Learning Objectives

_Upon conclusion of this activity, participants should be able to:_

- **Define** general principles of USP<797> and aseptic technique
- **Explain** current changes in regulation of sterile compounding and how to assess your facility using a Gap Analysis tool
- **Identify** how complying with USP <797> can prevent medication errors associated with contamination
- **Describe** examples of deviations from USP <797> associated with adverse events related to CSPs
- **Describe** the differences in manipulations when compounding sterile products in a vertical versus a horizontal laminar airflow hood.
Key Abbreviations

- BUD beyond use dating
- CSP compounded sterile preparation
- HEPA high efficiency particulate air
- SVP small volume parenteral
- LAF laminar airflow
- LVP large volume parenteral

What is compounding......

Art of preparing customized medications by a pharmacist or under the direct supervision of a pharmacist pursuant to an order from an licensed prescriber for a specific patient.
What cannot be compounded...

Per FD &C Section 503A

- Any product on the FDA list of drugs that have been removed from the market
- Any inordinate amounts of drug products that are “essentially copies” of commercially available drug products
  - Doesn’t include products in which a change is made for an individual patient which produces a significant (i.e., clinical) benefit as determined by the prescriber between the compounded product and the commercially available version

Why this is important....

- “When one pharmacist’s mistake hurts or kills a person, it hurts all pharmacists.”
- “A pharmacist is often a patient’s last chance for safe drug therapy.”

David W. Newton, BS, PhD, FAPhA
Bernard J. Dunn School of Pharmacy
Shenandoah University
Winchester, Virginia
Famous Dates in Infusion History

- 1628 - William Harvey describes the anatomy of the vascular system
- 1660's - Christopher Wren observed that access to a dog’s entire body could be gained via a foreleg vein
- 1687 – Edict of Church and Parliament “animal to man transfusions prohibited in Europe” – 150 years lapsed.
- 1832 - Thomas Latta wrote of using saline solutions in the great cholera epidemic

Sterile Products Compounding

- 1926 – USP lists only 2 injections and the National Formulary lists 7 injectables
  - 2013: USP lists 566 injectables
- Until 1933, hospitals compounded their own sterile products
  - 1933 LVPs become available for purchase
  - Majority of products still compounded in patient care areas, not in the pharmacy
What does sterile look like?

Dark Days in Sterile Products Compounding

- 1971 – 100 patients die from contaminated Abbott IV fluids
- 1988, 1990 – patients die from contaminated cardioplegia
- 1990 – 2 cases of blindness from contaminated eye drops
- 1994 – 2 women die due to calcium phosphate precipitation in PN

………the list goes on
Since 2001 over 25 compounding pharmacy events have resulted in more than 1000 REPORTED adverse events, including death.

Dark Days in Pharmacy History
May – Aug 2012
17,500 vials of contaminated methylprednisolone compounded

- Over 14,000 patients received tainted medication
  - Exserohilum rostratum
- 751 affected, 64 deaths (as of October 2013)
- 14 people were charged in a 131-count indictment
- May 2015, a $200 million settlement plan was approved
FDA Response to NECC Disaster

Increased inspections of compounding pharmacies nationwide

MA BoP Response
Chapter 159 of Acts of 2014

- BoP membership changed
- Trained and expanded BoP staff
- Additional pharmacist CE requirements
  - 20 per year
  - 5 hours CE for Sterile/3 hours CE non-sterile
- New Pharmacy licensure types
  - Retail/hospital based sterile compounding
  - Retail complex non-sterile compounding
- Defined compounding
USP 797

- Refers to USP Chapter 797, “Pharmaceutical Compounding—Sterile Preparations”
- Consists of recommendations & regulations regarding IV admixture programs
  - Risk levels for products
  - Addresses immediate-use CSPs
  - Training, policies & procedures
  - Garb, aseptic technique, process validation, end-product evaluation
Before USP 797

- Compounded under procedures in Chapter 1206 [Sterile Drug Products for Home Use] (voluntary)
  - Compliance poor
  - Fall 2002, after several 1990-2002 patient deaths and injuries from unsterile preparations
    - FDA considered cGMPs-like regulations

- 2000-2005 USP Sterile Compounding Committee (SCC)
  - charged to radically revise <1206> to an enforceable general chapter numbered less than 1000
  - forestall stricter FDA regulations

USP Numbering System

- Chapters over 1000
  - States can decide whether or not to inspect for compliance

