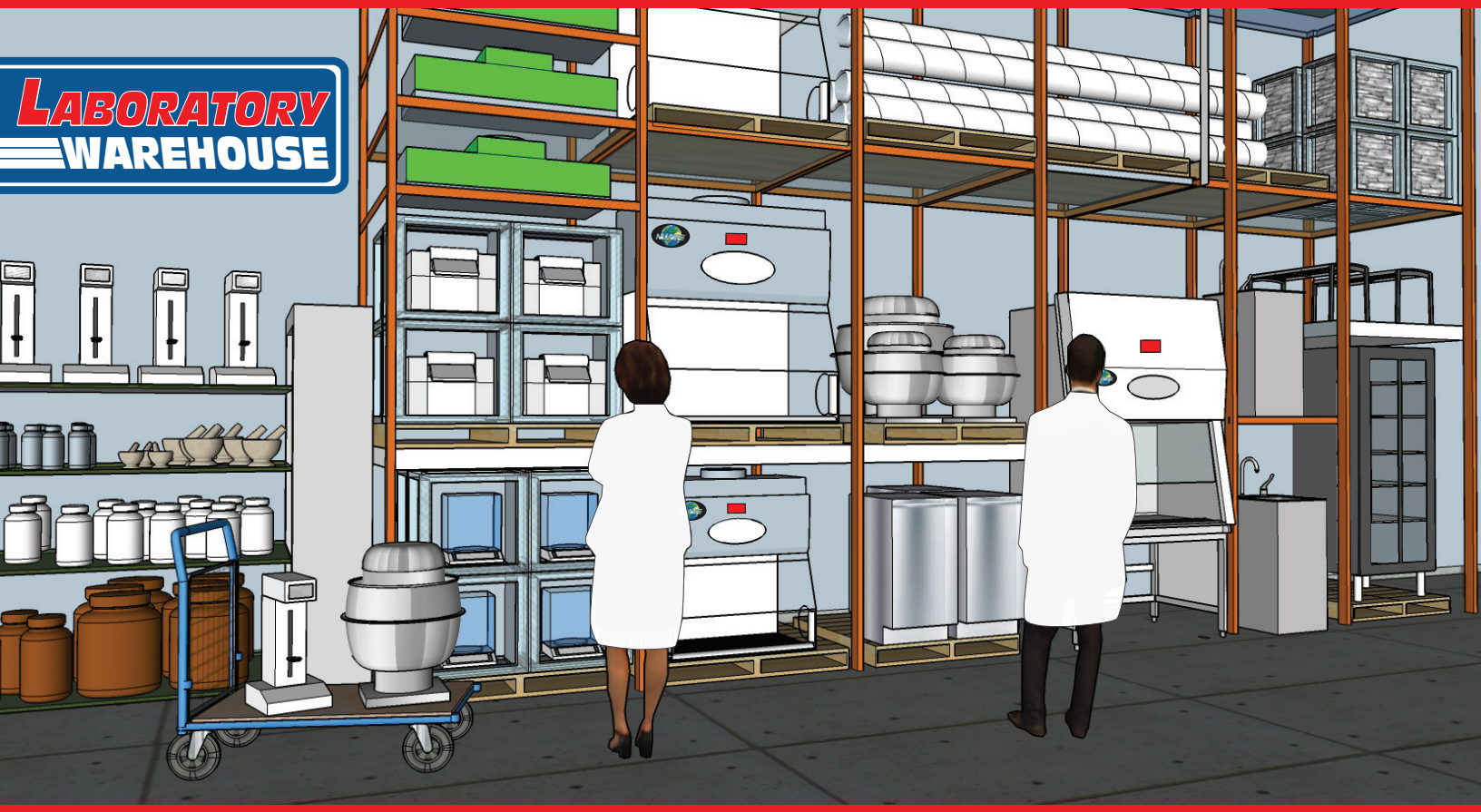
USP 800 GAP ANALYSIS: A BUSINESS PERSPECTIVE



