00 PM - 1:10 PM	<b>Introduction and Overview</b> Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP President, Institute for Safe Medication Practices (ISMP)
1:10 PM - 1:30 PM	<b>Times Change, and We Need to Change with Time</b> Christina Michalek, BSc, FASHP, Medication Safety Specialist Institute for Safe Medication Practices (ISMP)
1:30 PM – 1:55 PM	<b>We Know the Target, So How Do We Get There with Safety in Mind?</b> Rita K. Jew, PharmD, MBA, BCCPS, FASHP, Vice President of Operations Institute for Safe Medication Practices (ISMP)
1:55 PM - 2:15 PM	<b>Putting Recommendations into Action: Using Compounding Technology Safely</b> Kevin Hansen, PharmD, MS, BCPS, BCSCP, Assistant Director of Pharmacy: Pharmaceutical Compounding, Residency Program Director: HSPAL Cone Health / Moses H. Cone Memorial Hospital
2:15 PM – 2:30 PM	<b>Question and Answer Session</b>
2:30 PM	<b>Adjourn</b>

## CONTINUING EDUCATION INFORMATION



This CE activity is jointly provided by ProCE, LLC and the Institute for Safe Medication Practices (ISMP). ProCE is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number 0221-9999-21-278-L05-P/T has been assigned to this knowledge-based live CE activity (initial release date 12-8-21). This activity is approved for 1.5 contact hours (0.15 CEU) in states that recognize ACPE providers. This CE activity is provided at no cost to participants. Successful completion of the online post-test and evaluation at [www.ProCE.com](http://www.ProCE.com) no later than January 7, 2022 is required to receive CE credit. CE credit will be automatically uploaded to NABP/CPE Monitor upon completion of the post-test and evaluation. No partial credit will be given. Conflict of interest disclosures are required of all faculty and shall be provided to participants at the conference.

## **FACULTY INFORMATION**

### **Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP President, Institute for Safe Medication Practices, Horsham, PA**

Dr. Cohen's long-standing dedication to medication safety has made a tremendous difference for patients everywhere. He is president of The Institute for Safe Medication Practices (ISMP), a non-profit healthcare organization that specializes in understanding the causes of medication errors, providing error-reduction strategies to the healthcare community, policy makers, and the public. Cohen serves as co-editor of the ISMP Medication Safety Alert! publications that reach over one million health professionals in the US as well as regulatory authorities and others in over 30 foreign countries. He is also co-editor of the ISMP consumer website, [www.consumermedsafety.org](http://www.consumermedsafety.org). Cohen is the Chairperson of the International Medication Safety Network ([www.intmedsafe.net](http://www.intmedsafe.net)). He has served terms on the US FDA Drug Safety and Risk Management Advisory Committee (DSaRM) and the Nonprescription Drugs Advisory Committee (NDAC). He is currently a consultant to FDA and a member of the USP Expert Committee on Nomenclature and Labeling. Among recognitions he has received, he is a recipient of the John M. Eisenberg Patient Safety and Quality Award from the National Quality Forum and the Joint Commission, the Harvey A. K. Whitney Award from the American Society of Health-System Pharmacists and he has also been recognized as a MacArthur Fellow by the John D. and Catherine T. MacArthur Foundation.

### **Christina Michalek BSc Pharm, RPh, FASHP Medication Safety Specialist, Institute for Safe Medication Practices, Horsham, PA**

Christina is a Medication Safety Specialist and Administrative Coordinator for the Medication Safety Officers Society at the Institute for Safe Medication Practices. She began working with ISMP as an external consultant and advisor in 2001 and later joined the ISMP staff in 2010. At ISMP, Chris works collaboratively with health-system leaders and clinical staff in order to define, design, and improve medication safety initiatives. She has a passion for empowering others to enhance medication safety efforts and enjoys collaborating with healthcare practitioners and sharing best practices through educational programming at national, international, state, and local-level professional conferences. Chris also manages the update and analysis of ISMP's Targeted Medication Safety Best Practices for Hospitals and is the ISMP lead for medication-related technology issues. Additionally, she has been serving as a Patient Safety Analyst to ECRI Patient Safety Organization since 2013.

Learn more about Christina here: <https://www.ismp.org/staff/christina-michalek-bsc-pharm-rph-fashp>

### **Rita Jew PharmD, MBA, BCPPS, FASHP Vice President of Operations, Institute for Safe Medication Practices, Horsham, PA**

Rita K. Jew, Pharm.D., MBA, BCPPS, FASHP is Vice President of Operations at the Institute for Safe Medication Practices (ISMP). She has more than 30 years of experience leading pharmaceutical care services. Prior to joining ISMP, she served as Principal of RKJ Health Partners, where she provided consulting services related to medication safety, pharmacy operations, pharmacy finance, specialty pharmacy, and sterile compounding. She also provided coaching and leadership training and advised technology start-ups. Before starting her own consulting business, Dr. Jew held leadership positions at well-known acute care institutions, including University of California San Francisco (UCSF) Health, Children's Hospital of Orange County, and Children's Hospital of Philadelphia.

Learn more about Rita here: <https://www.ismp.org/staff/rita-jew-pharmd-mba-bcpps-fashp>

## **FACULTY INFORMATION (continued)**

### **Kevin Hansen PharmD, MS, BCPS, BCSCP**

#### **Assistant Director of Pharmacy, Moses H. Cone Memorial Hospital**

Kevin Hansen, PharmD, MS, BCPS is Assistant Director of Pharmacy at Moses H. Cone Memorial Hospital in Greensboro, N.C. Dr. Hansen provides leadership and operational oversight for pharmaceutical compounding and pharmacy perioperative services. He serves as the Residency Program Director for the Health-System Pharmacy Administration residency program. In addition, Dr. Hansen serves as adjunct faculty for the University of North Carolina Eshelman School of Pharmacy. Dr. Hansen earned his Doctor of Pharmacy degree from Lake Erie College of Osteopathic Medicine (LECOM) in Erie, PA and completed an ASHP-accredited PGY1/PGY2/MS Health-System Pharmacy Administration residency at the University of North Carolina Medical Center. He is board certified in pharmacotherapy through the Board of Pharmacy Specialties. Within Moses H. Cone Memorial Hospital, Dr. Hansen is involved in several committees and initiatives related to his practice interests of pharmaceutical compounding, handling hazardous drugs, medication and compounding safety, drug shortage management, and pharmacy perioperative services. He has taken a lead role in developing multidisciplinary teams, such as the Pharmaceutical Compounding Advisory Council and the Hazardous Drug Committee. He also provides pharmaceutical compounding guidance and standardization across Cone Health, a multi-hospital health system.

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

Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP, President, ISMP

Christina Michalek, BSc Pharm, RPh, FASHP

The speakers listed below disclosed potential conflicts of interest\*:

Rita K. Jew, Pharm.D., MBA, BCPPS, FASHP

Kevin Hansen, PharmD, MS, BCPS, BCSCP

*\*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.

## OVERVIEW

Sterile compounding is an essential component of pharmacy practice for pharmacists and pharmacy technicians and efforts to identify and reduce potential adverse events during the preparation of sterile products is imperative to provide safe, optimal patient care.

Over the past 10 years there has been increased growth and maturity in the compounding technology market and an increased uptake by pharmacies in the use of technology during the sterile compounding process. However, despite advancements, a recent ISMP survey on pharmacy compounding systems and practices completed by over 600 practitioners revealed there remains an opportunity to improve the safety of sterile compounding practices as well as increase and enhance the safe use of technology in the process.

In September 2021, The Institute for Safe Medication Practices convened an invitational, virtual sterile compounding safety summit to specifically address safe practices related to the use of robotic compounding automation, sterile compounding workflow software, and automated compounding devices.

Join us for a symposium that will take you from the spark that triggered the summit, through the objectives, targets and structure used to develop new ISMP Best Practice Guidelines, concluding with a discussion of one organization's journey using various sterile compounding technologies to reduce the risk for errors and the steps they took to minimize threats to safe technology use.