- Chapters 1-999
  - Legally binding; FDA, DEA, Board of Pharmacies & accreditation agencies can inspect for compliance
Chapter <797> in the USP 27 became the first practice standards for sterile pharmacy compounding in US history that may be enforced by the FDA

CONSIDERED A REQUIREMENT
USP 797

- Based on 3 risk levels classified by the potential for:
  - Microbiological contamination
    - Microorganisms
    - Endotoxins
  - Particulate contamination
    - From environment
  - Chemical contamination
    - Precipitation
    - Other incompatibilities

Highlights of the 2008 Revision

Avoid/Minimize Contact Contamination (vs. airborne emphasis in original 2004 chapter):
- Personnel cleansing and garbing ± Appendix III
- Personnel training ± Appendix IV
- Surfaces and gloves disinfection
- Gloves and ISO class 5 surfaces sampling
- Immediate-Use CSPs
  - few personnel and no environmental standards
- Hazardous Drugs (antineoplastics)
  - personnel protection
  - separate storage
  - no room-to-room drift
Highlights of the 2008 Revision

- Hand hygiene
  - waterless alcohol-scrub with persistent activity
- Sterile gloves to reduce initial bioburden
- Wipe ampules, swab stoppers, re-disinfect gloves with sterile IPA (70% v/v isopropyl alcohol)
- Do NOT misuse single dose as multiple dose containers

AND THEY’RE BEING REVISED AGAIN!

www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision

But until they are ratified, we must comply with the 2008 version of USP 797
Reasons for 2015 Revision of 797

- To improve clarity, respond to stakeholder input, and reflect new science
- Major edits to the chapter include:
  - Reorganized existing chapter to group similar topics together, eliminate redundancies, and clarify requirements
  - Collapsed CSP microbial risk categories from three to two and changed terminology
  - Removed specific information on handling of hazardous drugs
  - Introduced “in-use time” terminology for CSPs
    - Time before which a conventionally manufactured product used to make a CSP must be used after it has been opened or punctured
    - Time a CSP must be used after it has been opened or punctured
  - Requirements added for maintaining master formulation and compounding records
  - Provide guidance on use of isolators
  - Adds guidance for sterility testing of CSP prepared in batch sizes of less than 40
Aseptic Technique

- Manipulating sterile products without compromising their sterility
  - proper use of LAF hoods/benches
  - strict aseptic technique
- Conscientious work habits

Aseptic Technique

Definition….

“practices, performed immediately before and during compounding, that help reduce the risk of exposure to personnel and patients by decreasing the likelihood of microorganisms entering the body…”
Let’s face it….we’re germy....

- Humans have up to 200 different classes of bacteria on their bodies
- Hands typically have more than 100,000 organisms per square millimeter
- 5 grams of skin particles are shed daily
  - Serve as a vector for bacteria

Photo courtesy of Francis P. Mitrano, MS, RPh, Director of Pharmacy, Beth Israel Deaconess Medical Center, Boston, MA, November, 2005.

The Risks of Intravenous Therapy

- Infection
- Air embolus
- Allergic reactions
- Incompatibilities
- Particulates
- Pyrogens
ATTIRE

PROPER GOWNING

Rationale

- Contains both viable and nonviable particulate matter generated by personnel
- Cleanroom garments are designed to be lower in particulate matter (i.e., lint free)
  - Should always be worn when compounding sterile products
- Mask
  - Masks must cover the nose and mouth
- Hair bonnet
  - All hair must be contained within the hair cover
- Beard cover
- Shoe covers
- Gloves
- NO JEWELERY, MAKE UP, VISIBLE PIERCINGS
- NO ARTIFICIAL NAILS, NO LONG NATURAL NAILS ABOVE THE FINGERTIPS
Scrub Suits

- Should not be worn home
- Must be covered when leaving the pharmacy
- Should be tucked in correctly

Gowning Area

- Separate but adjacent to cleanroom
- Air should be HEPA-filtered
  - Continuous air movement
  - Removed particulates off personnel
  - Minimizes particulates on cleanroom clothing
- Needs to be cleaned daily
Proper Gowning
- Keep cleanroom clothes clean
  - Don’t touch the floor
  - Excellent hand hygiene while wearing them
- Dress from the head down

Gowning
- Bouffant hair cover or hood
  - All hair tucked in
- Beard cover
  - Beard and sideburns
- Mask
  - Soft or molded
- Booties
  - Over shoes or dedicated clean room shoes
Hand Hygiene