Bryan Prince, LAB·RED Pharmacy Consultants
Gary Meyer, R.Ph

Sponsored by

USP 800 GAP Analysis: A Business Perspective

There are quite a few articles and great resources for developing and conducting a comprehensive *Gap Analysis* around the compliance details defined in the United States Pharmacopeia (USP) chapter <800>. Despite the title of this article we do not intend on simply repeating those articles, instead we want to address details for performing a gap analysis focused on the business side of the compliance equation. USP 800 is going to financially impact your pharmacy's future business model so this article will focus on five important details that define the "why" for considering the capital investment. In this article we will offer up some examples that show how the gap analysis is a simple and effective analytical process that can help you understand if the capital investment is advantageous. It is difficult to design a "one size fits all" hazardous drug handling compliant facility without taking into consideration your pharmacy's specific business model, but towards the end of this article we will propose a financial model based on some generic assumptions to put capital investment into business perspective.

Why Use the Gap Analysis?

A *Gap Analysis* is a simple tool whereas we compare what is currently happening in our pharmacies versus that of a future desired result. In this USP 800 pre-implementation timeline scenario, we are trying to move towards the future desired result which is a facility that is in compliance with USP 800 standards and fits our specific production needs. The gap analysis extends further into strategic thought by taking into consideration time and resources for an actual current event and compares making operational improvements and/or investing in new equipment, all in an effort to accomplish three business goals:

1. Save time
2. Save money
3. Improve quality

These three business goals are not necessarily interdependent and may, at times, seem like a three legged stool making our strategic business goals seemingly mutually exclusive. To save time, you may have to invest money in better equipment. Saving time should save money with increased efficiency, and yet saving money is not always an immediate gratification with capital investment because an undetermined amount of time is required to recuperate investment cost. And finally, when you emphasize improvements in quality (and safety) it may seem difficult to find ways to save both time and money.

Case-In-Point

During a site visit to do both a workflow observation and USP 800 design-engineering assessment we noticed that an active nonsterile compounding room had five technicians and only three Containment Ventilated Enclosures (CVE) which are more commonly referred to as containment primary engineering controls (C-PEC) in the USP 800 chapter. All three C-PECs were running at full capacity throughout the day.

(cont.)

Case-In-Point (cont.)

The two additional technicians kept busy for the most part, helping to stage bulk chemical bottles, washing glassware and capsule plates, and even rotating in to perform new script production while the previous technician handled final labeling and dispensing activities. All five technicians were being as productive as they could be and utilized time and equipment quite well. The daily output in this nonsterile lab was at approximately 75 compounded scripts per day, which equals our years of research that one technician is typically limited to 20 < 30 scripts per day per C-PEC. Further discovery of the production model was that they were always running two to three days behind. To increase daily script capacity the capital investment was $15,000 for an additional C-PEC, capsule machine, and electronic balance. Saving time and money with the capital investment seemed intangible and became a highly debated topic amongst management. This is a common debate being played out weekly in the compounding pharmacy community.

The 'Why' of Capital Investments

There is an outward market perception that implementing USP 800 compliance engineering standards will only cost us money and not return any residual benefit, so why make the capital investment in the first place? First let's understand some reasons for making capital investments:

- Compliance Requirements
- Risk Aversion
- Improved Quality and Safety
- Market Advantage
- Enhanced Workflow Efficiency

Compliance Requirements

Welcome to the "*new normal*" in the compounding pharmacy industry because compliance and government oversight is not going away and neither are the costs associated. The USP 800 engineering compliance component requires pharmacies to connect Containment Primary Engineering Controls (C-PECs) and Containment Secondary Engineering Controls (C-SECs) to external exhaust systems while compounding hazardous drugs (HDs). This is the most significant business component of the USP 800 chapter because it will require a capital investment. With the obvious being stated, now is a good time to do a gap analysis all of those items outlined in the USP 800 chapter that will involve additional financial investment and construction such as C-PECs, shelving, walls, counters (e.g. *smooth, impervious, free from cracks and crevices, and non-shedding*) for USP 800 HD handling compliance.