## OBJECTIVES

The target audience for this activity includes pharmacists and pharmacy technicians in health-system settings. At the completion of this symposium, the participant will be able to:

1. Discuss ISMP survey results regarding sterile compounding
2. List key areas addressed during a recent sterile compounding safety summit
3. Describe safety gaps that exist when using technology to support sterile compounding
4. Identify best practices for the safe use of technology and automation during the compounding process

# Raising the Bar on Sterile Compounding Safety



## Raising the Bar on Sterile Compounding Safety

A Midday Symposium Conducted at the 2021 ASHP Midyear Clinical Meeting and Exhibition

This symposium is funded through an educational grant from Omnicell.

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3

## Online Evaluation and Statement of Completion

- [www.ProCE.com](http://www.ProCE.com)
- Login with username and password
- Deadline: **January 7, 2022**



**Attendance Code = ??????**



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4

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## Objectives

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

1. Discuss ISMP survey results regarding sterile compounding
2. List key areas addressed during a recent sterile compounding safety summit
3. Describe safety gaps that exist when using technology to support sterile compounding
4. Identify best practices for the safe use of technology and automation during the compounding process



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## Times Change, and We Need to Change With Time

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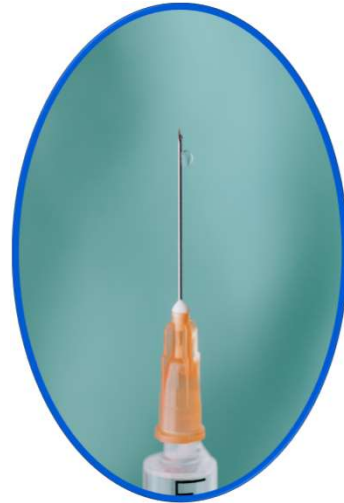
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# Raising the Bar on Sterile Compounding Safety

## Sterile Compounding

- *Essential component of pharmacy practice*
- *Prescribing is common and ubiquitous*
- *Safety is a journey that never ends*



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## ISMP Pulse Check in 2020



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8



# Raising the Bar on Sterile Compounding Safety

## Current Practice Insight- Our Goals

### Within Pharmacy

- Learn
- Increase awareness
- Identify opportunities
- Identify safety challenges



### Outside Pharmacy

- Learn
- Understand safe practices
- Identify training
- Identify safety challenges



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9

## Compounding *outside* the pharmacy

- 444 respondents
- 77% nurses
  - Anesthesia providers
  - Decentralized pharmacy staff, physicians
- 81% acute care
  - Ambulatory surgery center, infusion center, physician practice, long term care

- Most frequently prepared sterile injectables:
  - Intravenous push medications
    - Mostly medications transferred from vials to syringes (e.g., opioids, antiemetics, antibiotics, proton pump inhibitors)
  - Intermittent infusions
    - Mostly using vial and bag adapter systems
  - Intramuscular injections
    - Mostly vaccines, antipsychotic and, antibiotics

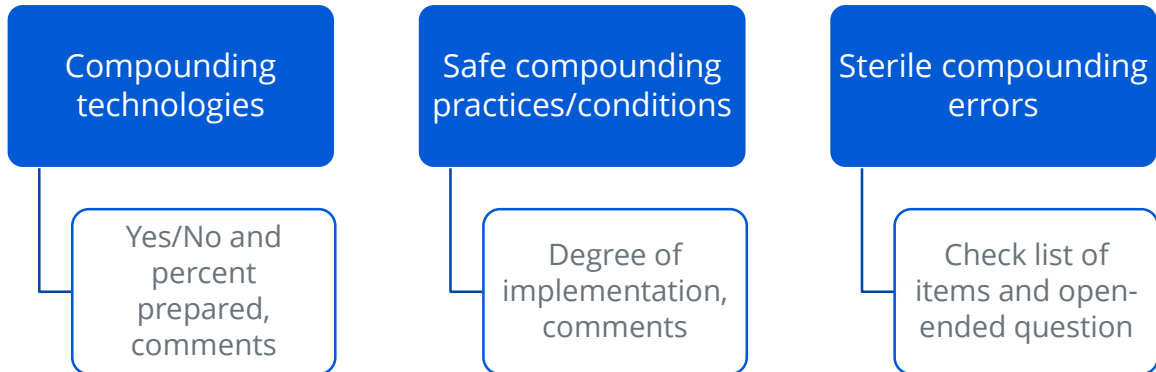


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## The Pharmacy Survey



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11

## The Results – Pharmacy Practices

634 pharmacy practitioners

- 80% pharmacists
- 18% technicians
- 2% pharmacy students, residents, or medication safety officers

46% staff

47% manager/director/administrator

7% instructor/lead/coordinator/supervisor

87% from hospital pharmacy environment

- 5% ambulatory infusion
- 3% outpatient/compounding pharmacy
- 5% home infusion/ specialty/research

19% prepare non-sterile to sterile preparations



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12

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## Compounding Technologies

*Why focus on this?*

- Observational studies of accuracy identified a mean daily error rate of 9%
- In a more recent study, automation identified 7.1% error rate
- When compared to manual processes, technology-assisted compounding provided a safety benefit detecting 14 times more errors
- Analysis of causes of compounding errors resulting in patient harm reveal opportunity for technology use

*When there are manual components to our processes, we can err*



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13

## ISMP Targeted Medication Safety Best Practices

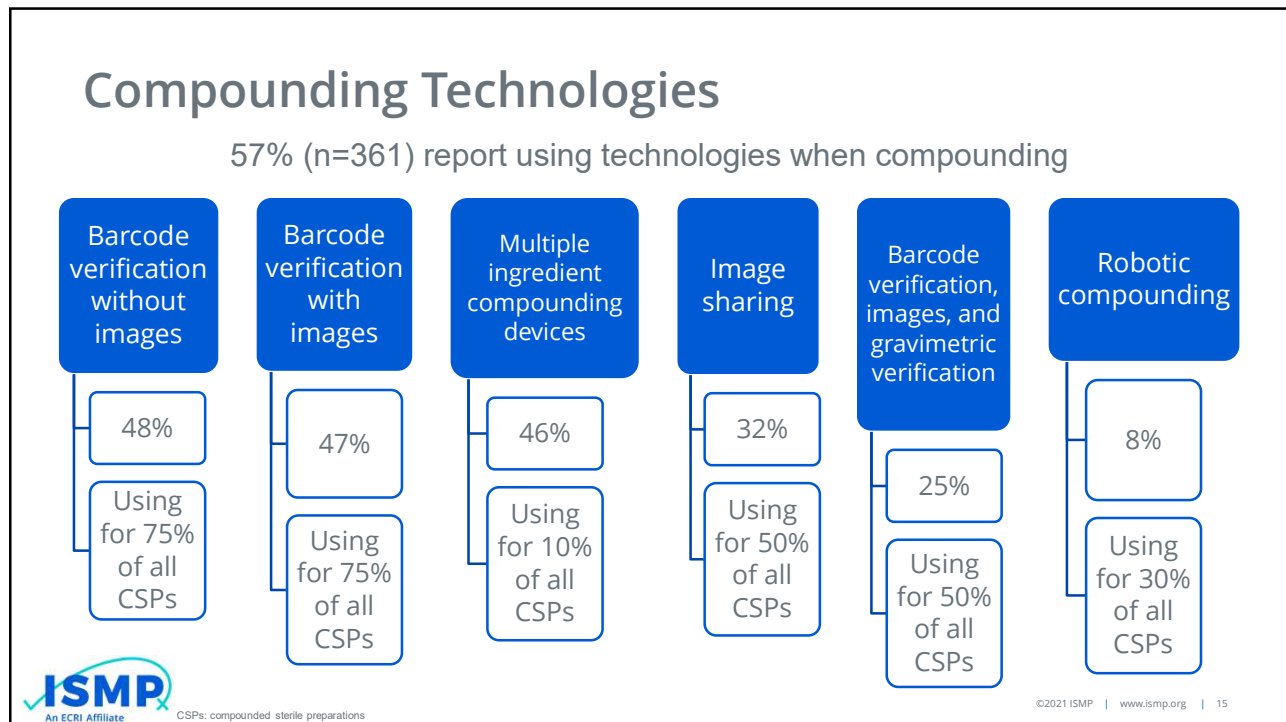
- Best Practice #11
- When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.
- *Use technology* to assist in the verification process (e.g., barcode scanning verification of ingredients, gravimetric verification, robotics, IV workflow software) to augment the manual processes.



