USP Chapter <800>: Focus on Approaches to Addressing Surface Contamination in Healthcare Settings

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  - Cardinal Health: employee
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- Wendy R. Gaudet, Pharm D.
  - BD: consultant, research support
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Learning Objectives

At the conclusion of this activity, participants should be able to
• Review the status of the section in USP Chapter <800> pertaining to environmental quality and control
• Describe the evidence related to surface contamination and where it occurs in healthcare systems
• Describe approaches and emerging technologies for protecting healthcare workers from exposure to hazardous drugs (HDs)
• Explain key elements of a surface wipe sampling plan

USP Chapter <800>: What’s in It for Me?

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USP Chapter <800>: Focus on Approaches to Addressing Surface Contamination in Healthcare Settings

Related Affiliations

• Member of the USP Compounding Expert Committee and speaker for USP compounding courses, but this talk is not affiliated with or endorsed by USP

• Author of *The Chapter <800> Answer Book* and *Assuring Continuous Compliance with Joint Commission Standards*, 8th Edition, published by ASHP

Why USP <800>?  

• Protect patients  
• Protect workers  
• Protect the environment

USP chapter <800> hazardous drugs: handling in healthcare settings.  
U.S. Pharmacopeial Convention, 2018.
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Key Elements of <800>

• Engineering controls
  – Hoods
  – Rooms
  – Closed-system drug-transfer devices (CSTDs)
• Personnel
• Personal protective equipment (PPE)


NIOSH Approach to Limiting Risk

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How Do We Know Our Practices Are Safe?

• Need a method to detect rogue HDs that have escaped containment
• Wipe sampling provides a check on our practices

Has your testing revealed contamination?

a. No – no detectable levels have been reported
b. Yes – but only one or two drugs with very low levels
c. Yes – multiple drugs or concerning levels
d. We haven’t yet received results of our testing
e. NA – do not test or don’t know
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Are You Skeptical?

• NIOSH Health Hazard Evaluation Report
  – Platinum in surface wipe samples
  – Cyclophosphamide detected on the pharmacy floor, on the drug container, in the treatment room
  – Cyclophosphamide on every surface wipe sample in the checkout area


Keeping Us Safe

• Science behind surface contamination
• Available technology
• Template of one health system’s approach
Surface Contamination: What the Evidence Tells Us

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Which of the following objects and surfaces has been shown to have drug contamination? Select all that apply.

a. Cytotoxic waste containers
b. Toilets
c. Patient linens
d. Door handles
Surface Contamination

• What is surface contamination?
• Results from the literature
• Exposure limits
• How to test for surface contamination
• Ways to reduce surface contamination

What Is Surface Contamination?

• HD residue may be found on surfaces or objects due to
  – Spills
  – Inadequate housekeeping
  – Inadvertent transfer
• Dermal contact is the most likely route of occupational exposure to hazardous drugs
What Is Surface Contamination?

• Absorption through skin can result in systemic exposure

• Documented health effects due to exposure
  – *Acute*: skin rash, eye or throat irritation, nausea
  – *Chronic*: reproductive health risks, genetic damage


Evidence of Health Effects

• The meta-analysis of micronuclei frequency from 24 studies confirmed an association between occupational exposure to antineoplastic drugs and cytogenetic effects with an overall meta-estimate of 1.67 [95% CI: 1.41–1.98]

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Evidence of Health Effects

- A meta-analysis confirmed a significant association between occupational exposure to antineoplastic drugs during the course of a normal work day and increases in chromosomal aberrations in healthcare workers


Results from the Literature

Results from the Literature

• In 1993, McDevitt et al. published the first study demonstrating antineoplastic drug contamination on surfaces

• Surfaces and objects are contaminated with more than one drug

• Drug contamination found in areas besides pharmacy and drug administration units

Results from the Literature

• Variety of healthcare workers are potentially at risk of exposure

• Contamination found on various surfaces and objects
Partial List of Contaminated Objects