Gap Example

Current State:

Discover if your current C-PECs have the capability of being connected to an external exhaust system (because some C-PECs have been engineered to only recirculate) by calling the manufacturer with make/model numbers.

Future State:

1. If C-PECs are compatible: Purchase of manufacturer-specific canopy connections and/or thimble connections.
2. If C-PECs are not compatible: Additional capital investment in new C-PECs with external exhaust compatibility.

Consider the future:

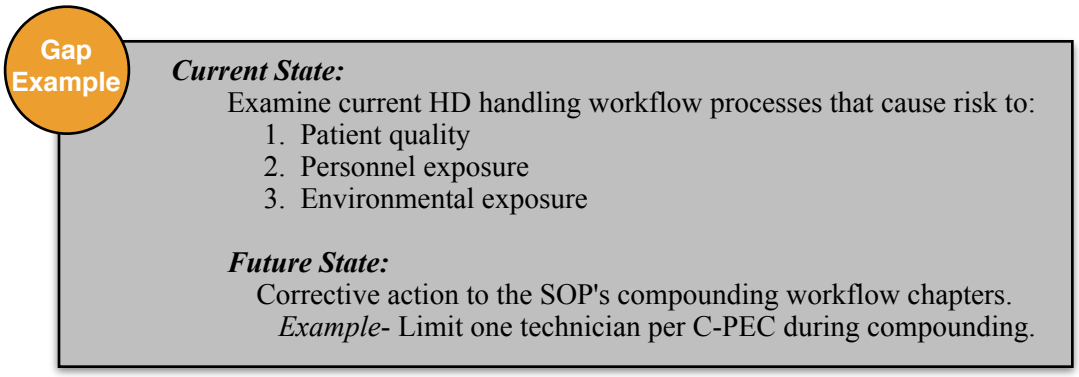
Take a moment for additional consideration for your pharmacy's projected and/or desired future business model because additional pieces of capital equipment will affect the C-SECs engineering standards. As an example, each incremental workstation with a C-PEC connected to external exhaust requires additional supply air for balance. If the make-up air unit (MAU) supplying the C-SEC cannot facilitate additional supply due to its size, then an additional MAU will have to added to the facility, which is more capital investment. The main point is, having a vision for the future is important during these early planning stages because now is your best time to understand the total capital investment picture.

Risk Aversion

It was not too terribly long ago that our travels and site-visits would inevitably reveal a compounding pharmacy that was still doing progesterone encapsulation on an "open bench" with some-to-none Personal Protective Equipment (PPE) on the technician. At that time, very few state Boards of Pharmacy had written requirements for a negative pressure powder hood while handling hazardous chemicals in the nonsterile compounding room. Regardless of the absence of previously defined state parameters for HD handling, USP 800 is now requiring compounding pharmacies to avert risk through implementation of SOPs, training requirements, engineering controls, PPE standards, and active management of the HD program.

During another workflow observation we came across a situation where two technicians were simultaneously weighing two different chemicals on two different electronic balances, inside the same C-PEC. The Pharmacy manager's case for having two balances in the same C-PEC was because the two chemicals would eventually be mixed in the same compounded script and that there is no harm in this practice and it also helps speed up production. However, further

examination of the workflow process would reveal that there are multiple potentials risks. When two bulk chemical bottles are opened, scooped, and weighed in close proximity to each other (in this case less than 12" apart) there is opportunity for cross contamination of the chemicals. Two technicians working side by side in front of the C-PEC are blocking 90% of the air intended to be pulled into the face opening, creating insufficient airflow which is the C-PEC's safety control. Now's there's an additional risk for personnel exposure because the primary engineering control cannot operate properly.



