Use of Automation and Robotic Technology to Improve the Process for Preparing Compounded Sterile Products

Presented as a Live Webinar Monday, October 25, 2010

Planned and conducted by ASHP Advantage and supported by an educational grant from McKesson.





Webinar Information

How do I register?

Go to www.ashpadvantage.com/ivautomation and click on the "Register" button. You will be emailed computer and audio information.

What is a live webinar?

A live webinar brings the presentation to you – at your desk, in your home, through a staff inservice program. You listen to the presentation in "real time" as you watch the slides on the screen. You will have the opportunity to ask the speaker questions at the end of the program. Please join the conference at least 5 minutes before the scheduled start time for important program announcements.

How do I process my Continuing Pharmacy Education (CPE) credit?

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What do I need in order to participate in the webinar?

- 1. Computer with internet access and basic system requirements. When you register, the webinar system will assess your system to ensure compatibility.
- 2. Telephone to dial the toll-free number and listen to the presentation (if you choose not to use Voice Over IP [VoIP] via your computer).

Webinar System Requirements

PC-based attendees

Required: Windows® 7, Vista, XP, 2003 Server or 2000

Macintosh®-based attendees Required: Mac OS® X 10.4.11 (Tiger®) or newer

What if I would like to arrange for my colleagues to participate in this webinar as a group?

One person serving as the group coordinator should register for the webinar. That group coordinator will receive an e-mail confirmation with instructions for joining the webinar. A few minutes before the webinar begins, the group coordinator should launch the webinar link. Once the webinar has been activated, the coordinator will have the option to open the audio via VoIP (Voice Over IP) on the webinar toolbar or use a touch tone phone with the provided dial-in information. At the conclusion of the activity, the group coordinator will complete a brief online evaluation and report the number of participants at that site. Each participant will process his or her individual continuing education statement online at the ASHP Learning Center.

How do I ask a question of the presenter?

Follow the instructions provided at the beginning of the activity for submitting text questions using the webinar tool. The speaker will answer as many questions as possible at the conclusion of the activity.

Faculty

William W. Churchill, M.S., B.S.Pharm.

Chief of Service Department of Pharmacy Brigham and Women's Hospital Boston, Massachusetts

William W. Churchill, M.S., B.S.Pharm., is Chief of Service for the Department of Pharmacy at Brigham and Women's Hospital in Boston, Massachusetts, where he is responsible for leadership of the pharmacy department and Anticoagulation Management Services. Mr. Churchill serves Brigham and Women's as Chairperson of the Drug Safety Committee, Vice Chairperson of the Pharmacy and Therapeutics Committee, and Co-Chairperson of the eMAR/Bar Code Scanning Project Team. He also served the Partners Healthcare Network as the Co-Chairperson of the High Performance Medicine Improvement Team that focused on the implementation of medication safety technology. Mr. Churchill is immediate past Chairperson of the University Hospital Consortium (UHC) Pharmacy Financial Performance Committee and a member of the UHC Pharmacy Executive Committee.

Mr. Churchill's primary practice interests include improving the safety and efficiency of medication administration systems; designing and implementing technology, robotics, and automation that promote patient safety; and expanding the role of clinical pharmacy specialists through the use of medication safety technology.

For his efforts in improving medication safety worldwide, Mr. Churchill was awarded the 2007 American Society of Health-System Pharmacists (ASHP) Distinguished Leadership Award. He was also named the 2008 Massachusetts Health-System Pharmacist of the Year by the Massachusetts Society of Health-System Pharmacists. In 2009, Mr. Churchill was selected by ASHP and Northeastern University to receive the 25th John W. Webb Lecture Award, which recognizes a hospital or health-system pharmacy practitioner or educator who has exemplified extraordinary dedication to fostering excellence in pharmacy leadership. He was awarded the Boston Business Journal's Health Care Champion Award for Innovation in 2010.