- Biological safety cabinet
- Vials and IV bags
- Preparation equipment
- Trays and shelves
- Waste containers
- Computer keyboard
- IV pump
- Patient bedside table
- Linens
- Toilets
- Door knobs
- Sink handles

Results from the Literature

- Concentration generally at ng/cm² levels
- Reduction in surface contamination following implementation of safe drug handling guidelines

Results from the Literature

- “Every published surface contamination study has identified at least one drug present by wipe sample analysis”
  

- 1 ng/cm² has been suggested as a threshold of exposure for cyclophosphamide only in USP Chapter <800>
  
  – Based on work of one research team – Sessink et al.

Occupational Exposure Limits?

- No established occupational exposure limits
  
  – No ACGIH threshold limit values (TLVs)
  – No OSHA permissible exposure limits (PELs)
  – No NIOSH recommended exposure limits (RELs)

- Suggested ‘hygienic guidance values’ developed in other countries

ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration

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Occupational Exposure Limits?

• Since there are no occupational exposure limits, the ALARA principle applies

  A L A R A
  s o w
  s e a s
  n o n a b l y
  c hi e v a b l e

How to Test for Surface Contamination

• **Wipe sampling** is a suitable means to i) evaluate work practices, ii) evaluate the effectiveness of applied control measures, and iii) identify the risk for healthcare workers

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Wipe Sampling

• Widely recognized as a means to assess risk, but there is no standardized method

• Good summary of wipe sampling by Connor and Smith (2016)

Traditional Wipe Sampling

• Use a template to delineate area to be wiped

• Typically select 100 cm² (only applies to flat surfaces)

• Solvent is either applied directly to the surface to be sampled or applied to the wiping material

• Wiping materials vary - tissues, filter paper, or special sampling swabs

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Traditional Wipe Sampling

- The surface is wiped in a predetermined pattern, usually in one direction and then perpendicular to that direction.
- Wipe sampling video demonstration – [https://www.youtube.com/watch?v=6Wv-sLMyOkA](https://www.youtube.com/watch?v=6Wv-sLMyOkA)
- Labelled and sent to a lab for analysis via HPLC-MS/MS – results available in a few weeks.
- Some methods can be used to perform simultaneous analysis for multiple HDs
  - Limit of detection varies (can be as low as pg/cm²)

HPLC-MS/MS = high-performance liquid chromatography-tandem mass spectrometry

Near Real-Time Detection

- Relatively new.
- Employs lateral flow immune assay (LFIA)
  - Typically have two lines: 1) a test line that varies in intensity with the concentration of analyte and 2) a control line that is relatively constant and mainly used to assure that the cassette is working properly.
- A cotton swab wetted in sampling buffer is used to wipe surface, and the swab is then extracted in 1 mL sampling buffer.
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**LFIA**

![LFIA Diagram](image)


**Near Real-Time Detection**

- Qualitative only – used as a screening tool
- Results available in minutes
- Limit of detection is higher than with traditional surface wipe sampling
- Limited to certain drugs at this time

Factors Associated with Surface Contamination

• Studies are mixed regarding a correlation between the amount of drugs handled and the extent of surface contamination

• However, certain work practices result in a lower number of positive wipe samples, including routine monitoring

Importance of Routine Monitoring

• Long-term evaluation of drug contamination with repeated monitoring seems beneficial to a) characterize the actual exposure and b) assess surface contamination over time


• Regular environmental monitoring is a good practice to maintain contamination as low as reasonably achievable

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Ways to Reduce Surface Contamination

• Use of CSTDs when preparing HDs significantly reduces surface contamination as compared with standard HD preparation techniques

• Cleaning the exterior of vials from suppliers is a best practice

Ways to Reduce Surface Contamination

• Education should be provided to all healthcare workers who may be at risk of exposure

• Repeated environmental monitoring has a stronger effect on the contamination level than a single measurement
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Ways to Reduce Surface Contamination

- Adoption of safe drug handling practices is known to reduce potential exposure

- Priming of IV tubing should be centralized in the pharmacy

- Surfaces that may become contaminated should be routinely and properly cleaned

Key Takeaways

- Surface contamination is a source of occupational exposure to hazardous drugs
- Routine environmental monitoring should be performed to assess risk
- Practices should be implemented to minimize surface contamination and achieve levels as low as reasonably achievable (ALARA)
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Selected Resources


Making Surface Sampling Work: Practical Issues to Address

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Why Test?

