Exploring the Future of Sterile Compounding

Glen J. Gard CPhT-Adv, CSPT

National Director, Sterile Compounding Compliance

Option Care Health

Preceptor: Fred Massoomi, Pharm.D., BCSCP, FASHP

National Director, Sterile Compounding Compliance

Option Care Health

The speaker and preceptor have no conflicts of interest to disclose in relation to this program.

Objectives

1. Recognize the opportunities for Pharmacy Technicians in cleanroom compliance

2. Discuss the proposed 2021 USP Chapter <797>

3. Review future cleanroom automation capabilities

? Polling Question ?

Does your health-system utilize any of the following technology? Select all that apply

1. Barcode scanning
2. Workflow management software
3. Pictures or remote video verification
4. Gravimetrics
5. Robots

Technology Used in Sterile Compounding

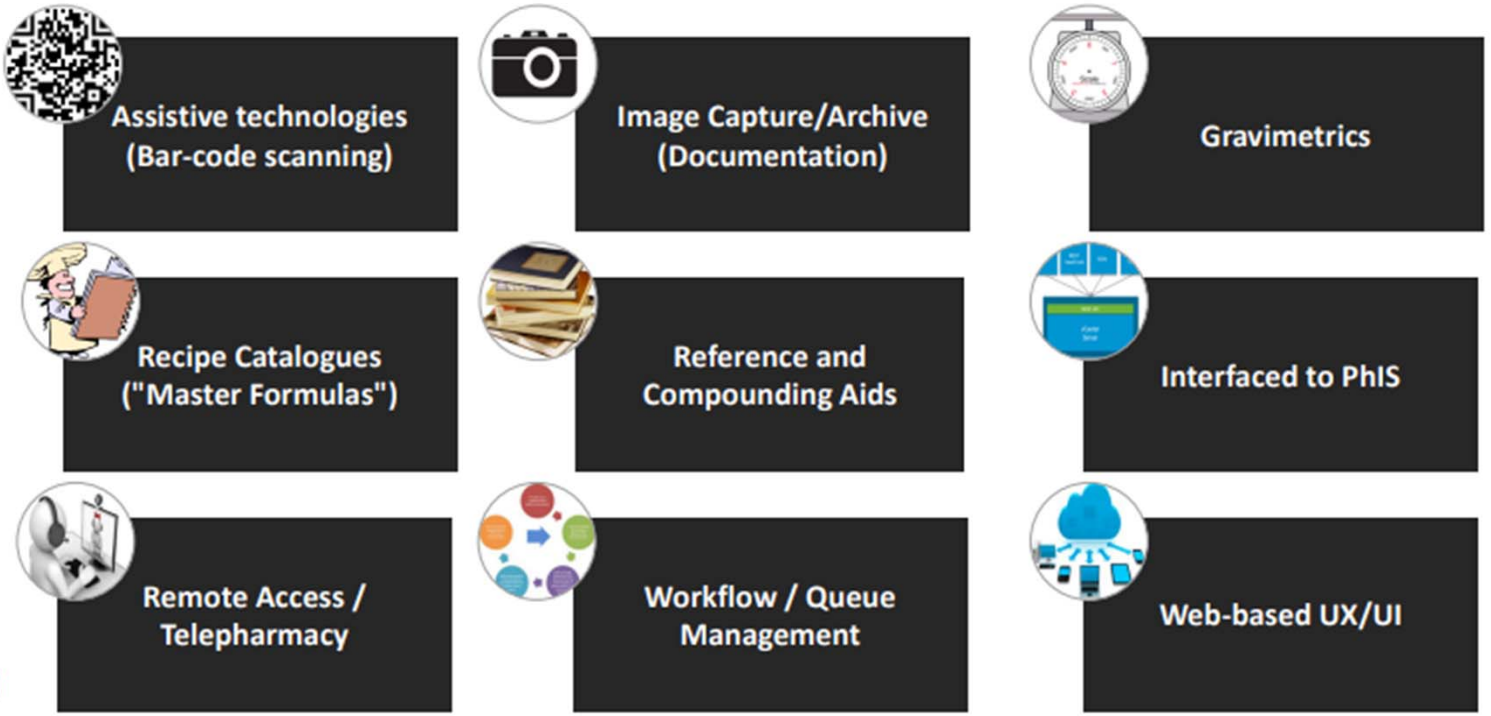
Staffed beds	Barcode scanning	Workflow mgmt. software	Pictures or Remote video supervision	Gravimetrics	None used	Non-HD i.v. robot	Chemo i.v. robot
<50	14.5	7.3	16.4	0.0	78.2	1.8	0.0
50-99	24.2	15.2	21.2	0.0	60.6	3.0	5.6
100-199	45.7	34.3	31.4	14.3	34.3	2.0	0.0
200-299	46.7	23.3	30.0	0.0	40.0	0.0	0.0
300-399	58.5	31.7	34.1	12.2	24.4	2.4	2.7
400-599	58.5	48.8	41.5	9.8	19.5	19.5	0.0
≥600	65.5	40.6	34.4	18.8	21.9	9.4	15.6
All hospitals – 2020	**33.8**	**21.3**	**25.3**	**5.0**	**52.7**	**3.4**	**1.6**
All hospitals – 2017	26.9	12.8	12.5	5.5	64.0	2.3	0.9
All hospitals – 2014	19.5	6.5	--	--	--	2.9	0.3
All hospitals – 2011	11.9	--	--	--	--	2.5	0.1
All hospitals – 2008	--	--	--	--	--	1.1	--

ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration – 2020 . Am J Health-Syst Pharma. 2021;78:1074-1093

IV Workflow Technology

IV WorkFlow DIRECTS:	• Using ENFORCING/FORCING functionality, to DOCUMENT the manual sterile compounding process • Through template algorithms
Enforcing Function:	• Mechanisms built into the workflow to WARN users when something is outside safety parameters
Forcing Function:	• Mechanisms built into the workflow to PREVENT specific errors or reduce their impact
DOCUMENT:	• Through barcode scanning, pictures and videos the process

IV Workflow Technology



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IV Workflow Technology

Consistent medication safety through algorithms at the point of compounding

- Allows for real-time changing of processes

Remote Verification

- Allows pharmacist or Pharmacy Technician remote verification
- Locally and regionally

Live tracking of orders during compounding and dispensing process

- Orders are prioritized in real-time

Provides real-time quantity and quality safety metrics

IV Workflow Technology

Increased efficiency in workflow

- Gravimetric checks with hard stops
- Eliminates the “Syringe pull-back” proxy method

Error Reduction

- Step-by-step checks during compounding
- Step-by-step photo log of each compounding step

Waste Reduction and Inventory Management

Final Notes on IV Workflow

- Even with IV Workflow in place a final visual inspection of each CSP may still be required
- Consider utilization of a black and white background for final visual inspection
- Several organizations have, or are planning, to endorse IV Workflow legislation

? Polling Question ?

Which of the following is an advantage of IV Workflow?

A. Increased efficiencies
B. Reduces waste
C. Gravimetric verification
D. Remote Verification
E. All of the above

Cleanroom Automation & Technology

Cobot: a robot or automation that collaborates and interacts with humans

- Basic peristaltic pumps
  - Assist with repeated volumetric aliquots
  - Assist with large volumetric aliquots
  - Assist with volumetric filling of elastomeric devices
- Total Parenteral Nutrition compounding devices
  - Bar code scanning at the ingredient level
  - Uses volumetric delivery with gravimetric quantity validation
  - Critical safety stops

Cleanroom Automation & Technology

- Smart Repeater Pumps / Cobot generation 2
  - Integrated volumetric and gravimetric validation
  - Ingredient bar code validation
  - Interface documentation
  - Critical manual step automation
  - Potential for electronic documentation of compound records and master formulation records

Cleanroom Automation & Technology

Robotics

- IV Robotics current capabilities
- Placement inside of a cleanroom
- Require a pharmacy technician to operate
- Most health-systems or 503a pharmacies have limited use
- Difficult case to prove a return of investment (ROI)

Future Technology Considerations

Automation Bias	• Over-reliance on automation aids and decision support systems
Automation Complacency	• Human operator monitoring an automated system develops suboptimal monitoring
Redundant manual system integrity	• What is the back-up strategy when automation is not functioning?

? Polling Question ?

Which of the following is an advantage to increased automation and technology in the cleanroom?

A. Reduces repetitive motion
B. Reduces waste
C. Increased safety
D. Remote Verification
E. All of the above

Proposed USP Chapter <797> Key Updates

Training

- Didactic training
- Increase Media fill and GFT requirements and frequency
- Visual observation
- Training required for supervisors

Clean Room

- Microbiological monitoring
- Transfer of materials
- Cleaning
- Use of CSPs as components

Compounding

- Designated person
- BUDs
- Risk levels and Categories
- Annual review of QC / QA and policies
- Master Formula and Compound Records

? Polling Question ?

Which of the following is a proposed key change made by USP in the new Chapter <797>?

A. Increase surface sampling to every other month
B. Increase media fill to every three months
C. Changes in risk level terminology
D. Requires sterile gowns or sleeves

Opportunities for Pharmacy Technicians

- There is a shortage of experienced pharmacy technicians with sterile compounding experience
- Illinois now allows barcode scanning or other technologies to implement tech check tech
- There are several certificates and certifications available through ASHP and the PTCB

Opportunities for Pharmacy Technicians

- Pharmacy technicians can advance their roles in sterile compounding to help ensure compliance with regulatory standards, as well as safe patient care
- The United States Pharmacopeia (USP) has requirements for designated persons in compounding and hazardous drug compounding in their newest standards
- Each advanced software or handwear requires an advanced expert user to train and maintain

? Polling Question ?

Which of the following are opportunities for Pharmacy Technician advancement?

A. Quality oversight
B. Training
C. Tech check Tech
D. All of the above

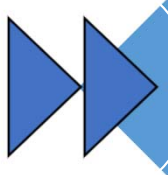
Key Takeaways

Key Takeaway #1

- Automation increases the safety and quality of CSPs

Key Takeaway #2

- The new USP Chapter <797> is coming start now



Key Takeaway #3

- Advancement of technology in cleanrooms will lead to advancement of the pharmacy technician profession

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Questions?