Mr. Churchill earned his Bachelor of Science and Master of Science degrees from Northeastern University in Boston. He is Adjunct Clinical Professor of Pharmacy Practice at Northeastern University Bouvé College of Health Sciences, and he also holds an appointment as Visiting Professor at the University of London School of Pharmacy.

Disclosure Statement

In accordance with the Accreditation Council for Continuing Medical Education's Standards for Commercial Support and the Accreditation Council for Pharmacy Education's Guidelines for Standards for Commercial Support, ASHP *Advantage* requires that all individuals who have control in planning or presenting educational content disclose all relevant financial relationships with any commercial interest. This includes faculty, teachers, authors, activity directors, and members of planning committees. An individual has a relevant financial relationship if the individual or his or her spouse/partner has a financial relationship in any amount occurring in the last 12 months with a commercial interest whose products or services are discussed in the educational activity content over which the individual has control. Relevant financial relationships will be disclosed to the activity audience.

All faculty and planners for ASHP Advantage education activities are qualified and selected by ASHP Advantage and required to disclose any relevant financial relationships with commercial interests. ASHP Advantage identifies and resolves conflicts of interest prior to an individual's participation in development of content for an educational activity.

The faculty and planners report the following relationships:

William W. Churchill, M.S., B.S.Pharm.

Mr. Churchill declares that he has no relationships pertinent to this activity.

Carla J. Brink, M.S., B.S.Pharm.

Ms. Brink declares that she has no relationships pertinent to this activity.

Continuing Education Accreditation



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1 hour (0.1 CEU) of continuing pharmacy education credit (ACPE activity #204-000-10-466-L05P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education (CPE) credit at the ASHP Learning Center at http://ce.ashp.org following the activity.

Complete instructions for processing CPE can be found on the last page of this handout.

Methods and Format

This is a live web-based activity consisting of audio, presentation slides, and an activity evaluation tool. Participants must participate in the entire presentation and complete the course evaluation to receive continuing pharmacy education credit. Participants may print their official statements of continuing pharmacy education credit immediately. This activity is provided free of charge.

Target Audience

This continuing pharmacy education activity was planned to meet the needs of pharmacists in a variety of practice settings, including large and small health systems, other health-care settings where compounded sterile products are prepared, and academia. This activity would be particularly beneficial for pharmacists, pharmacy managers, leaders, and educators who are interested in patient safety, technology, and future directions in pharmacy practice.

Available soon www.ashpmedia.org/symposia/ivautomation

A web-based version of this educational activity is being developed, and it is approved for 1 hour of CPE. Encourage your pharmacist colleagues who were unable to attend today's webinar to look for this free online educational activity in December 2010.

Please note that individuals who claim CPE credit for the live webinar are ineligible to claim credit for the web-based activity.

Activity Overview

The process of preparing compounded sterile products (CSPs) is one that requires compliance with strict guidelines and procedures to minimize errors and ensure patient safety. This educational activity will provide an overview of why pharmacists should be concerned with current methods of preparing CSPs and the need to move to a safer preparation process that may include automation and the use of robotic technology for both hazardous and nonhazardous medications. The challenges of using these new technologies will be discussed, as well as lessons learned by those who have implemented robotic systems for this purpose. The financial impact of using these technologies will also be addressed.

Time for questions and answers will be provided at the end of the presentation.

Activity Learning Objectives

At the conclusion of this knowledge-based educational activity, participants should be able to

- Discuss the need for patient safety-related improvements in the process for preparing CSPs in many health-system pharmacy departments.
- Describe the pros and cons of the volumetric and gravimetric systems for preparing CSPs.
- Describe at least two types of quality control testing that should be done when implementing a robotic or a gravimetrically-based system for preparing CSPs.
- Describe at least two examples of improvements to patient care resulting from the integration of optical scanning and bar-code verification into the CSP preparation process.
- Identify at least two steps involved in developing a strategic plan for improving a health system's process for preparing CSPs.