- We deal with drugs that are hazardous to us
  - NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings
- Studies tell us that HDs escape under real-world conditions


Hazardous Drugs in Our Settings

- Receive
- Clean
- Transport
- Administer
- Store
- Mix
Surface Wipe Sampling

• Where and how often should I sample?
• Is it only for chemo?
• Why is it only a Chapter <800> recommendation, not a requirement?

USP chapter <800> hazardous drugs: handling in healthcare settings.
U.S. Pharmacopeial Convention, 2018.

USP Chapter <800> Recommendation

• Environmental wipe sampling for HD surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment)
• Because of the growing number of assays available for HDs, surface wipe sampling ... should be done to document the effectiveness of any agent used for decontamination of HD residue from work surfaces

USP chapter <800>, sections 6 and 15.2.
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ASHP Guidelines

• 2018 ASHP Guidelines on Handling Hazardous Drugs
  – Section on environmental sampling for HDs


Is Wipe Sampling Only for Chemo?

NIOSH list of antineoplastic agents and other hazardous drugs in healthcare settings.

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24
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Evolving Technology

- Harm based on specific levels
- Oversight of testing methods and results

For those who perform wipe sampling, what locations do you sample?
Select all that apply.

a. In the hood
b. Other compounding areas
c. Patient treatment areas
Suggested Surfaces to Sample

- Interior of the hood and equipment contained in it
- Pass-through chambers
- Surfaces in staging and work areas near the hood
- Areas adjacent to hood (e.g., floors directly under hood, dispensing area)
- Areas immediately outside the HD compounding areas
- Patient administration areas

Barriers to Wipe Sampling

- Desire for safety
- Uncertainty about how to implement sampling
- Cost of sampling
  - Prevention
  - Reaction to concern

USP chapter <800>, section 6.
Available Technology - Quantitative

• Test kit with wipes
• Defined area sampled
• Send wipe to company
• Results returned with list of drugs and nanogram levels of detection
Available Technology - Qualitative

- Drug specific
- Wipe sampler and device
- Defined area sampled
- Results shown as HD detected or not

Photos courtesy of BD.
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Thoughts on Utility

• What’s your goal?
  – Ideal → No detectable levels
  – Demonstrate safety or need to correct

• Compounding areas
  – Variety of drugs
  – Multiple compounders

Protecting Nurses and Patients

• Surrogate for types of dosage forms administered
  – Infusion
  – Injection

• Ability to demonstrate results within the shift administered and with the personnel on duty
Your Roadmap

- How can you best develop a plan to check for HD contamination?
- What disciplines should be involved?
- How do you respond to results?
- What is the best plan for correction?

Key Takeaways

- USP <800> recommends environmental wipe sampling to detect HD surface contamination
- Methods to detect surface contamination from hazardous drugs are widely available
- Monitoring for HD contamination is needed to keep workplaces safe
Implementing a Surface Wipe Sampling Plan: Key Steps and Lessons Learned

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Director of Pharmacy
LSU Health Baton Rouge, OLOL Livingston, and MBP-OLOL Cancer Center
Our Lady of the Lake Regional Medical Center
Baton Rouge, Louisiana

Our Lady of the Lake

- Not-for-profit 800-bed medical center in Baton Rouge, Louisiana
- Dedicated Children’s Hospital and St. Jude Affiliate
- Primary teaching site for graduate medical education programs
- Recognized in the areas of heart and vascular, trauma and emergency care, stroke, and cancer care
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Key Elements of a Wipe Sampling Plan