- **Water scrub**
  - Done when entering cleanroom at beginning of compounding period, coming back from breaks or when hands are visibly soiled

- **Waterless scrub**
  - Used after initial scrub as long as no visible dirt

- **Must be done every time re-entering buffer area**

How to scrub

- Top to bottom
- Use approved agent (betadine, chlorhexidine)
- Use brush, nail cleaner
- From fingertips to elbows
- Apply soap on one arm, then the other
- Rinse the first arm, then the other
  - Hold hands up so dirty water runs down arms and not onto hands
- Maximize contact time
- Scrub between fingers and clean under nails
- At least 30 seconds (2 rounds of “happy birthday”)
- Dry with clean, lint free towel
- Do not touch anything
- Put on gown, gloves
Gloves

- Should be sterile
- Put on before entering the inside of the hood
- Gloves must extend over the gown cuffs
- Gloves should be sprayed with sterile isopropyl alcohol 70% and rubbed thoroughly
- Allow gloves to air dry before proceeding with sterile preparations

Sterile Compounding Area

- Compounded sterile products (CSPs) must be free of:
  - living microorganisms
  - pyrogens
  - visible particles
- Reduce number of particles in air
  - no cardboard in clean room
- Clean work surfaces & floors daily
- Clean walls, ceilings, & shelving monthly
Sterile Compounding Area

- Use anteroom for non-aseptic activities
  - order processing
  - gowning
  - handling of stock
- ISO Class 5 environment
  - no more than 100 particles per cubic foot that are 0.5 micron or larger in size
- LAF hoods are used to achieve an ISO Class 5 environment
- All items should be cleaned and sanitized prior to entering the buffer and anterooms

Laminar Airflow Hoods

- Principle of LAF hoods
  - twice-filtered laminar layers of aseptic air
  - continuously sweep work area inside hood
  - prevents entry of contaminated room air
- 2 common types of LAF hoods:
  - horizontal flow
  - vertical flow
Laminar Airflow Hoods

Do not produce sterilization, but merely prevents contaminants from settling onto the surface of the sterile product

Interruption Laminar Air Flow = Contamination

- **Downstream contamination**
  - occurs when any object comes between the HEPA filter and the sterile product, interrupting the parallel flow and creating dead space

- **Cross-stream contamination**
  - occurs due to rapid movements of the operator in the hood

- **Backward contamination**
  - caused by turbulence created by objects being placed in the hood, by fast traffic passing the hood, or by coughing, sneezing, etc. by the operator
Zone of Turbulence

- Created with any movement of greater velocity and different direction than that of the hood's air flow
- Reduces the hood's effectiveness
- Contamination may be minimized by working at a smooth, steady pace at least 6 inches into the hood

http://pharmlabs.unc.edu/labs/parenterals/hoods.htm

Horizontal LAF Hood

- Air moves from back to front
- Blower draws room air through a pre-filter
  - Removes gross contaminants
  - Should be cleaned or replaced on regular basis
  - Pre-filtered air moves through final filter
- Entire back portion of hood’s work area is HEPA
- Removes 99.97% of particles that are 0.3 micron or larger

http://www.globalph.com/sepsis.htm
Working in a Horizontal LAF Hood

- Critical sites must remain in the airflow and not be blocked
- No products should be placed **behind** another product or device
- Individuals should avoid rapid movements while working in the hood
- Avoid clutter

**NO HAZARDOUS DRUG PREPARATION SHOULD OCCUR IN A HORIZONTAL FLOW HOOD**
WRONG!

RIGHT!

https://www.youtube.com/watch?v=Fy7Qo8DHIVY
Vertical LAF Hood

- Air emerges from the top and passes downward
- Exposure to airborne drug particulates minimized
- Used for preparation of antineoplastics
- Referred to as biological safety cabinets (BSCs)
- Space between the HEPA filter and the sterile object
  - critical area
- Must prevent downstream contamination
- Zone of turbulence

http://www.terrauniversal.com/

Working in Vertical Flow Hoods

- Critical sites should not be obstructed
- Do not place vials or supplies over critical sites
- Do not clutter hood
- Avoid sweeping or rapid hand movements
General LAF Principles

- Avoid talking, coughing into the hood
  - Masks aren’t 100% effective
- Position away from excess traffic, doors, air vents, etc.
- Must run for 15 -30 minutes if turned off & back on
Cleaning LAFWs

