CASE STUDY

Workflow Strategies to Minimize Personnel and Environmental Exposure to Hazardous Drugs in the Compounding Pharmacy

Bryan Prince, MBA
Owner and Lead Consultant
~ Red Pharmacy Consultants

Handling hazardous drugs in the compounding pharmacy, per USP chapter <800> guidelines, involves strategic workflow strategies with the goal of minimizing personnel and environmental exposure. In our previous article, "Can A Class I and Class II Biological Safety Cabinet be in the Same Sterile Hazardous Room" (Learn.Nuaire.com) we discussed varying workflow methods and the potential for exposure points during the hazardous drug (HD) presterilization process. The purpose of this article is to pull all of those chemical handling and compounding workflow strategies together into a more sequential model in an effort to minimize personnel and environmental exposure. The main focus of this article is on nonsterile hazardous drug handling processes, but the principles of GLP are applicable with both sterile and nonsterile chemical handling. We would also make the assertion that there is a higher likelihood of surface and airborne contamination in the non-sterile compounding rooms due to the volume and activity of dry powders being handled.

Where Does Contamination Come From?

Over the years we have visited many pharmacies and have witnessed consistent and similar workflow processes that create chemical exposure in compounding rooms. Here are the four most common workflow processes that contribute to environmental and personnel exposure.

1. Technicians breach the face of the C-PEC while actively weighing and manipulating powders to retrieve additional materials and/or interact with formulation documentation.
2. Dry-contaminated weigh boats, wipers, and gloves are disposed in open-face trash cans in the lab environment.
3. Contaminated weighing utensils, glassware and capsule plates are removed from the C-PEC and transported across the lab to the sink.
4. Bulk-chemical containers are not wiped down prior to placing back in storage.

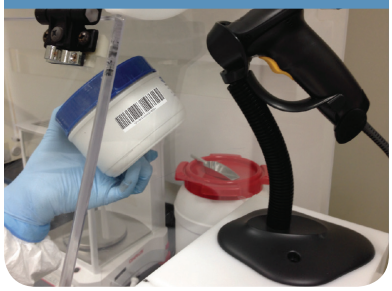
The good news is that all of the four exposure points listed above are easily remedied with some simple process improvements that incur little to no additional cost to the pharmacy. The biggest hurdle will probably be changing old habits to create a new culture change within the pharmacy. The following recommendations below are proven chemical handling workflow methodologies that will minimize and even eliminate personnel and environmental exposure. What we guarantee is that if you change the process it will change the results for the betterment of your pharmacy's staff and facility.

The Integral Step 1: Planning and Staging

The "Compounding Record" is commonly the first document reviewed by the technician for the purpose of planning the formulation workflow process. The compounding record outlines the chemicals and ingredients necessary to formulate the script, but sometimes it's not the best directional roadmap for consistent process replication or for safe handling procedures. The detailed steps like mixing and quality control information are usually part of the Master Formulation Record, but what is missing on the compounding record is a more detailed list of materials required, such as proper utensils, mixing vessel, additional tools, and even the number of weigh boats required. Although this attention to written detail may seem quite trivial, we would make the case that the presence of such a concise planning document can better direct technicians safety workflow habits, in an effort to avoid the points of exposure as defined in the previous section "Where Does Contamination Come From?" We would also further the case by strongly recommending more detailed safety process documents in the HD compounding rooms to satisfy USP 800 language that states, "Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures." The "appropriate procedures" include all stages of the HD handling process and especially during the intimate stage of active chemical handling during compounding. This goal can be easily achieved by adding new language to the Master

CASE STUDY

Additional Commentary



The best quality control method for interacting with formulation software is to scan one chemical and then weigh that chemical. We have witnessed varying methods of this process where a technician scans all chemicals first into the software, then loads the chemical bottles inside the CPEC. Although we commend them for trying to make the workflow process containment friendly, it overrides the software's quality control method.

Formulation Record and copied onto the compounding record by including references to:

1. HD Safety Handling Procedures for the chemicals and workflow process Example: Chemical bottles must be opened inside the primary engineering control.
2. Required Personal Protective Equipment (PPE) Example: A half-mask respirator with P100 cartridge filters must be worn during weighing and mixing of <name of chemical>.
3. All necessary materials needed to complete the compounded script Example: This formulary requires: 1-large weigh boat; 2-small weigh boats; 3-weighing utensils; 1-large mortar/pestle; etc.
4. Cleaning, deactivation, or decontamination processes for the HD chemicals Example: Initial bulk cleaning should be done with 70/30 Isopropyl Alcohol; Final cleaning must be done with peroxyacetic acid /hydrogen peroxide-based sporicidal disinfectant.