What is your organization’s biggest challenge to implementing a wipe sampling program?

a. Cost
b. Awareness of why it needs to be done
c. Cultural acceptance
d. Already implemented or no challenges
e. Not in practice
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Wipe Sampling: What We Already Know

- OSHA: Controlling Occupational Exposure to Hazardous Drugs, 2016
- USP Chapter <800> Section 6. Environmental Quality and Control
- 2018 ASHP Guidelines on Handling Hazardous Drugs


What's meaningful? Who needs to be involved? What do we do with the results? How do I gain buy in?
How much residue is too much? Is this even in the budget? Do we have enough data?
We need to validate what again?

Where do we even start?
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Our Bumpy Start to Wipe Sampling

- Implemented use of CSTDs in 2013
  - Collected baseline wipe samples before going live and 6 months after going live
  - Showed improvement between the two samples but the collections were flawed
- Wipe samples were not collected again until 2018

Our 5-Year Struggle to Overcome Challenges

- Leveraged wipe study cost in CSTD contract renewal
- Participated in studies at no cost
- Hazardous Drug Task Force (HDTF) development
- Senior Leaders’ and stakeholders’ buy-in
- Quality and safety review
- Recent surveys by TJC
- USP800, OSHA, NIOSH
- Louisiana Board of Pharmacy
- More current studies available
- NIOSH, OSHA
- CSTD data
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Increasing Awareness

- 8-week study collecting multiple wipe samples once weekly in the same locations
- Found we had problems with 5-fluorouracil (5-FU) contamination
  - Detected an unknown spill in one automated dispensing cabinet (ADC)
- Process gaps identified
  - Inconsistent use of CSTDs
  - Inconsistent decontaminating and cleaning processes
- Reported findings to our HDTF

Changing the Culture

HDTF established

<table>
<thead>
<tr>
<th>Executive Sponsor: Vice President of Quality and Safety</th>
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<tbody>
<tr>
<td>Chair: Pharmacy</td>
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<tr>
<td>Co-Chair: Nursing</td>
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<td>Linen Services</td>
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<td>Environmental Services</td>
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<td>Supply Management</td>
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<td>Education</td>
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<td>Regulatory</td>
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The heavy lifting of getting started, then building a safety program was on all of us as a team.
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Deciding on Wipe Sampling Kits

- Cost
- Result turnaround time
- Quantitative measurements
- Multidrug assay or single
- Collection method
- Aligned with current structure

Types of Wipe Samples Available

**Chromatography with Mass Spectrometry**
- Accurate and sensitive test
- Can detect contamination with multiple drugs in a sample
- Measured in ng/cm²
- Very costly method
- Results require a lengthy turnaround time
- Limited number of laboratories able to perform analysis

**Fluorescence Covalent Microbead Immunosorbent Assay (FCMIA)**
- Detects residue of multiple drugs simultaneously
- Collection method is simple
- Provides timely results
- Lower cost than mass spectrometry
- Limitation – possible cross reactivity among HDs assayed
- Limitation – need for assays to detect contamination with more HDs than currently are available

**Lateral Flow Immunoassay (LFIA)**
- Direct field reading with portable monitors
- Single drug assay readings
- Easy to use
- Rapid availability of results
- Lower cost than mass spectrometry
- Limitation – currently available for testing only selected HDs currently

Our New Wipe Sampling Plan

- Used mass spectrometry wipe sampling kits
  - Collected baseline samples in all pharmacies and high risk administration areas