- All interior working surfaces should be cleaned
  - SWFI
  - 70% isopropyl alcohol/other disinfecting agent
- Use a clean, lint-free cloth
- SWFI first, alcohol 2nd
- Clean sides of hoods using up & down direction
  - start at HEPA
  - work toward outer edge of hood
  - Use long strokes, do not go back over an area
- Order of cleaning (top to bottom, back to front)
  - walls 1st
  - floor of hood 2nd
Cleaning LAF Hoods

Frequency

- beginning of each shift
- before each batch
- not longer than 30 minutes following previous surface disinfection when ongoing compounding activities are occurring
- after spills
- when surface contamination is known or suspected

Cleaning LAF Hoods

- If materials not soluble in alcohol, initially use water
  - follow with alcohol
- Do not use spray bottles of alcohol in hood
- Let alcohol air dry
- Clean Plexiglas sides -warm, soapy water
  - alcohol will dry out Plexiglas
  - clouds & cracks
Additional LAF Hood Guidelines

- Nothing should come in contact with HEPA filter
- Nothing in the hood that is not essential to IV preparation
  - no paper, pens, labels, or trays
- No smoking, eating, drinking in aseptic area
- Manipulations at least six inches within hood

Additional LAF Hood Guidelines

Must test LAFs at least every 6 months
- Also test if hood moved, or if filter damage suspected
- Specific tests
  - airflow velocity
  - HEPA filter integrity
Aseptic Environment
Key Points
- Personal Attire -Cover
  - Shoes, head & facial hair, use face masks/eye shields
  - cover scrub suits when leaving pharmacy
- Hand washing
  - touch is most common source of contamination
  - scrub hands, nails, wrists, forearms to elbows for at least 30 seconds with a brush, warm water, & appropriate bactericidal soap
- Gloving
  - only sterile until they touch something unsterile

Aseptic Preparation P&P
Admixture preparation program includes:
1. Development & maintenance of good aseptic technique in all personnel who prepare & administer sterile products
2. Development & maintenance of sterile compounding area, complete with sterilized equipment & supplies
3. Development & maintenance of skills needed to properly use laminar airflow (LAF) workbench or laminar airflow hood
Equipment & Supplies

Syringes
Syringes

Never touch the tip or plunger of the syringe

http://www.upmc.com/patients-visitors/education/publishingimages/a-c/shotgeninstructions-image201.jpg

Syringe Connections
Syringe Calibrations

2.2ml
Each line is 0.2 ml

Handling Syringes

- Select appropriate size for the volume of solution
  - Typically 1/2 to 2/3 of syringe capacity
- Open syringe package in hood to maintain sterility
- Peel wrapper & discard out of hood
- Leave syringe tip protector in place until time to attach needle
- To attach needle to Luer-lock-type syringe ¼ turn is usually sufficient to secure needle to syringe
- Measuring-line up final edge to calibration mark on barrel
Needles

- Needle size
  - Length
    - 3/8 inch to 3 1/2 inches
  - Gauge
    - size of the lumen,
    - 27 (the finest) to 13 (the largest).

- Vented needles
- Filter needles
- Dead space

Selecting the Proper Size Needle

- Two considerations
  - the viscosity of the solution
  - nature of the rubber closure on the parenteral container.
- Needles with larger lumens should be used for viscous solutions
- Smaller gauge needles are preferred if the rubber closure can be cored easily
Handling Needles

- Never touch any part of the needle
- Open needle packages within hood to maintain sterility
- **Peel** open the needle wrapper
  - Tearing the paper introduces paper particulates into the hood
- Needles and syringes must be disposed of in the sharps container

Vials
Vials

- Glass or plastic container typically with a rubber stopper and flip top cap surrounded by an aluminum band
- Closed systems – air/fluid cannot freely enter or leave
- Can contain powders or liquids
- Protective cap does not ensure the sterility of the rubber vial stopper
  - Rationale for wiping vial top with an alcohol prep pad prior to performing any manipulations

Withdrawing Fluid from a Vial

- Swab the rubber top of the vial with an alcohol prep
- Use firm strokes in a **unidirectional** sweeping motion at least 3 times
  - Disinfects surface
  - Removes particulate matter
- Allow the alcohol to air dry
- Inject an equal amount of air for the volume of fluid to be removed to prevent vacuum formation (i.e., “blow-back”)
Vial Pressure Considerations