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14

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15

## Compounding Technologies

*Stop the line/In line verifications*

- 63% who utilize images to verify CSPs stop production for specific medications
- Some indicated doing it for all
- Specific medications:
  - All or certain hazardous drugs
  - All or certain high-alert medications
  - All or certain blood products
  - Biologics including monoclonal antibodies
  - Medications requiring dilution

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16

# Raising the Bar on Sterile Compounding Safety

## Safe Compounding Practices

- ISMP identified nine best practices related to pharmacy sterile compounding
- Highest level of implementation: ensuring cleanroom design supporting one staff member working at a time per primary engineering control device (73% always, 15 often)
- Challenges to achieving this best practice: location, time of day, urgency of preparation, overall workload



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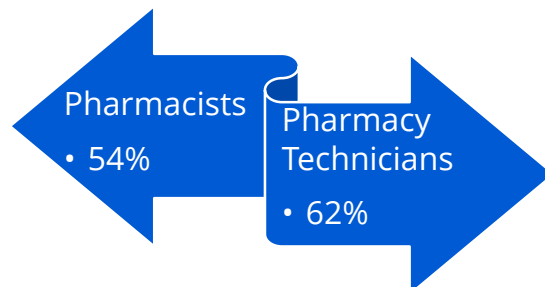
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## Safe Compounding Practices

### Standard Operating Procedures (SOPs)

- 56% defined and *always* followed
- 34% defined and *often* followed
- 10% *never, rarely, or sometimes* defined and followed

### Differences in reporting of compliance

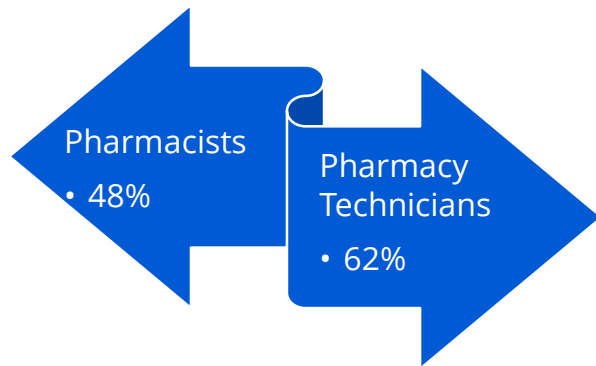


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18

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## Safe Compounding Practices



*During the verification process, it is easy to identify without any uncertainty which drugs, diluents, and volumes were used (including the number of vials/ ampules/bags used) to prepare each CSP*

52% *always* easy to identify



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19

## Safe Compounding Practices

### Labeling Workflow

- 49% always follow a standard workflow
- Technicians tended to report higher compliance with a standard workflow for applying final product labels (58% compared to 46% for pharmacists)

### Compounding Workflow

- 47% reported only one CSP is prepared at a time
- Some exceptions noted



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20

# Raising the Bar on Sterile Compounding Safety

## Safe Compounding Practices

### Preparation Information

- 49% dose volume information is *always* available
- Technicians reported differently from pharmacists (58% versus 46%)
- 20% reported that best practice is followed less than half the time

### Workspace/Environment

- Sufficient counterspace, allowing room for separation of products, measured lighting and noise consistent with USP
- *Scored the lowest of all best practices in the survey*



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21

## Sterile Compounding Errors

- 74% of all respondents were aware of at least one pharmacy compounding error in the past 12 months
  - This included those caught and corrected in the pharmacy as well as those discovered after dispensing
  - A higher percentage of pharmacists were aware of the errors (79%) compared to technicians (67%)



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# Raising the Bar on Sterile Compounding Safety

## Sterile Compounding Errors

Incorrect dose or concentration

- 58%

Incorrect base solution

- 51%

Incorrect base solution volume

- 43%

Issue or error (or omission) with labeling of a CSP

- 41%

Incorrect reconstitution (volume, diluent)

- 36%

Incorrect drug

- 35%

Wrong preparation technique (filtering, tubing)

- 26%

Expired drug, base solution, or CSP

- 16%

Wrong timing (preparing on the wrong date)

- 12%

Omission of a drug

- 5%



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## Challenges

*Lack direct verification*

*USP standards*

*Training*

*Competency*

*Insufficient technology*

*Space*

*Staffing*

*Variability*

*Workload*

*Failed leadership*

*Lack supervision*



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24



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## Pharmacy Purchasing & Products Magazine

- Automated compounders: the larger the facility, the more likely they were to be using; use reported in almost half of facilities over 400 beds
- IV workflow automation: 36% overall
  - Ingredient product barcode scanning; in process image or video capture
  - Gravimetrics: 22%
  - Implementations are projected to continue in both mid- and large-sized facilities
- IV Robotics: 7% overall; however, almost one-fourth of larger facilities are using this technology- an increase from last year
  - Most have one robot and use it on a single shift



Pharmacy Purchasing & Products State of Pharmacy Compounding Vol.18 No.4 April 2021

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25

## THRIV

- THRIV coalition for iv accuracy
- 2020 Survey IV Preparation Practices and Related Technology in US Hospital Pharmacies
- Setting: hospitals less than 50 to over 600 beds
- Half of the respondents were using a semi-automated IV workflow management system; 20% also using gravimetrics
- Over two-thirds of the respondents did not feel that manual compounding processes were sufficiently safe without IV workflow management systems



www.thrivecoalition.org

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26

# Raising the Bar on Sterile Compounding Safety

## American Society of Health-System Pharmacists

- ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration—2020
- Sterile compounding technology
  - Sterile preparation workflow management technology: 21.3% of hospitals
  - Barcode scanning to verify ingredients: 33.8%
  - Larger hospitals more likely than smaller to be using; steady increase in use
  - Gravimetrics: 5% - this has remained steady over the last 3 years
- Sterile compounding automation
  - Overall, 3.4% are using; robotic chemotherapy devices are used in 1.6% of hospitals



American Journal of Health-System Pharmacy, Volume 78, Issue 12, 15 June 2021, Pages 1074–1093