Use of Automation and Robotic Technology to Improve the Process for Preparing Compounded Sterile Products



William W. Churchill, M.S., B.S.Pharm. Chief of Service Department of Pharmacy Brigham and Women's Hospital Boston, Massachusetts

Learning Objectives

- Discuss the need for patient safety-related improvements in the process for preparing compounded sterile products* (CSPs) in many health-system pharmacy departments.
- Describe the pros and cons of the volumetric and gravimetric systems for preparing CSPs.
- Describe at least two types of quality control testing that should be done when implementing a robotic or a gravimetrically-based system for preparing CSPs.

*Also called compounded sterile preparations.

Learning Objectives (continued)

- Describe at least 2 examples of improvements to patient care resulting from the integration of optical scanning and bar-code verification into the CSP preparation process.
- Identify at least 2 steps involved in developing a strategic plan for improving a health system's process for preparing CSPs.

What keeps us awake at night?

- Many pharmacy directors say....
 - "What keeps me awake at night is what goes on during the day in my i.v. room!"





Evidence Demonstrating Concerns about CSPs Prepared by Health Care Workers

Occurrence and Impact of Unanticipated Variation in Intravenous Methotrexate Dosing

Medication Errors Detected in Infusions

Discrepancies between ordered and delivered concentrations of opiate infusions in critical care

> Frequency of Medication Errors with Intravenous Acetylcysteine for Acetaminophen Overdose

> > Parshuram CS et al. Ann Pharmacother. 2006; 40:805-11. Anton C et al. Arch Intern Med. 2003; 163:982. Parshuram CS et al. Crit Care Med. 2003; 31:2483-7. Hayes BD et al. Ann Pharmacother. 2008; 42:766.

More Evidence Demonstrating Concerns about CSPs Prepared by Health Care Workers

Systematic evaluation of errors occurring during the preparation of intravenous medication

Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France

An observational study of intravenous medication errors in the United Kingdom and in Germany

> Parshuram CS et al. *CMAJ.* 2008;Á178:42-8. Cousins DH et al. *Qual Saf Health Care.* 2005;Á14:190-5. ÁWirtz V et al. *Pharm World Sci.* 2003; 25:104-11.

Why We Need to Know What's in Our CSPs

Homepage > Local News > Latest Local News > Ex-Cleveland pharmacist gets 6 mos. in fatal chemo dose

By Associated Press

POSTED: 12:11 p.m. EDT, Aug 14, 2009

CLEVELAND: A former Ohio pharmacist has been sentenced to six months in jail and six months of house arrest in the death of a toddler given an incorrect tumor treatment.

At Friday's sentencing in Cleveland, 41-year-old Eric Cropp also was ordered to tell professional groups about his case as part of 400 hours of community service when he leaves iail.

Cropp pleaded no contest in May to involuntary manslaughter in the 2006 death of 2-year-old Emity Jerry. Prosecutors said Cropp was responsible because he oversaw the mixing of the girls chemotherapy at Rainbow Babies and http://www.ohio.com/news/break_news/53230327.html (accessed 2010 Oct 13).

Rationale for Robotic Preparation of CSPs

- Medical literature has defined the risks associated with improper preparation of CSPs by humans
- USP <797> requires sterile product preparation to be completed in an appropriate sterile environment
- The Joint Commission requires all nonemergent CSPs to be prepared by the pharmacy department
- Volumetric process is less accurate than gravimetric process

Why Is Innovation Needed?

- Improve the quality of our health care system and patient outcomes
- · Reduce expenses
- Improve efficiency and productivity
 - Must be able to do more with less!
- · Increase revenues and funding
- Become more agile and responsive as a department



Leader's Role in Change Management Facilitate and enable change Have training in place to get ready for the change Celebrate success

WE MUST BE THE CHANGE

- Recognize employees when change goals are met
- · Do not punish failure
- Keep lines of communication open
- · Adapt, overcome, and persevere