- Air pressure inside vial typically same as room air
- To prevent a vacuum from forming inside the vial
  - Normalize pressure by injecting an equal volume air to the volume of fluid that is going to be withdrawn
- When reconstituting a powder in a vial
  - An equal volume of air equaling the fluid to be added must be removed to prevent positive pressure from forming

Non-coring Technique
### Ampules

- Move fluid from the neck to the body of ampule
- Swab neck with alcohol pad
- Snap at neck
- Break ampules **away** from the HEPA filter
- Tilt ampule
- Place needle bevel sided down near opening of ampule
- No need to withdraw air first
- Pull back on syringe plunger
- Use a filter needle to remove ampule contents and switch to new needle to inject into container

**Or**

- Use a needle to withdraw from ampule and then use a filter needle to push contents out of the filled syringe into a sterile empty vial or other container

*Filter needles can only be used in one direction; otherwise glass particles originally filtered are reintroduced.*

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### How to Break an Ampule
Filter Needles vs. Filter Straws

Filter needles
- Needle with 5 micron filter in the hub
- Traps glass or paint chips from ampules

Filter straws
- Plastic tubing, can reach bottom of ampule
- Once fluid withdrawn/filtered it is discarded and a new needle is attached to the syringe

Filters
Filters

- Used to remove particles from solutions
  - particulate matter
  - microorganisms
- Do not confuse with "terminal sterilization" that use steam (moist heat), dry heat, ionized radiation, or gas to sterilize product
- Filtration will sterilize the product, but after filtration, the sterile solution must be aseptically combined with its packaging
- Used for materials that are chemically or physically unstable if sterilized by heat, gas, or radiation

IV Containers

- Large Volume Parenterals (LVPs)
- Small Volume Parenterals (SVPs) or “Piggyback” Systems
- Add-Vantage
- Vial Spike Systems
- Flexible Plastic Bags
- Glass Containers
Closures & Seals

- Luer lock caps
- IV port seals
- Tamperproof caps

Preparation of IV Admixtures

- Assemble all materials & visually inspect
- Clean hood-only needed products in hood
- Disinfect all injection surfaces
- Withdraw & measure drug fluid
- Remove air bubbles from syringe
- Discard syringes & uncapped needles
- Recapping needles is generally unsafe practice
  - use one-handed scoop method if recap needed
Flexible Bags

- Typically made with PVC, DEHP
- Don’t remove the protective overwraps until ready to use
- To reduce turbulence in LAF hood, position the injection port toward the HEPA filter when adding drugs to the container

Automated Compounding

- Sterile product preparation is technically complex
- Verification challenging
- Automation can eliminate preparation errors
- Enclosed IV preparation environments & robotics
  - used in high volume situations
  - or may prepare patient specific doses
Labeling of IV Preparations

1. Patient name, identification #, room #
2. Bottle or bag sequence number if required
3. Name & amount of drug(s) added
4. Name & volume of admixture solution
5. Final total volume of admixture
6. Prescribed infusion rate (in milliliters per hour)
7. Date & time of scheduled administration
8. Date & time of preparation
9. Expiration date
10. Initials of person who prepared/checked IV admixture
11. Auxiliary labeling
12. Bar coding

Beyond Use Date

- Label & final sterile product- validated by registered pharmacist
- Label with beyond use date (BUD)
  - The date or time the CSP shall not be stored or transported
  - Date determined from the date or time the CSP in compounded
- Factors used to determine BUD:
  - Chemical stability
  - Sterility based on the risk level based on the complexity of the manipulation
  - Environmental conditions where the compounding is taking place
ALWAYS INSPECT THE FINAL PRODUCT BEFORE DISPENSING

- Check for particulates, leaks
- Double check any calculations
- Check the label for accuracy, including auxiliary labels

WHEN IN DOUBT, THROW IT OUT!!!

http://www.theguardian.com/

DEFINING RISK LEVELS
Determining the Appropriate Risk Level

- The decision as to which risk level (and the associated quality assurance needs) of specific preparations resides with the compounding personnel.
- USP Chapter <797> gives general descriptions of the types of sterile compounded medication in each of the three categories, low-risk, medium-risk and high-risk, with examples.
- Compounding personnel are responsible for making the judgment on each specific product and also for being able to defend their decisions should the need arise.