The language defined in points one through four above sound a lot like Standard Operating Procedures (SOP) language and it very well could be, but we contend that important SOP language is also unfortunately absent from the compounding records. SOPs are written for well intended purposes, but "repetition is the mother of skill," so without some consistent reinforcement of the intended purpose, it is possible we can sink back into old habits. One of the purposes of USP 800 is to create new habits for hazardous drug handling to make environments cleaner and keep employees safer, so we advocate a new iteration of detailed compounding records that more clearly defines purpose.

"Staging" is an extension of planning and might be the most important strategic step towards minimizing exposure because it requires the technician to think all the way through the formulary workflow process prior to actually starting. Do not discount the importance of this front-end mental exercise in which a technician asks, "What do I need to complete this formulation from start to finish?" If the process of staging is handled correctly, then a large percent of opportunity for environmental exposure is solved because the technician has introduced all necessary materials inside the C-PEC. Now there should be no reason for them to breach containment with contaminated gloves for the reason of retrieving additional materials.

Here is a basic example of staging an encapsulation formulation: (See also Reference-1)

1. Three Chemicals
2. Three Weigh Boats
3. Three Weighing Utensils
4. Mortar and Pestle (or Mixing Vessel) Capsule Machine and Plate
5. Capsules
6. Capsule Tamper
7. Wipers for Cleaning

Space inside a compounding room is always a premium, as is the space inside the C-PEC. Staging chemical bottles, weigh boats, and utensils definitely takes up space, especially after you add-in an electronic balance and even a capsule machine. So in an effort to have enough real estate to stage all the necessary materials, it is highly recommended to use no less than a four-foot wide C-PEC to provide adequate space for the technician and for the CPEC's airflow to perform properly. Staging all the chemicals inside the C-PEC is probably a new concept for most because it is more common that we have witnessed staging of chemicals directly outside the C-PEC and retrieving as needed, which is why a wider C-PEC will entice the technician to follow the proper workflow procedure. Just to reinforce, the goal of "staging" is making sure once the technician commits to the C-PEC, they stay inside the C-PEC during the entirety of the formulation process.

Step 2: Documenting Chemicals and Weighing

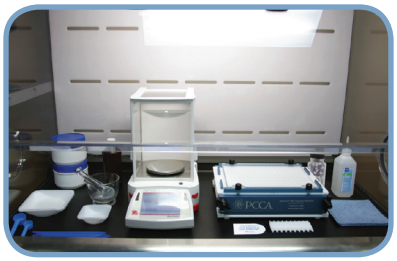
At this pivotal point we have fully established that all the necessary materials are staged inside the C-PEC, the technician has donned appropriate Personal Protective Equipment (PPE) and is willing to commit to the compounding formulation. Unfortunately the workflow process of documenting each step of the formulation is riddled with opportunities for contamination. Let's walk through the two most common methods of documentation, which are software-based and paper-based, and point out some opportunities for contamination, as well as solutions for minimizing exposure.

Software Documentation

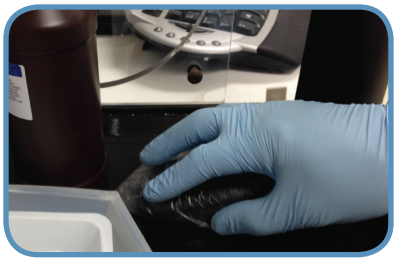
Interacting with the formulation software has always been a challenge because it requires the technician to actively engage the technology, which oftentimes causes contaminated hands to breach containment. Software processes that require technician interaction include: 1) Scanning the barcode on a chemical bottle; 2) Clicking the mouse to proceed to the next step; 3) Making an input on the keyboard.

Let's analyze each of the active software engagement processes and offer solutions. The infrared (IR) scanner should be strategically placed to shine through the sidewall of the C-PEC. This will allow the IR beam to read and scan the bar code into the software. So staging all of the chemical bottles inside the C-PEC is still a valid solution.