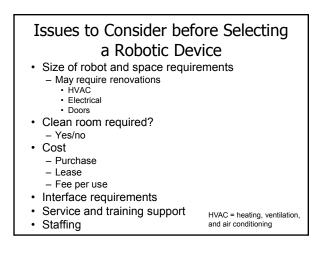
Volumetrics vs. Gravimetrics

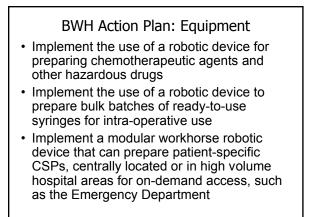
- Gravimetric processes use specific gravity (SG) to backcalculate dose of medication prepared – Ordered dose of chemo drug Y = 1000 mg in 50 mL
- SG of drug Y 20 mg/mL = 1.06 g/mL
- Weight of robot-prepared bag = 52.90 g
- Volumetric process relies on accurate drawing up of fluid volumes by pharmacy technicians
 - Weight of human-prepared bag = 49.97 g
- "Who" is more accurate?
 - Theoretical weight = 1.06 g/mL x 50 mL = 53.0 g
 - Robot variance = 52.90 g ÷ 53.0 g x 100 = 99.8%
 Human variance = 49.20 g ÷ 53.0 g x 100 = 92.83%
- Robot is programmed with a pass/fail variance setting of
- 5%
 - Which dose of chemo would you rather get?
 998 mg (robot) vs. 928 mg (human)

| BWH Annual CSP Doses | | |
|--|-----------|--|
| BWH pharmacy prepared | 400,000 | |
| Commercially available premix | 700,000 | |
| Outsourced or robot prepared | 375,000 | |
| Urgently needed nurse prepared | 25,032 | |
| Require pharmacy preparation | 41,472 | |
| Total annual CSP doses | 1,541,504 | |
| BWH = Brigham and Women's Hospital | | |

BWH Strategic Vision for Compounded Sterile Products

- Minimize number of CSP preparation errors by eliminating human preparation of these products both in the pharmacy and in patient care areas
- Prepare medications in house that were previously prepared and compounded by outside vendors
- Use quality and safety features of IV robotic devices to insure that all products are made with the highest degree of accuracy, sterility, and safety





Robotic Devices for On-site, On-demand Preparation of CSPs

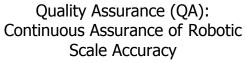
- Integration with pharmacy systems interfaces
 - and eMAR information Real time bi-directional
 - Remote verification capability for checking pharmacist
 - Medications prepared quickly in ISO class 5 environment
 - Documentation available for central data warehouse

Staffing and Labor Requirements Added two FTE certified pharmacy technician positions to support the new technology Revised an existing pharmacy manager job description to include

- oversight of all robotic and medication safety technology operations
- Re-assigned one FTE pharmacy technician from TPN preparation to on-demand CSP support

Issues with Using Gravimetics

- The Specific Gravity (SG) Lynch Pin
 - Pharmaceutical manufacturers often do not have SG information readily available for customers
 - If SG is available, many will not share in writing
 - Outside testing labs can do test
 Need to send product from inventory
 - Testing can be expensive
 Gravimetric method
 - Uses laboratory grade volumetric pipette and scale for manual calculation of SG



- Verification of scale sensitivity using apothecary grade weights
- Record values in log to monitor variance
 trending



QA: Environmental Monitoring of Syringe Robot

- Weekly TSB media paddle testing – Air sampling
 - 4 samples day 1 prior to cleaning robot
 - 4 samples day 1 after cleaning robt
 - Surface sampling
 - 7 samples day 1 prior to cleaning robot
 - 7 samples day 2 after cleaning robot
- · Weekly TSB media syringes
- Ten x 5 mL TSB media syringes prepped twice weekly before and after cleaning
- All air and surface paddles and TSB syringes checked daily for contamination
 TSB = tryptic soy broth

QA: Microbiological Monitoring of Chemotherapy Robot Microbiological testing Surface monitoring using contact plates (TSA and SAB) Testing done monthly

- Sterility of the
- compounded solution – Full runs of all manufacturing
- processes with TSB
 Sterility of partially used vials
- Use of TSB vials