<table>
<thead>
<tr>
<th>Pharmacy Locations</th>
<th>Administration Locations</th>
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<tbody>
<tr>
<td>Hood surfaces</td>
<td>IV poles</td>
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<tr>
<td>Hood foils</td>
<td>Floor under IV poles</td>
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<tr>
<td>Floors adjacent to hoods</td>
<td>Area near HD yellow waste bins</td>
</tr>
<tr>
<td>Computers in cleanrooms</td>
<td>Work stations on wheels</td>
</tr>
<tr>
<td>Pass-through chambers</td>
<td>Medication room storage bins</td>
</tr>
<tr>
<td>Order entry stations</td>
<td>Charge nurse desk</td>
</tr>
<tr>
<td>ADC bins</td>
<td>Patient rooms</td>
</tr>
</tbody>
</table>

Wipe Sample Results

- Results reported to HDTF
- Walked through the entire process to identify gaps and opportunities for improvement
- Frontline staff brainstormed on what success should look like
  - Rewrote standard operating procedures and re-educated staff
  - Considered scheduling with semi-annual certification due dates
  - Incorporated and scheduled wipe sampling task into IV workflow software
- Planning for 6-month wipe sample follow up
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What We Are Considering

- New study with lateral flow immune assay (LFIA)
  - Need quicker validation of SOPs
- Working with HDTF on possible uses of rapid testing in conjunction with mass spectrometry
  - Spills
  - Spot checking by Environmental Services in high risk patient rooms and procedural areas
  - Incorporate in competency check off during training and at least annually thereafter
  - Random checks to validate safe handling program
    - Identifying and tracking any trends

Key Takeaways

- Awareness and cultural acceptance are keys to a successful wipe sampling program
- Work with vendors for sponsoring projects to help promote your plan
- Perfect processes are a moving target
- Barriers are a mere obstacle; keep pushing “The Why”
Which of these practice changes will you consider making?

- Discuss with colleagues and other staff the importance of monitoring for potential HD contamination in health systems
- Investigate types of surface sampling methods that are available
- Conduct evaluation to assess baseline surface contamination
- When detected, investigate causes of surface contamination with HDs
- Develop a plan for testing surfaces for HD contamination, including testing locations and frequency
- Develop a plan for achieving any remaining gaps in monitoring compliance with USP Chapter <800> before December 2019
Assessment Questions

1. What method of environmental monitoring can detect hazardous drugs that have escaped containment?
   a. Settling plates
   b. Air sampling
   c. Wipe sampling
   d. Gloved fingertip testing

2. Chronic health effects due to exposure to surfaces contaminated with hazardous drugs include all of the following EXCEPT
   a. Miscarriage
   b. Inability to conceive
   c. Genetic damage
   d. Nausea

3. What level of contamination has typically been found in studies identifying surface contamination of hazardous drugs in health systems?
   a. mg/cm²
   b. µg/cm²
   c. ng/cm²
   d. pg/cm²

4. What is the current acceptable occupational exposure limits for hazardous drugs?
   a. Undetectable at pg level
   b. 10 ng/cm²
   c. Hygienic guidance values developed in other countries
   d. As low as reasonably achievable

5. Which of the following best describes the usefulness of wipe sampling in health systems?
   a. Evaluate work practices, evaluate the effectiveness of applied control measures, and identify the risk for healthcare workers
   b. Evaluate work practices, identify the risk for healthcare workers, and comply with the USP <800> monitoring requirement
   c. Evaluate the effectiveness of applied control measures, identify the risk for healthcare workers, and comply with the USP <800> monitoring requirement
   d. Evaluate the effectiveness of applied control measures, identify areas of microbial contamination, and evaluate work practices

6. Compared with traditional wipe sampling, newer wipe sampling methods using lateral flow immune assay (LFIA) have the advantage of
   a. Provision of quantitative results
   b. Provision of results in minutes
   c. Ability to detect multiple drugs with a single swab
   d. Lower limit of detection
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7. According to USP Chapter <800>, environmental wipe sampling for hazardous drug surface residue should be conducted at least every
   a. Month
   b. 3 months
   c. 6 months
   d. 12 months

8. A reasonable goal for a health system that has established a routine monitoring plan for hazardous drugs every 6 months (samples collected in drug preparation, storage, and administration areas) would be to have no detectable levels in at least 50% of samples collected.
   a. True
   b. False