CASE STUDY



Reference-1: Proper Staging Inside the C-PEC



Reference-2: Wireless Mouse Inside the C-PEC with Plastic Protective Cover

The electronic balance is communicating with the formulation software and when the correct chemical weight is accepted by the software the technician usually has to click the mouse to proceed to the next step. The solution is to place a wireless mouse inside the hood near the right sidewall. Most people are right-handed and so the computer monitor workstation that displays the software should be also set up on the right side of the C-PEC for best ergonomics. To avoid contaminating the mouse place sticky cellophane wrap (this is a dental supply product) over top of the mouse or bag the mouse in clear sandwich bag (See Reference-2 picture). Now the technician can interact with the wireless mouse inside the hood without breaching containment.

The keyboard is a challenge because it will not fit inside the C-PEC. The good news is that there are very few encounters with the keyboard, but it does occur. When faced with this challenge we recommend the technician spray their gloves with isopropyl alcohol (IPA) solution and wipe thoroughly to remove as much of the visible powder as possible from their gloves. Now when the technician breaches containment it is not a bad idea to have clear cellophane over the keyboard as another layer of safety. We have witnessed quite a few visibly contaminated keyboards during site visits and often recommend throwing them away because thoroughly cleaning all of the keys and crevices is impossible.

Paper Documentation

Compounding pharmacies using a paper-based documentation method is more common than software, so for this reason, it is important to know how paper contributes to contamination. It is not uncommon to see nonsterile compounding rooms with reams of papers. Each one of those papers are a source for harboring contamination because paper is an organic and porous material. Moving forward towards USP 800 implementation, both the sterile HD and nonsterile HD rooms should be minimalist, which means we would strongly encourage implementing some level of digital technology over creating more paper based records.

It is a safer practice to manually document chemical information (e.g. lot number, expiration date, NDC, etc.) on the compounding record prior to staging all the chemical bottles inside the C-PEC. To safely document chemical weights using the electronic balance we strongly recommend attaching a printer, but placing it outside the C-PEC. The printer's ticker-tape will document all the weights through the formulary process and not require the technician to interact with the ticker-tape paper until after formulation completion. As well, the Pharmacist-In-Charge can interact with the ticker-tape at a safe distance.

Handling Chemicals During Compounding

Opening bulk chemical containers should only be done inside the C-PEC. Now this may seem like a logical statement but we still witness situations where a technician opens a container right off the storage shelf, maybe just to visually inspect whether or not a sufficient quantity of chemical exists to complete the current formulation, but it does happen. So the point of opening chemicals only inside the C-PEC is worthy of reinforcing in written form on SOPs and verbal form during training. A good rule with handling chemicals is, unless a sufficient risk assessment has clearly documented that the chemical is safe to open outside of the C-PEC and requires no PPE, then always assume that the chemical has an exposure risk and requires containment.

Powder micronizes all the time, even inside a low-flow C-PEC. As each chemical is weighed in boats (or other vessel) and poured into the mixing vessel, the discarded weigh boats should stay inside the C-PEC. All mixing, manipulation, trituration, and encapsulation of dry powders should be performed inside the C-PEC. The only time it is safe to pull chemicals out of the CPEC is if they are in wet solution, such as a cream base, or in final dosage form like capsules. As well, the only time the discarded weigh boats, wipers, and gloves should be removed from the hood is if they are in a sealed bag. In a future article we will discuss waste removal and cleaning of the C-PEC, but the main point here is again, no dry materials are removed from the front face opening of the C-PEC.

Final Thoughts

There are many opportunities for environmental and personnel exposure during the laborious path of HD handling and compounding. We have revealed only "qualitative" examples of exposure in this article during the active chemical handling phase. Yet our industry still lacks more "quantitative" validation through surface sampling to establish a real case for contamination acceptance. Regardless, what our goal was with this article was to identify common areas where chemical exposure can occur and to offer simple and inexpensive workflow solutions that will have a real impact on your compounding room's cleanliness. Safe chemical handling processes will yield safer workplaces and in turn produce better quality products for patients so it is important to understand the synergistic relationship between safety and quality for overall USP compliance.

MEDICATION WORKFLOW COMPATIBLE

BIOSAFETY CABINETS AND LAMINAR AIRFLOW WORKSTATIONS

MAXIMIZE YOUR SAFEY, PRODUCTIVITY, AND ACCURACY WITH A PRIMARY ENGINEERING CONTROL DESIGNED FOR YOUR IV WORKFLOW AUTOMATION SOLUTION.

Primary Engineering Controls by NuAire.

www.nuaire.com