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27

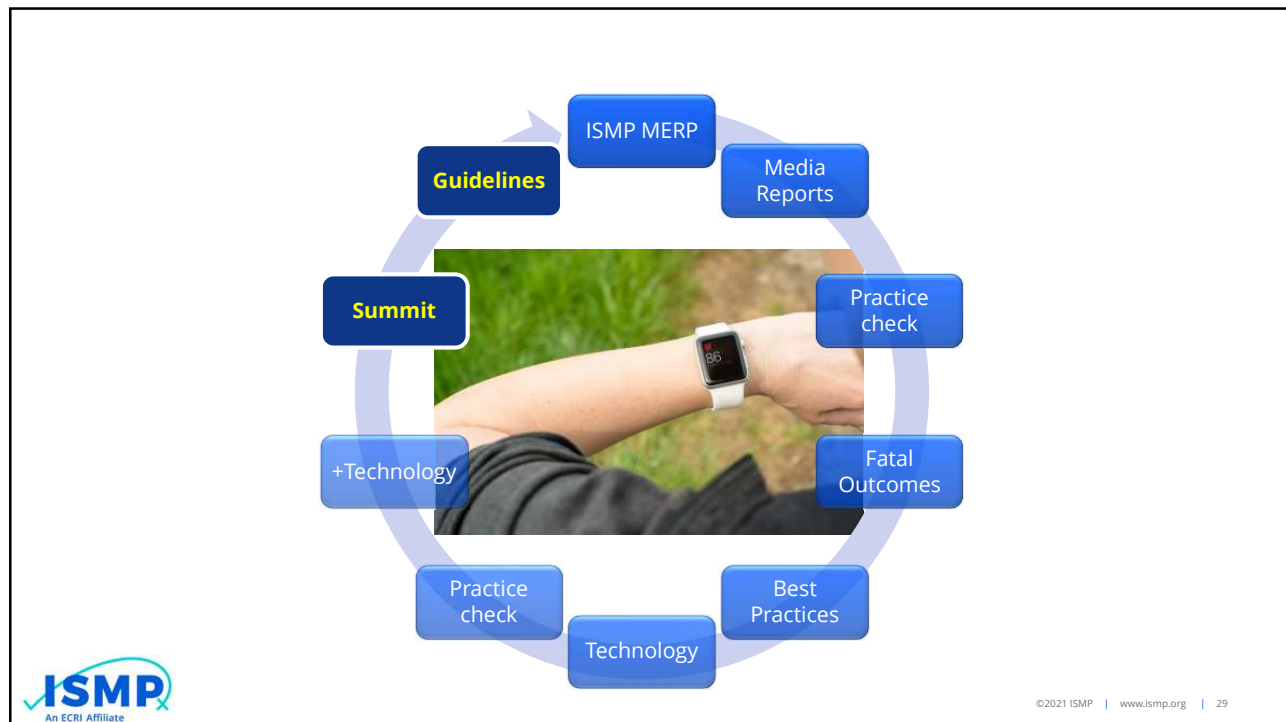


## *Why a Summit?*

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28

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29



## We Know the Target, so How Do We Get There with Safety in Mind?

**Rita K. Jew, Pharm.D., MBA, BCPPS, FASHP**  
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31

# Raising the Bar on Sterile Compounding Safety

## Goal of Summit

- Update guidelines initiated 10 years ago and revised in 2016
- Focus on safety of compounding technology
- Explore safety gaps
- Consensus on best practices
- Guidelines will be evolving



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32

## Key Areas Addressed at Sterile Compounding Summit

- Automated compounders
- IV workflow software
- IV robots
- Manual compounding
- Essential technology attributes
- Safe pharmacy processes
- Identify safety gaps
- Propose best practices



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33

# Raising the Bar on Sterile Compounding Safety

## Automated Compounders

### *Essential technology attributes*

- Integration with EHR to eliminate transcription
- Clinical decision support with soft and hard stops for dosage limits and compatibilities
- Automated calculations and conversions
- Barcode verification of source products
- Validation process for calibrating the machine
- Gravimetric validation at completion of compounding process
- Near misses intercepted captured in a report to facilitate error analysis and process improvement



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34

## Automated Compounders

### *Safe Pharmacy Processes*

- Workflow in place to capture new products prior to them being available for use
- Visual inspection of final product prior to dispensing
- Downtime procedures include backup equipment needs and annual tabletop simulation to identify gaps and revise procedures as necessary



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# Raising the Bar on Sterile Compounding Safety

## Automated Compounders

### ***Safety Gaps***

- Manual additives
- Tubing and source product connection mix ups

### ***Proposed Best Practices***

- Strategy to limit amount of manual additives
- Utilize IVWFS or barcode scanning for manual additives
- Dedicated hood for automated compounder



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36

## IV Workflow Technology

### ***Essential technology attributes***

- Integration with EHR
- Ability to build a master formula record
- Automated calculations and conversions
- Barcode verification of all source products, including diluents for reconstitution
- Tracks all steps via video or images and/or gravimetrics
- Image captures clear pictures to differentiate essential information
- Allows for remote verification via images, video, and/or gravimetrics
- Tracks beyond use dating of opened or reconstituted drugs
- Near misses intercepted captured in a report to facilitate error analysis and process improvement
- Technology provides workload reports



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37

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## IV Workflow Technology

### *Safe Pharmacy Processes*

- Labels should remain in the queue until the time of compounding
- Hardware set up facilitates compounding without frequent sterility breaches
- Workflow in place to capture new products prior to them being available for use
- Visual inspection of final product prior to dispensing
- Downtime procedures include backup equipment needs and annual tabletop simulation to identify gaps and revise procedures as necessary



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## IV Workflow Technology

### *Safety Gaps*

- Multiple vial or bag required & scanning policy
- Tolerance/minimum volume accurately measured by scale
- Overrides
- Label swapping



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39

# Raising the Bar on Sterile Compounding Safety

## IV Workflow Technology

### ***Proposed Best Practices***

- IV workflow software required for compounding of ALL CSPs – minimum standard
- Scanning of every vial or bag required for compounding
- Vendor guidance on tolerance/minimum volume based on scale accuracy
- Image documentation & gravimetrics
- Hard stop when wrong product (NDC) is used
- One-piece workflow to prevent label swap
- Auxiliary label information included in product label



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## IV Robots

### ***Essential technology attributes***

- Integration with EHR
- Ability to build a master formula record
- Barcode verification for source products, including diluents for reconstitution
- Final product should have dispensing label attached



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41



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## IV Robots

### *Safe Pharmacy Processes*

- Staff operators are adequately trained & validated on robot operations prior to use & annual competency assessments thereafter
- Robust SOP for how to train the robot
- Staff ensure that routine calibration & certification of critical equipment is performed & documented
- Visual inspection of final product prior to dispensing
- Downtime procedures include backup equipment needs and annual tabletop simulation to identify gaps and revise procedures as necessary



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## IV Robots

### *Safety Gaps*

- Label swapping
- Unreadable barcodes

### *Proposed Best Practices*

- One-piece workflow to prevent label swap
- Auxiliary label information included in product label
- Comprehensive user service agreement



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# Raising the Bar on Sterile Compounding Safety

## Use of Compounding Technologies

### ***Proposed Best Practices***

- Overarching technology infrastructure
- Employ human factor engineering principles
- Optimize utilization of technology
- Total productive maintenance
- FMEA



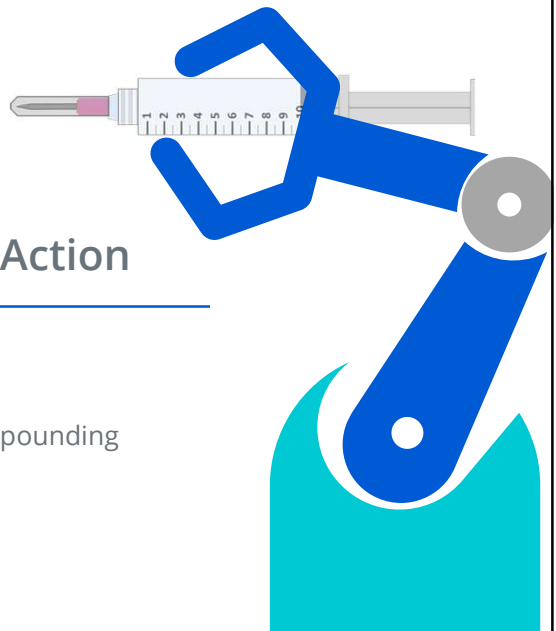
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44



## Using Compounding Technology Safely: Putting Recommendations into Action

Kevin N. Hansen, PharmD, MS, BCPS, BCSCP  
Cone Health | Moses H. Cone Memorial Hospital  
Assistant Director of Pharmacy: Pharmaceutical Compounding



45

# Raising the Bar on Sterile Compounding Safety

## Objective

— Identify best practices for the safe use of technology and automation during the compounding process



### ISMP RECOMMENDATION

Current recommendations from ISMP Guidelines



### BEST PRACTICE

Future considerations for best practice recommendations



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46

## Compounding Technology & Automation



### Compounding Technology

Application of scientific knowledge put into practical use during compounding processes to solve or identify problems (e.g. barcodes and scanners, gravimetric scales, etc.)