9. As described by Dr. Gaudet, what was the value of conducting an 8-week study of hazardous drug contamination at her hospital that consisted of multiple wipe samples once weekly in the same locations?
   a. Identified problems with 5-fluorouracil (5-FU) contamination and pinpointed the source of the problem
   b. Identified problems with contamination from multiple hazardous drugs and pinpointed the source of the problem
   c. Identified problems with 5-FU contamination and stimulated internal investigation to identify the source of the problem and associated process gaps
   d. Identified problems with contamination from multiple hazardous drugs and stimulated internal investigation to identify the source of the problem and associated process gaps

10. When developing a surface wipe sampling plan, which of the following potential uses of rapid testing monitoring would be most valuable when training staff on procedures for safe handling of hazardous drugs?
   a. Incorporate in competency check during training and at least annually thereafter
   b. Conduct random checks in varied areas of the facility
   c. Conduct spot checks in high risk patient rooms and procedural areas
   d. Verify appropriate cleaning and decontaminating after a spill occurred
About the Faculty

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Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP, is Director of Accreditation and Medication Safety for Cardinal Health Innovative Delivery Solutions in Wilkes-Barre, Pennsylvania. She received her pharmacy degree from Philadelphia College of Pharmacy and Science and a Master in Public Administration degree from Marywood University in Scranton, Pennsylvania. She completed the Executive Fellowship in Patient Safety from Virginia Commonwealth University and is Adjunct Associate Professor at Wilkes University in Wilkes-Barre.

Ms. Kienle has served on the ASHP Board of Directors and as President of the Pennsylvania Society of Health-System Pharmacists. She is a fellow of ASHP and received the ASHP Distinguished Leadership Award. She has served on the Pharmacotherapy Specialty Council of the Board of Pharmaceutical Specialties, Pennsylvania Patient Safety Authority, Hospital Professional and Technical Advisory Committee of The Joint Commission, and Board of Governors of the National Patient Safety Foundation. She is a member of the USP Compounding Expert Committee and chair of the Subcommittee on Hazardous Drugs.

Ms. Kienle is co-author of Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide, 8th Edition and author of The Chapter 800 Answer Book. She frequently gives presentations on medication safety, compounding sterile preparations, accreditation, and regulatory issues.

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Dr. Hon has participated in several occupational health studies based in the healthcare sector, with a focus on understanding healthcare workers’ exposure to chemotherapy (hazardous) drugs. To date, he has a dozen publications in this subject area, some of which have been referenced in best practice documents. Generally speaking, Dr. Hon’s research interests are occupational exposure assessments, risk assessment methods, and evaluation of intervention measures to prevent occupational exposure.

Dr. Hon has nearly 20 years of experience as an occupational hygienist, including working at a large health authority in the province of British Columbia. In addition, he possesses designations as a Certified Industrial Hygienist (CIH) and as a Canadian Registered Safety Professional (CRSP).

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Dr. Gaudet serves on multiple hospital and system committees and chairs the Franciscan Ministries of Our Lady Health System Hazardous Drug Task Force System Committee, as well as the OLOL Hazardous Drug Task Force Local Committee. She also serves on a statewide work group with Louisiana Hospital Association for medical marijuana in the healthcare setting.

Dr. Gaudet earned her Bachelor of Science degree at University of Arkansas at Monticello and her Doctor of Pharmacy degree from University of Louisiana at Monroe.

Dr. Gaudet is a member of ASHP and Louisiana Society of Health-System Pharmacists. Among her recognitions are the 2018 Baton Rouge Business Report’s Top 40 Under 40, 2017 Mother Gertrude Hennessy Leadership Award, 2017 Proven Leader Program of OLOL, Class of 2015 Baton Rouge Area Chamber Leadership Program, and 2007 President’s Award at Baton Rouge General Hospital.

www.ash paddvantages media.com/hdmonitoring

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