Improved Quality and Safety

Let's expand further on the previous example of two technicians simultaneously weighing chemicals inside the same C-PEC because it is our assertion that risk aversion and quality are certainly interconnected processes. By removing one technician from the weighing operation, we have:

1. Maximized personnel safety by allowing proper airflow to enter inside the C-PEC
2. Created a more laminar and less turbulent airflow pattern inside the C-PEC
3. Removed an additional set of contaminated gloves from the workflow process
4. Lessened the opportunity for cross contamination of chemicals

USP 795, USP 797, and the majority of the *USP Compounding Compendium* are a written set of standards with the goal of producing the best quality products for the patient. So one could argue that the best risk aversion strategy for a pharmacy owner is in comprehensive implementation of USP compliance standards, established in facility's written SOPs, and reinforced through safe workflow processes that eliminate opportunity for contamination, which yields a quality product. The argument could be taken even further to say that the aforementioned risk aversion strategy of compliance is interconnected to personnel safety, the ultimate goal of chapter 800. It is safe to assume that processes that are safe for personnel and environment are in-turn producing quality formulations.

Market Advantage

For years we have told pharmacy owners and their marketing professionals to use "quality" as a sales advantage. Marketing is about telling your story and part of that story should reveal your competitive advantage. Your pharmacy's marketing person is definitely not the only person out

“pounding the pavement” visiting local providers trying to win over scripts through either relationship and/or competitive advantage. So to better combat the competitive environment we recommend actually increasing the number of samples being sent to the third party analytical testing labs for strength and stability testing. From our research, consistency of sending out samples for analysis is greatly lacking in nonsterile compounding pharmacies because it's not required and there is a cost associated. Yet, nonsterile hormones are such a huge part of many pharmacy's HD script volumes that it seems justified to use a consistent quality statement as a marketing tool in an effort to win more market share.

Gap Example

Current State:

Does our pharmacy's current marketing strategy discuss product quality and back-up the statement with consistent and up-to-date third party testing data?

Based on current script ratios and production volumes of both sterile and nonsterile, does our third party testing samples adequately match?

Future State:

Base our third-party sample testing on a percentage of volume and making sure our marketing people are using the data sets and quality statement as a sales tool.

Let's take the market advantage and quality idea one step further to include a consistent environmental wipe sampling protocol. USP 800 recommends (not requires) sampling for HD surface residue at least every six months. The sampling frequency and quantity should again be based on your pharmacy's volumes and script ratios. As an example, if 80% of your HD scripts are nonsterile, then by and large your protocol should equally reflect that in the number of wipe samples performed in the nonsterile HD room. It might seem like a moot point to infer that Physicians actually care about the cleanliness of your compounding rooms, but patient quality is still the real issue, so don't dismiss the importance of touting your quality standards because the point may actually resonate as a competitive advantage.

More than just a sample:

The process and result of sending consistent samples to an analytical lab can be a multifaceted tool for a Pharmacy. Both PCAB Surveyors and FDA Inspectors both consistently agreed that a common area of concern is the pharmacy's deficiency in, or complete lack of, employee training records and competency assessments. So now consider each analytical sample result as a key component to technician proficiency documentation that proves their understanding and adherence to the written SOP's, HD handling competency, and quality standards.

Last, but important point about market advantage and strategic positioning is going to be in natural selection within the compounding pharmacy market. There are going to be quite a few pharmacies that cannot not justify a $100,000(+/-) capital investment for a negative pressure compounding room because hazardous drugs are not a big enough percentage of their business. There will also be those compounding pharmacies that are not willing to take the perceived financial risk in an effort to retain their customers. So inevitably there will be new patients either referred to or seeking a pharmacy that has implemented compliance changes and can serve their compounded prescription needs.

Enhanced Workflow Efficiencies

It's difficult to make a compelling argument that implementing all aspects of USP 800 is going to enhance workflow efficiency. In the course of business, investment in capital equipment often hinges on the key factor of improving efficiency. Keeping up with production is seemingly a never ending battle from an operational perspective. Sometimes the pushback on implementing new processes and/or technologies is that it will cause production time to suffer. That's a short-term business perspective because more times than not, once a new process is implemented and adopted, it will eventually reset to the previous position in the efficiency curve. As an example, when C-PECs were first introduced into the powder weighing and manipulating process, efficiency initially slowed, but now they are such the norm that technicians' experience curves have efficiently evolved. This is the positive view point we need to perceive for the future of USP 800 compliance in our pharmacies.