- Accuracy/Precision
- Ingredient Verification
- Standardized process
- Prompts
- Documentation

### Compounding Automation

Technologies that reduce human interventions during the compounding process (e.g. compounding, labeling, packaging, verification, etc.)

- Sterility
- Repeatability
- Reliability
- Efficiency



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47

# Raising the Bar on Sterile Compounding Safety

## Compounding Technology & Automation Today

- Current standards focus on **manual practices**
- Technology and automation viewed as *best practice* with a focus on accuracy/precision and ingredient verification
- Many of the technologies do not address **sterility assurance**, and in some cases may introduce contamination risks (e.g., using touch-screen with sterile gloves)

“...the guidance encourages the adoption of new technological advances by the pharmaceutical industry. In particular, the guidance underscores the advantages that **automation** and **isolation concepts** offer in protecting the exposed sterile drug product during aseptic manufacturing.”

Pharmaceutical CGMPs for the 21<sup>st</sup> Century – A Risk-Based Approach. Sept 2004.





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48

## Barcode Ingredients

**Order:**  
ceFAZolin 2 g added to  
100 mL 0.9% sodium chloride  
for injection

 **ceFAZolin 1 g vial**  
Scanned 1 of 2 vials

 **0.9% Sodium Chloride  
for Injection, 100 mL**



### ISMP RECOMMENDATION

...the manual inspection of IV Admixture ingredients by pharmacy technicians and pharmacists is not a totally effective deterrent in preventing preparation and dispensing errors. ISMP believes that **barcode scanning of base solutions and ingredients should now be considered the minimum requirement for pharmacy IV admixture services.**



### Barcode Scan ALL Ingredients



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49

# Raising the Bar on Sterile Compounding Safety

## Compounding Segregation

✓

**ISMP RECOMMENDATION**

In facilities that care for adult and pediatric and/or neonatal patients, the preparation of CSPs for each population is separated by time or location.

▶▶ **Independent Cleanroom Suites**



Patient Specific:  
✓ **Adult**



Patient Specific  
✓ **Pediatric  
& Neonatal**



Non-Patient Specific:  
▶▶ **Batching**



Images courtesy of Cone Health  
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50


## Drug Inventory Storage and Replenishment

✓


**ISMP RECOMMENDATION**

Sufficient space for drug storage is provided to permit SEGREGATION of each drug and concentration....drug inventory in the compounding area is minimized....barcode verification is used.


▶▶ **HEPA Filtered Cleanroom Carousel**



**MAIN PHARMACY**



**CLEANROOM**

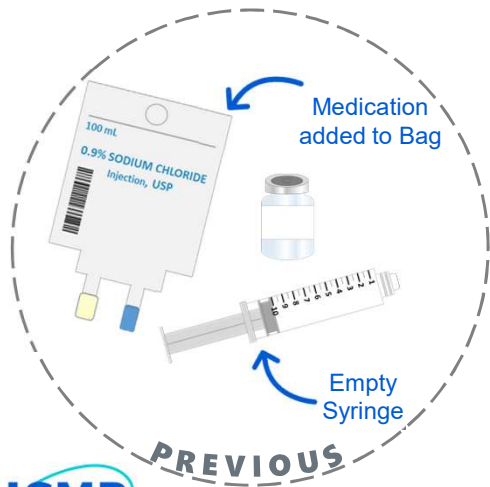


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51

# Raising the Bar on Sterile Compounding Safety

## Volume Verification

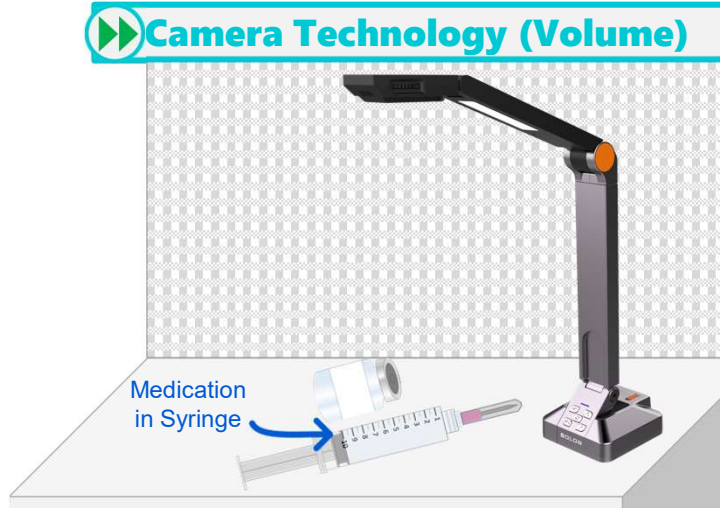


The diagram shows a 100 mL bag of 0.9% Sodium Chloride Injection, USP, and an empty syringe. An arrow labeled "Medication added to Bag" points to the bag, and another arrow labeled "Empty Syringe" points to the syringe. The word "PREVIOUS" is written in a dashed circle around the items.

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**ISMP RECOMMENDATION**  
Proxy methods of verification of ingredients, such as the SYRINE PULL-BACK METHOD of verification are never used.

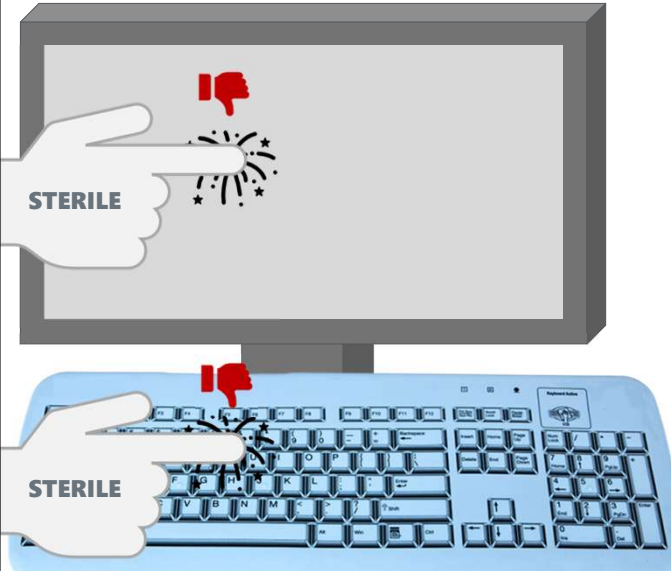
**Camera Technology (Volume)**



The diagram shows a syringe with medication inside, labeled "Medication in Syringe", being viewed by a camera mounted on a stand. The camera is labeled "Camera Technology (Volume)".

52


## Hands-Free Technology



The diagram shows a computer monitor and keyboard. A hand is shown pointing at the monitor, which has a red "X" and a thumbs down icon, indicating a non-sterile action. The word "STERILE" is written next to the hand. Another hand is shown pointing at the keyboard, which also has a red "X" and a thumbs down icon, indicating a non-sterile action. The word "STERILE" is written next to the hand.

**BEST PRACTICE**  
Use hands-free devices to the maximum extent possible while wearing sterile gloves and during compounding, to prevent removing gloved hands from hood requiring frequent disinfection.

**Foot Pedals**



The diagram shows three foot pedals. A blue footprint is shown on the right pedal, which has a green thumbs up icon next to it.

- Programmable to keyboard keystrokes
- Use with cameras: take, keep, discard
- Advance prompts

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53



# Raising the Bar on Sterile Compounding Safety

## Competency Assessment

### ▶▶ Camera Technology (Technique)

Hood-Integrated Video Camera

**Observation Methods:**

Undisguised

Disguised

**ISMP RECOMMENDATION**

All staff members involved in preparing CSPs or supervising the preparation of CSPs participate in a comprehensive orientation and training program as well as an ongoing competency assessment program.

Bottle Hanging

Wipes Hanging

Good Technique

**COMPETENCY**

Knowledge Skills Abilities Behavior

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54

## Competency Assessment

### ▶▶ Camera Technology (Room)

Garbing

Cleansing

Line of Demarcation

**BEST PRACTICE**

Restrict access to cleanroom suite only to compounding personnel or staff with completed training on maintaining a cleanroom environment and cleansing/garbing with supervision.