Immediate Use CSPs

- There is an emergent need for immediate administration of a CSP (i.e., OR, codes).
- Administration occurs within 1 hour of compounding.
- Does not include preparations that must be stored for future patient use.
- Involves not more than 3 commercially manufactured sterile, nonhazardous products or radio pharmaceuticals from their original manufacturers' containers with not more than 2 entries into any one container of sterile solution or administration.
- If the preparer does not administer the CSP, it must be labeled with all data elements and the exact BUD and time.
- Compounding must take place on a clean, clutter free surface.
Low Risk Level Compounding of CSPs

- CSPs which only involve the transfer, measuring or mixing of 3 or less commercially manufactured packages of sterile products.
- Compounding of the CSP does not involve no more than 2 entries into any one sterile container.

Low Risk Level Compounding with 12 hour or less BUD

- Applies when the LAF hood that cannot be located within an ISO 7 buffer area
- Only low risk, nonhazardous and radiopharmaceutical CSPs which are patient-specific and made according to a physician’s order may be prepared under this classification
- Administration occurs within 12 hours of preparation or per manufacturer recommendations, whichever is less.
Medium Risk Level Compounding of CSPs

- More than three sterile products or entries into any container
- Sterile products are pooled to make CSPs to be administered to one or multiple patients
- Complex aseptic manipulations take place (other than a single volume transfer).
- Compounding process is of unusually long duration (i.e. such that requires dissolving ingredients or homogenous mixing).
- Compounding of total parenteral nutrition fluids take place using manual or automated devices
- Filling of reservoirs of injection/infusion devices which contain three or more sterile drug products and air is evacuated from container prior to dispensing.

High Risk Level Compounding of CSPs

- Non-sterile ingredients and/or non-sterile devices are used to compound a sterile final product
- Commercially manufactured sterile products are exposed to air quality worse than ISO 5 for more than 1 hour.
- The CSP lacks effective antimicrobial preservatives and is exposed to air quality worse than ISO 5 for more than 1 hour.
- Sterile surfaces of preparation device and/or containers are exposed to air quality worse than ISO 5 or more than 1 hour
- Non-sterile water-containing preparations are stored for more than 6 hours before sterilization
### BUD and Risk Levels

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Controlled Room Temperature 20 to 25 degrees C</th>
<th>Refrigerator 2 to 8 degrees C</th>
<th>Frozen -25 to -10 degrees C</th>
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<tr>
<td>Immediate</td>
<td>1 hour</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Low w/ 12 hr or less BUD</td>
<td>12 hours</td>
<td>12 hours</td>
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<tr>
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</tr>
<tr>
<td>High Risk</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

### Single Dose Vials

- Once needled or punctured in an ISO class 5 environment, the vial shall be sealed with an IVA seal and used within 6 hours of the needle puncture *when kept in the hood*
- Once removed from the hood, the vial MUST be DISPOSED of within ONE HOUR of preparation
Multiple Dose Vials

- BUD after needle puncture is **28 days** unless otherwise stated by the manufacturer
- The first user should place the date they opened the vial on the vial label
Definition

- The gap analysis tool is meant to help facilities determine which areas of USP 797 they are in compliance with and which areas they have yet to become compliant with.

- The process
  1. Define your Risk Level
  2. Perform the Gap Analysis
  3. Develop an Action Plan
  4. Implement, adjust and monitor the Action Plan

PERFORM GAP ANALYSIS

(Available for download on activity page)
Develop an Action Plan

- Any criteria receiving a ‘no’ will require an action plan
  - separate action plan for each action item
- Any action plans developed should be documented and saved for survey purposes
  - used to document to the surveyor that the facility is in the process to achieving compliance with the particular standard

Implement, Adjust and Monitor the Action Plan

- The action plan should be reevaluated for its effectiveness
- The plan should include a time frame for how often it will be revisited and audited
  - For auditing purposes, the action plan should be written to include auditable data that is concise and quantitative
  - Thresholds should be determined for each auditable measure that is assessed as part of an action plan
- Audit results that exceed the facility’s threshold will require revisiting of the action plan and further follow-up
“If it wasn’t documented, it didn’t happen.”

Gap Analysis Resources

- American Society of Health System Pharmacists (ASHP)
- International Journal of Pharmaceutical Compounding
- International Academy of Compounding Pharmacists (IACP)
- Proprietary tools
  - CriticalPoint Gap Analysis Tool
  - LDT Health Solutions Inc., Gap Tool