TSA = trypticase soy agar SAB = Sabouraud dextrose agar (mold)

QA: Validation Protocols of Chemotherapy Robot

- Cross product contamination
- Accuracy and precision testing
- Correct vial recognition
- Correct bag recognition
- Final container labeling



QA: End Product Testing for Extended Beyond Use Dating (BUD)

- Testing performed by Dynalab with customer receipt of certified results
 - Potency and purity via HPLC
 - Sterility <USP 71>
 - Aerobic, anaerobic, and fungal
 - Endotoxin <USP 85>
 - Particulate matter <USP 788>
 - pH testing

HPLC = high performance liquid chromatography

Quality Improvement: Integrated End-product Bar-code Verification

- Bar code produced by the robot is integrated with BWH bar-code validation systems
 - Automated dispensing cabinets
 - Anesthesia dispensing cabinets
 - Pharmacy drug storage carousels
 - Pharmacy distribution bar-code verification systems
 - Point of care administration systems
- Bar code on the syringes is also used by the robot as internal verification of the endproduct during robot syringe preparation

Quality Improvement: Interface of Robot with Hospital's Medication-use System

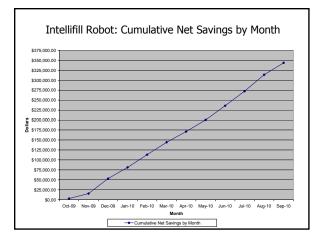
- Chemo robot has full HL7 interface with the BWH pharmacy information system
- Eliminates potential transcription errors
- Monitors inventory use and reduces waste
- Can use robot-generated final container label with institution's BCMA system
- Workhorse robot will use same HL7 interface engine from pharmacy system

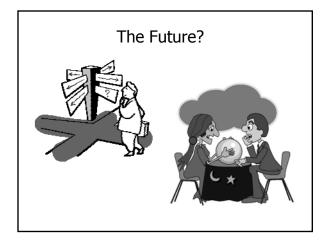
BCMA = bar-code-assisted medication administration

Financial Implications

- BWH did not spend any capital dollars to acquire robots
- Use of robotic devices in place of CSP outsourcing expected to yield \$1 million dollars in savings when fully deployed
- No jobs were lost due to implementation of robots for preparing CSPs

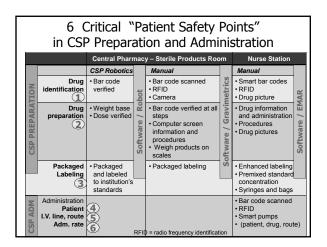






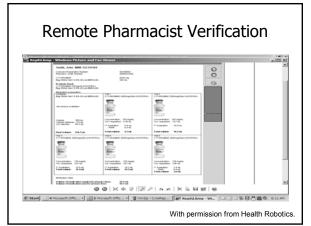
What About CSPs that Can't Be Made in a Robot?

- Must provide a consistent process that uses same tools and functionality as robot
 - Bar-code verification
 - Specific gravity and gravimetrics
 - Remote pharmacist verification
 - Optical scanning
 - Central data storage
 - High degree of accuracy and precision

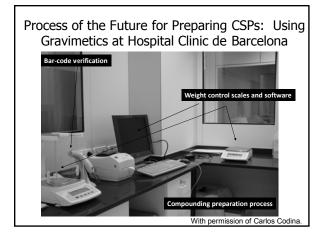


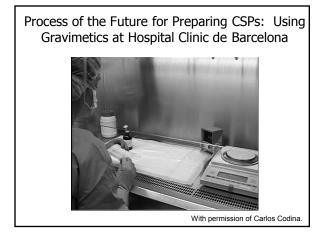


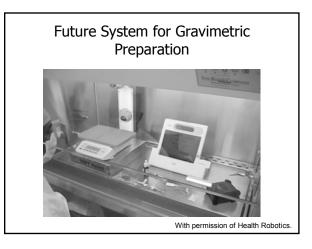
Enlarged slide on page 13.