### ▶▶ Remote Monitoring

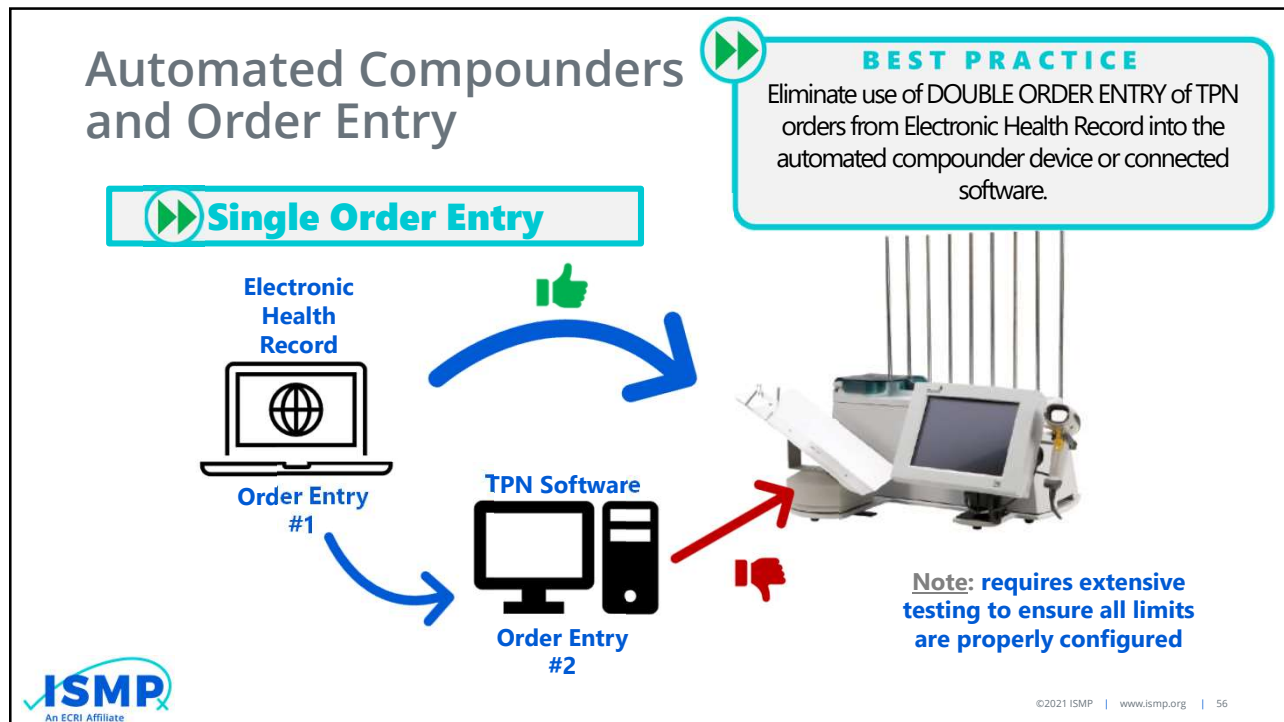
Monitor display in main pharmacy

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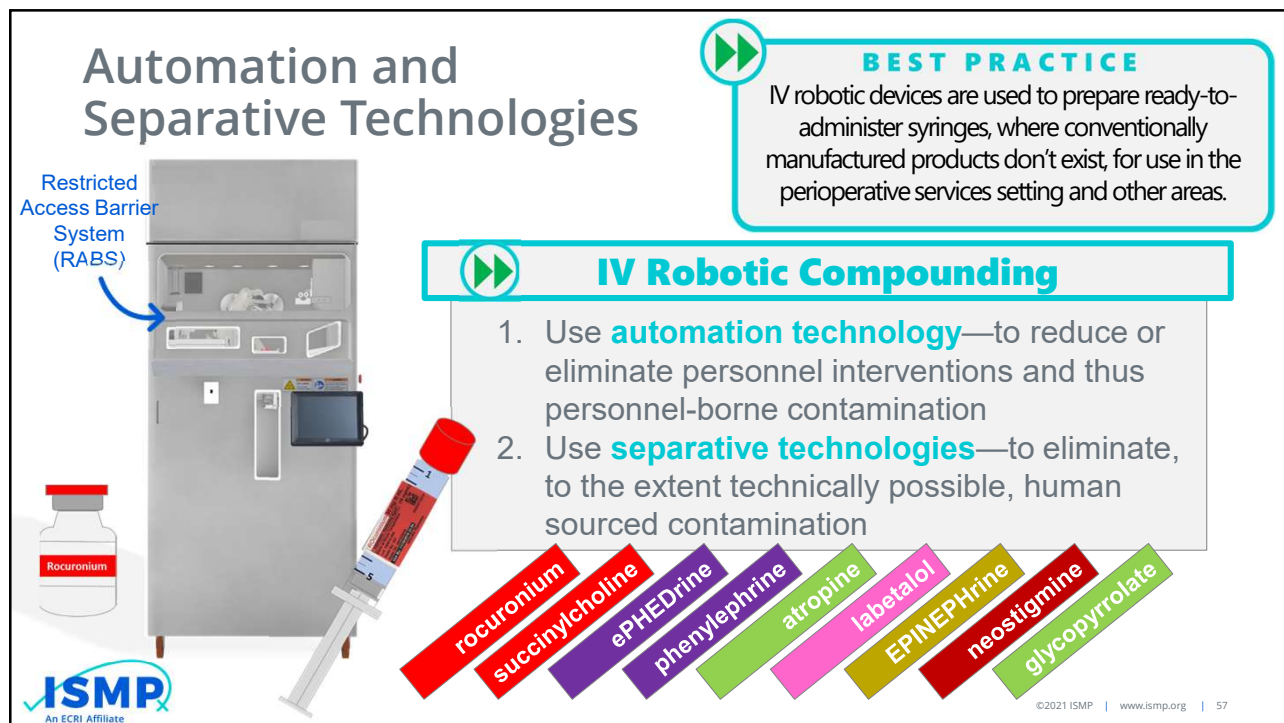
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55