Consider the process of receiving a new script formulary, which once received requires the laborious process of creating a new Master Formulation Record, additional chemical ordering, inputting new records into software, and defining the sequential formulation workflow process. You may not make a profit on the first script, but eventually the initial investment in time and money is recaptured through refills. If we are willing to accept the tedious process of initiating new scripts formularies into our business, with the hopeful promise of a continued revenue stream via refills, then lets also try our best to positively view UPS 800's HD handling processes and capital investment with the same perceived hopeful outcome.

Payback Period: A Hypothetical Example

On page one and two we presented the "*Case In Point*" highlighted in the orange box that presented the scenario of a pharmacy that more technicians than C-PECs and could handle more daily compounded script volume if there was an additional C-PEC workstation available. So with this same case scenario in mind let's explore a hypothetical example to perform a simple payback period on that pharmacy's possible financial investment in capital equipment.

Case: A capital investment of $15,000 (cost of C-PEC, electronic balance, additional software license, capsule machine) can be made to add additional daily production.

Assumptions:

1. A technician with assistance has an output of 25 compounded scripts per day.
2. Reallocating labor from the additional technician to her own workstation

will have a 50% to 75% increase in daily script production.
3. A 30-day encapsulation script yields a cash price of $65 at a 65% gross profit margin.

Summary:

1. The additional daily production of 15 scripts generates an additional:
   - $42 in gross profit dollars per script
   - $630 in gross profit dollars per day
   - $3,150 in gross profit per week
2. Capital Investment of $15,000 divided by $3,150 equals a payback period of less than six months.

The reality is that your pharmacy's script ratios include a variety of other formulations other than just encapsulation and gross margins are all over the board so look at your compounded script's "blended gross margins" as a holistic category and set a basic benchmark percentage for plugging into the payback equation. The payback method only gives a snapshot at perceived risk and should not be the only criterion for making an investment/purchase decision. The financial assumptions above are hypothetical to simply incur a thought process, and by no means are we financial experts, so it is our best advice is to involve your accountant when purchasing capital equipment. Financial professionals can offer a more scientific and accurate approach for investment recuperation, as well as potential tax advantages for those investments.

Conclusion

Sometimes a gap analysis is a very scientific process and sometimes we have to make business decisions based on the best factual information given. As pharmacy owners and entrepreneurs we have made financial investments based on solid market information and sometimes on market intuition. Now we are in a different decision phase because we are faced with making a significant business decision based on regulation. As the USP 800 deadline comes nearer we will know more about the market demand based on how many pharmacies invested in the capital infrastructure to support hazardous drug compounding. Regardless, there is no doubt that establishing compliance standards is our industry's new normal. It is our firm belief that the positive end-result of investing in USP 800 compliance standards will avert unnecessary risk for your pharmacy, create a safer compounding environment for your employees, and further facilitate quality patient drug care.

Author:

Bryan Prince, MBA is the owner and lead consultant at Lab·Red Pharmacy Consultants (website: http://pharmacyworkflow.com/) His early career in containment technology allowed him access to pharmaceutical labs around the U.S. where he gleaned extensive knowledge of chemical handling technique and safety strategies. In 2012 he started visiting compounding pharmacies to observe workflow habits and share his knowledge, which led to writing articles for the International Journal of Pharmaceutical Compounding (IJPC). Bryan has been invited to speak at conferences on "Quality, Safety, and Workflow in the Compounding Pharmacy" for the

American College of Apothecaries and PCCA. He has also contributed to the ACHC as an Expert Panelist on a series of USP 800 webinars. email: bryankprince@gmail.com

Contributing Author:
Gary Meyer R.PH. graduated with a BS Pharmacy from the University of Georgia. He was a former independent pharmacy owner for 20 years and specialized in custom compounding of sterile and non-sterile prescriptions. His pharmacy was PCAB accredited in 2015. He is a member of IACP and Georgia Pharmacy Association.