Enlarged slide on page 11.







Potential Concerns with Changing to New Processes for CSP Preparation

- Technology is relatively new – We are in the early adopter phase
- The technology is not proven yet with evidenced-based studies
- Potential exists for new kinds of errors due to introduction of the new technology
- Staff will need additional training to adapt to their new roles working with robotic technology

Some Good Advice

Some men see things as they are and say, "Why?" I dream of things that never were and say, "Why not?"

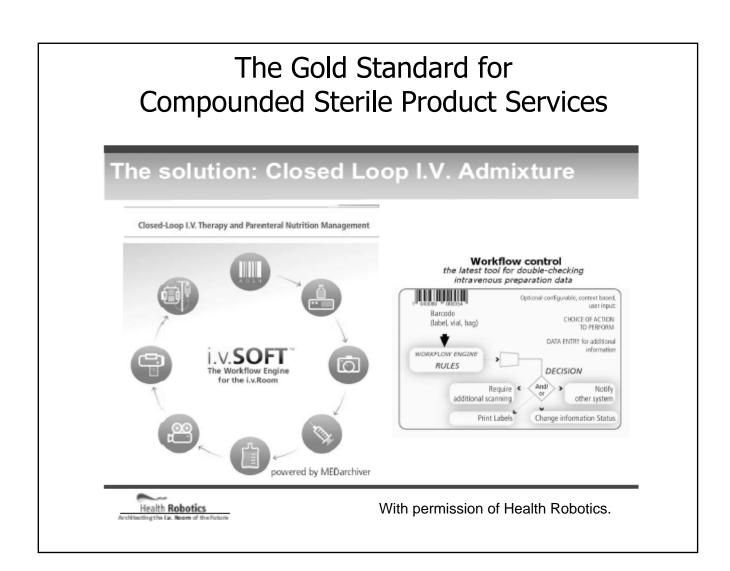


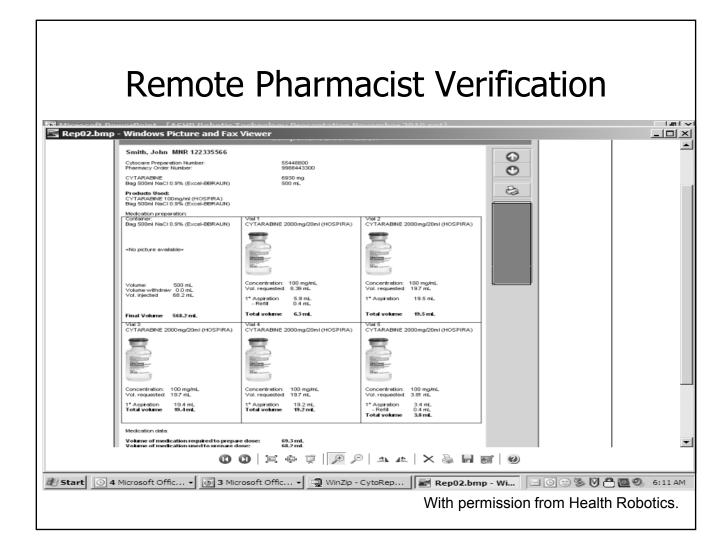
www.artwallpapers.net/

-Robert F. Kennedy, 1968

Conclusion

- It is time for the old process of volumetric preparation and visual checking to be retired
- Innovative technology is now available that will allow for precise and accurate preparation of CSPs
- Pharmacy leaders need to embrace the change and lead their departments into the future