# Raising the Bar on Sterile Compounding Safety



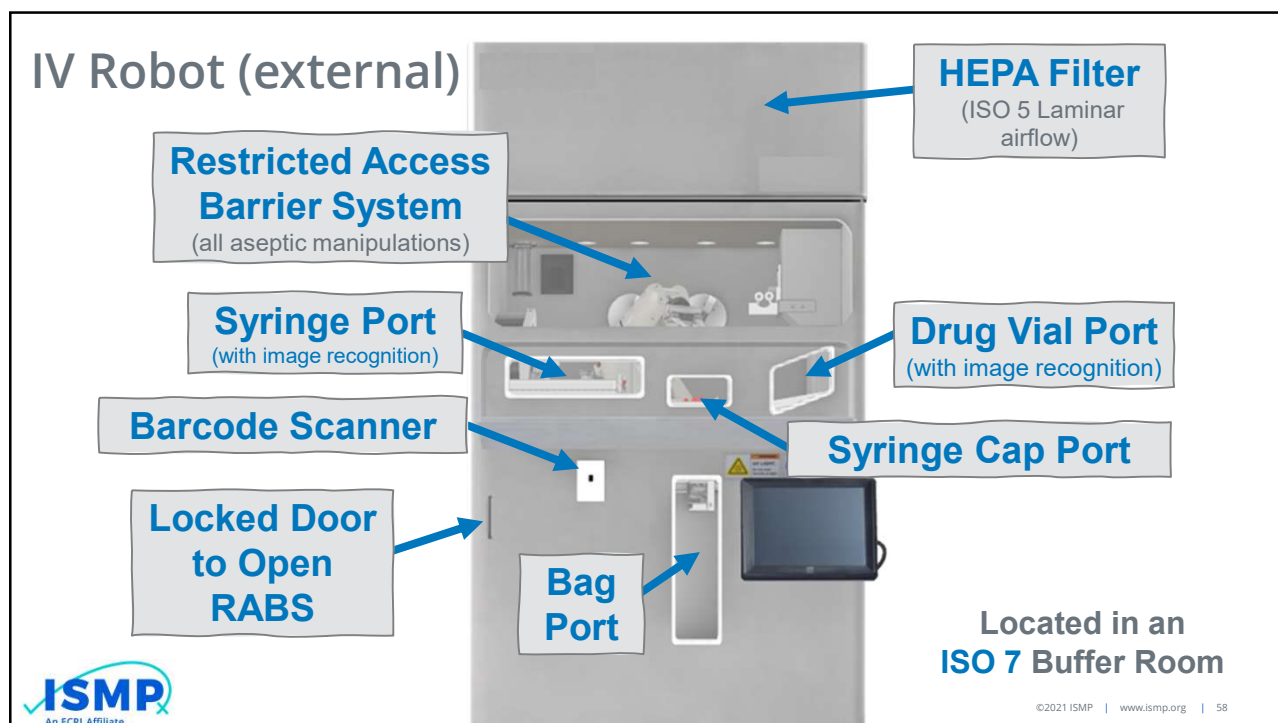
56



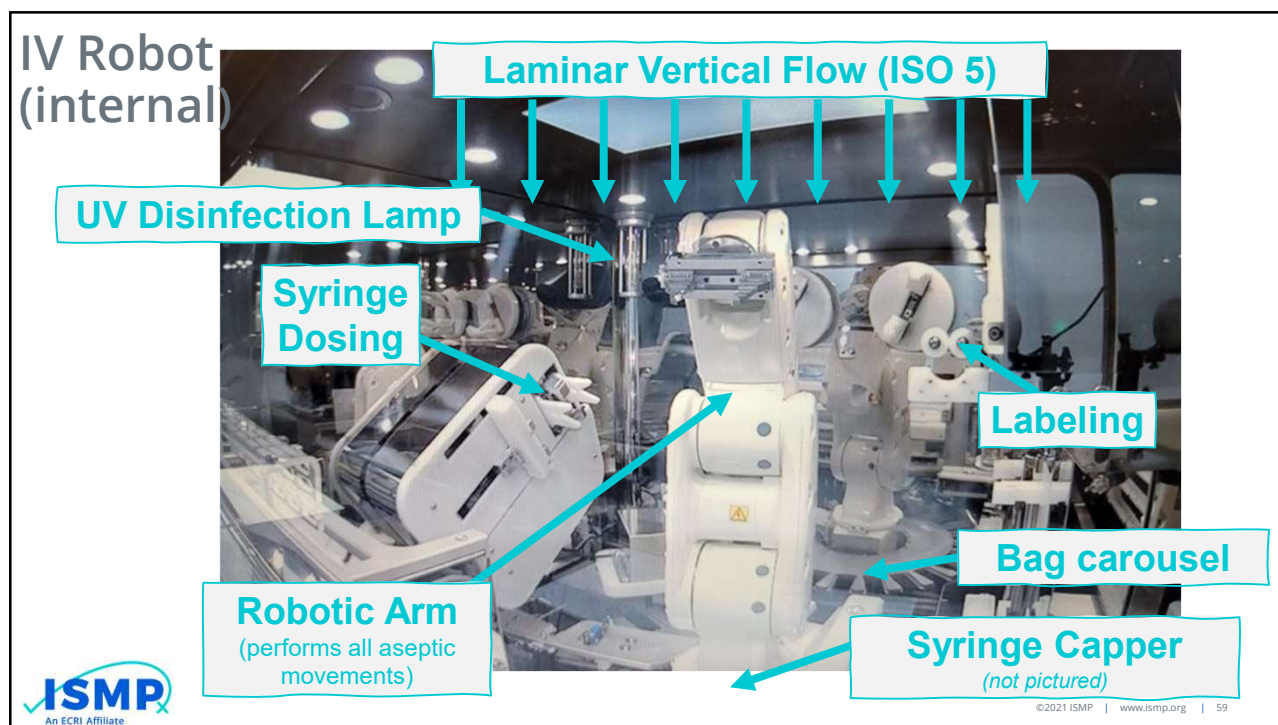
57



# Raising the Bar on Sterile Compounding Safety



58



59

# Raising the Bar on Sterile Compounding Safety

## Situation / Case Study

Your organization purchases ready-to-administer **rocuronium** syringes from a 503B to improve patient care, safety, and decrease bedside preparation. You receive an email from your 503B vendor that '**due to increased demand, all products will be shipping 3-4 weeks late**'. Due to the continued supply disruptions and impact to patient care, your organization evaluates using IV robotics to repackage **rocuronium** into ready-to-administer syringes.



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60

## Stability-Indicating Method Study

### Analytical Method Verification

- System suitability and calibration curve
- Accuracy / Precision
- Specificity

### Stability Study

- Conventionally manufactured ingredient → repackaged into sterile syringes
- Samples prepared on IV robot
- Triplicate lot testing
- Additional tests: Appearance, pH, particulate matter, endotoxin, sterility, container closure

### Extended BUD Study

Rocuronium Bromide 10 mg/mL 5 mL and 10 mL in 10 mL BD Syringe at Room Temp

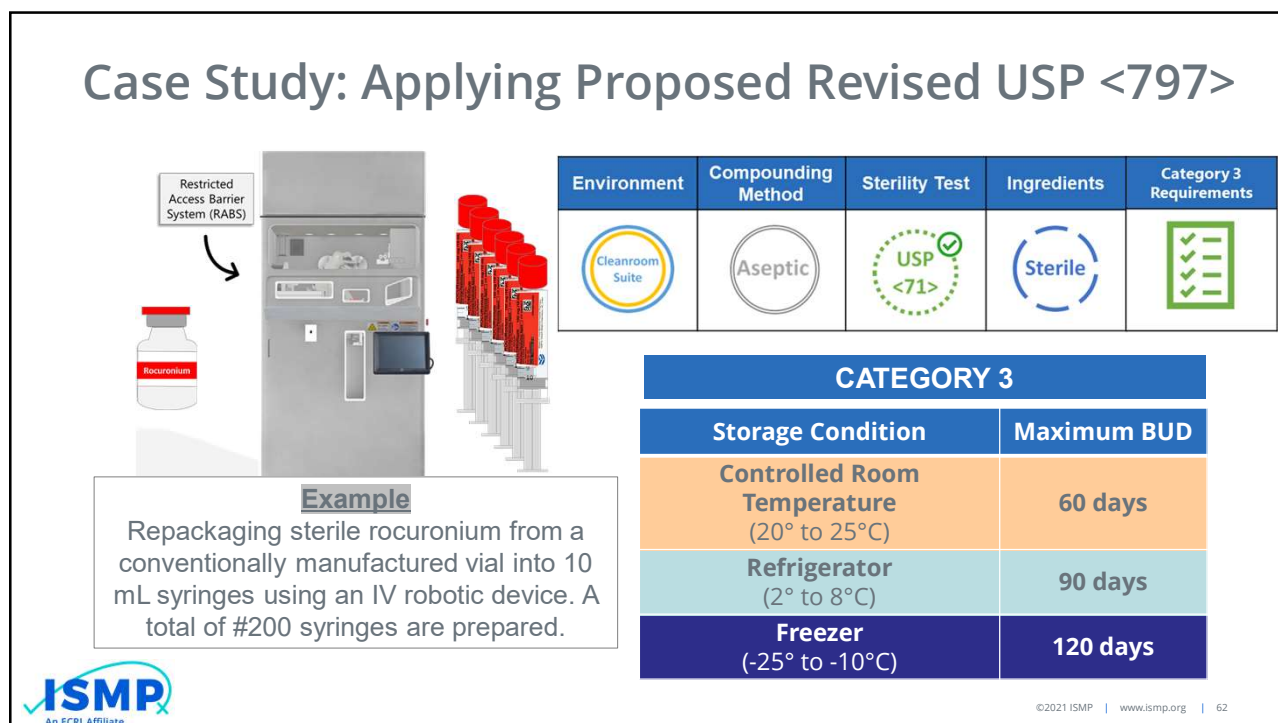


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61

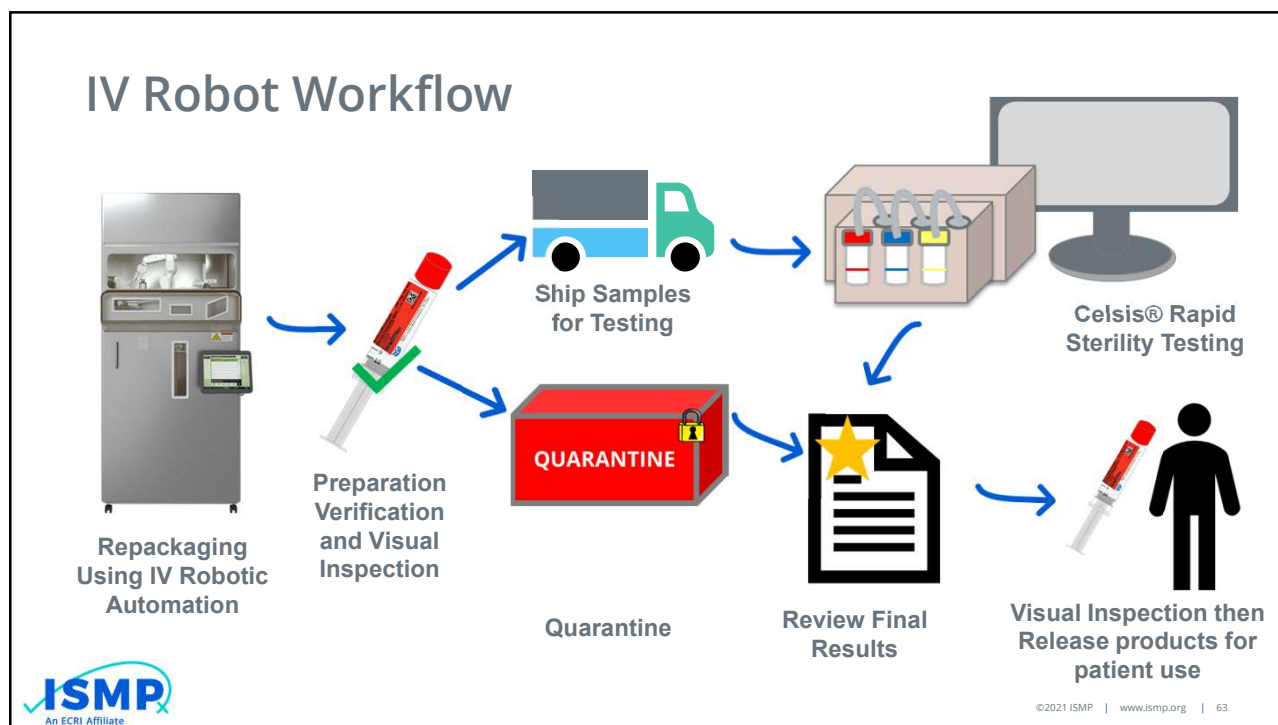
# Raising the Bar on Sterile Compounding Safety

## Case Study: Applying Proposed Revised USP <797>



62

## IV Robot Workflow



63

# Raising the Bar on Sterile Compounding Safety

## Grocery Store Self Check-Out



- Software guided with soft/hard stops
- Barcode scanner
- Gravimetric scale (x2)
- Video
- Image/object recognition
- Security tag deactivation
- Wireless payment
- Visual alerts for needing assistance



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64



## Questions?

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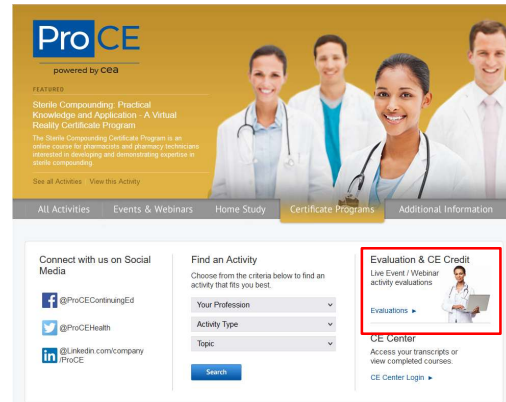
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65

# Raising the Bar on Sterile Compounding Safety

## Online Evaluation and Statement of Completion

- [www.ProCE.com](http://www.ProCE.com)
- Login with username and password
- Deadline: **January 7, 2022**



**Attendance Code = YACDP6**



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## CE ACTIVITY EVALUATION AND CREDIT INSTRUCTIONS

1. To receive CE credit for this activity, you must complete the post-test and activity evaluation online **no later than Friday, January 7, 2022.**
2. Visit **[www.ProCE.com/evaluation](http://www.ProCE.com/evaluation)**.
3. Click on the **Evaluation** button which is listed with the **Raising the Bar on Sterile Compounding Safety – December 8, 2021** CE activity.
4. Login to the ProCE Center. *Note: You will need to sign up for a new account if you have not previously used the ProCE Center.*
5. Enroll in the CE activity, then enter the **Attendance Code: YACDP6** (you will need this code to access the post-test and activity evaluation).
6. Take the post-test, complete the evaluation, and claim CE credit.
7. If you need assistance or have questions, please contact ProCE at 888.213.4061 or via email at **[info@proce.com](mailto:info@proce.com)**.

Note: It is ProCE policy that CE requirements (i.e. post-test, if applicable for the specific CE activity, and evaluation) be completed within 30 days of the live activity date to ensure an on-time submission to your CPE Monitor account.



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## **About ISMP**

The Institute for Safe Medication Practices (ISMP), an affiliate of ECRI, is an independent, nonprofit organization, internationally known as an educational resource for the prevention of medication errors. With more than thirty-five years of experience, the Institute provides independent, objective, multidisciplinary, expert review of errors reported through the ISMP Medication Errors Reporting Program (MERP) and the FDA MedWatch Program. ISMP shares all error reports and prevention strategies with the FDA. Working with practitioners, healthcare institutions, regulatory and accrediting agencies, professional organizations, the pharmaceutical industry, and many others, ISMP provides timely and accurate medication safety information to the healthcare community and encourages safe use of medications. ISMP has an interdisciplinary staff, which includes pharmacists, nurses, a medical director, and other support personnel who assist in ongoing safety efforts.

## **About ProCE**

ProCE, LLC is a leading ACPE-accredited provider and full-service medical education company that integrates the expertise of its staff to bring a depth of experience in pharmacotherapeutics, patient care, public health, medical writing, multimedia design and event management. The team has extensive experience developing and producing educational activities in partnership with professional pharmacy organizations, including the National Association of Specialty Pharmacy, the American Society of Health-System Pharmacists, the Academy of Managed Care Pharmacy, and the Society of Infectious Diseases Pharmacists. ProCE also has a longstanding history of partnering with respected healthcare organizations, including VA hospitals, community health systems, Ascension Health, colleges of pharmacy, the Institute for Safe Medication Practices (ISMP), and pharmacy benefits managers.

ProCE has extensive experience reaching the clinical and specialty pharmacist audience, delivering more than 50 symposia at the American Society of Health-System Pharmacists (ASHP) meetings during the past 11 years. Our CE activities are consistently well-attended and demonstrate significant increases in learner knowledge and competence. In addition to deep experience developing content related to the efficacy, safety, pharmacology, economics, and appropriate management of medication therapy in clinical practice, ProCE excels in addressing the unique educational and professional development needs of the pharmacy audience as well as those of the interprofessional, collaborative care team. ProCE is the ACPE-accredited partner for important interprofessional events, such as the Infectious Diseases Society of America (IDSA) IDWeek, the Intalere Elevate Conference, the Pharmacy Quality Alliance (PQA) Annual Meeting, and many others.