Selected References

- 1. Anton C, Ferner RE. Medication errors detected in infusions. *Arch Intern Med.* 2003; 163:982.
- 2. Associated Press. Ex-Cleveland pharmacist gets 6 mos. in fatal chemo dose. 2009 Aug 14. http://www.ohio.com/news/break_news/53230327.html (accessed 2010 Oct 13).
- 3. Cousins DH, Sabatier B, Begue D et al. Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. *Qual Saf Health Care*. 2005; 14:190-5.
- 4. Hayes BD, Klein-Schwartz W, Doyon S. Frequency of medication errors with intravenous acetylcysteine for acetaminophen overdose. *Ann Pharmacother.* 2008; 42:766-70.
- 5. Parshuram CS, Dupuis LL, To T et al. Occurrence and impact of unanticipated variation in intravenous methotrexate dosing. *Ann Pharmacother.* 2006; 40:805-11.
- 6. Parshuram CS, Ng GY, Ho TK et al. Discrepancies between ordered and delivered concentrations of opiate infusions in critical care. *Crit Care Med.* 2003; 31:2483-7.
- 7. Parshuram CS, To T, Seto W et al. Systematic evaluation of errors occurring during the preparation of intravenous medication. *CMAJ.* 2008; 178:42-8.
- 8. Wirtz V, Taxis K, Barber ND. An observational study of intravenous medication errors in the United Kingdom and in Germany. *Pharm World Sci.* 2003; 25:104-11.

Self-Assessment Questions

- 1. Robotic preparation of compounded sterile products (CSPs) is needed because
 - a. It is required by The Joint Commission.
 - b. It is required by USP<797>.
 - c. The medical literature demonstrates risks associated with improper preparation of CSPs by humans.
 - d. The volumetric process used in robotic preparation is more accurate than the gravimetric process.
- 2. A leader's role in change management includes all of the following responsibilities EXCEPT
 - a. Facilitate and enable change.
 - b. Assure that sufficient training takes place to get the staff ready for the change.
 - c. Keep lines of communication open with the staff.
 - d. Reject attempts to revise plans if met with opposition.
- 3. Which of the following best describes quality control testing that should be done when using robotics to prepare CSPs?
 - a. Air sampling only.
 - b. Air sampling and surface sampling only.
 - c. Air sampling, surface sampling, and sterility of compounded solutions.
 - d. No testing necessary because of assumed sterility of closed preparation system.
- 4. Why is it helpful to interface the robotic CSP preparation process with the hospital's pharmacy information system?
 - a. Enables use of robot-generated final container label with the bar-code-assisted medication administration system.
 - b. Eliminates need for pharmacist review of medication orders.
 - c. Provides billing information.
 - d. Rejects CSPs for patients with potential drug allergies.

Answers

- 1. c
- 2. d
- 3. c
- 4. a

Instructions for Processing Continuing Pharmacy Education (CPE) for Live Webinar Activities

To obtain CE statements for webinars, please visit the ASHP Learning Center at http://ce.ashp.org.

- 1. Select **Process Meeting CE** from bottom left. Log in to the ASHP Learning Center using your e-mail address and password.
- 2. If you have not logged in to the new ASHP Learning Center (launched August 2008) and are not a member of ASHP, you will need to create a free account by clicking on Register at the bottom of the Register as a New User panel.
- 3. Once logged in to the site, click on **Process Meeting CE.**
- 4. If this activity title does not appear in your meeting list, enter the 5-digit activity code in the box above the list and click submit. The Activity and Session Codes are announced at the end of the activity. Click Register again when prompted. When you receive the "thank you for registering" message, click Continue. This step will bring you back to your meeting list. Click on the Start link to the right of the activity title.
- 5. Enter the session code, which starts with the letter "A" and was announced during the activity, and select the number of hours equal to your participation in the activity. Participants should only claim credit for the amount of time they participate in an activity.
- 6. Click **Submit** to receive the attestation page.
- 7. Confirm your participation and click **Submit**.
- 8. Print and/or save your CE statement as appropriate.
- 9. Complete activity evaluation by selecting the **My Account** tab and continue to **My Transcript.**
- 10. Select the applicable year from the drop down menu and locate the activity.
- 11. Click **Complete Evaluation** under the **Status** column to be taken to the evaluation page.
- 12. Complete all evaluation questions and click Finish.

| Activity Code | |
|---------------|--|
| Session Code | |

NEED HELP? Contact ASHP Advantage at support@ashpadvantage.com.