Compounding Update for Technicians –

How USP and FDA is shaping the conversation !

NYSCHP New York State Council of Health-system Pharmacists

Annual Assembly – April 8, 2022

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Principal
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DISCLOSURES -

- Lou Diorio is a shareholder of LDT Health Solutions, Inc., an International Medication Safety and & Quality Management Consultancy.
- The opinions expressed are that of the presenter and based upon the information provided by USP & FDA at the time of the presentation.
  - For the latest USP compendial references go to; www.USP.org
  - The latest FDA information and resources can be found at; www.FDA.gov

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Session Objectives -

- **PHARMACISTS-**
- Describe the genesis of USP Compounding Chapters. Be able to describe their scope and the overlapping regulatory authorities who could enforce the USP standards.
- Describe the current regulatory environment with focus on the most common citations confronting compounders who manipulate drug product.
- List ten (10) tangible take-aways for pharmacy (compounding supervisors) to add to their USP compliance plan.
- **Technicians-**
- List three (3) attributes (design elements) of a USP compliant compounding space for sterile or non-sterile compounding
- Describe the current regulatory environment with focus on the most common citations confronting compounders who manipulate drug product.
- List ten (10) tangible take-aways for pharmacy (compounding supervisors) to add to their USP compliance plan.

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Question 1 -

- **TRUE or FALSE : Compliance to USP General Chapter <800> exempts a Pharmacy from the rigors of complying with USP <797> ?**

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Question 2 -

- **FDA Guidance Documents are:**
- (a) Published by FDA to share their current thinking of a particular subject.
- (b) Legally enforceable.
- (c) Are never amended once issued as “final.”
- (d) both b and c

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Question 3 -

- **Regarding the proposed changes to USP <795> and USP <797>, which of the following is FALSE:**
- (a) The comment period to submit to USP for consideration ended March 17, 2022.
- (b) The current Official Chapters (USP <795> & <797>) are in place and should be considered as the current reference standard for practice.
- (c) You must make changes to your standard operating procedures before March 17, 2022 in order to be in compliance with USP.
- (d) Compliance to the USP Compounding Chapters is considered by the Centers for Medicare & Medicaid Services (CMS) for program participation.

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Question 4 -

- **Under the proposed USP General Chapter <797>, which of the following is FALSE:**
- (a) There is a limit to the batch size of CSPs that can be prepared.
- (b) An Ante Room is required to maximize the ability of a pharmacy to assign the longest possible beyond-use date (BUD) to a compounded sterile prep (CSP).
- (c) "Gloveboxes", "Isolators" or other restricted access barrier devices ("RABs") are no longer usable under any circumstances for sterile compounding.
- (d) Changes in the frequency of environmental monitoring of your compounding rooms will be needed under the proposed chapter.

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Let's Properly Frame the Conversation -

- Please understand that the USP General Chapters being discussed are being reviewed in the context of PROPOSED CHANGES submitted USP Expert Committee versus the current, official USP/NF Chapters.
- The proposed changes are currently in a **public comment period until March 17, 2022**.*
  - Comments should be submitted to USP at: https://usp.az1.qualtrics.com/jfe/form/SV_aWexhZowjRBbKnP
- Please remember, draft revisions are not yet part of the compendia and are considered NOT Official.
  - <795> The 2014 revision is Official
  - <797> The 2008 revision is Official
  - <800> The July 1, 2020, is Official
  - <825> The December 1, 2020, is Official
- ** https://www.usp.org/news/usp-opens-extended-public-comment-period-for-revised-compounding-standards*

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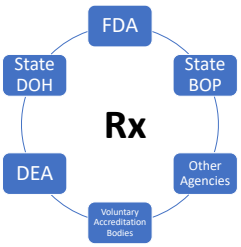
Regulatory Landscape -



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Do you understand the overlapping regulatory authorities who could visit your compounding establishment?

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Let's talk compliance !

How the FDA is shaping the conversation

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What is FDA Regulatory Guidance ?

Since July 2014 the FDA has issued 28 Guidance documents or Regulatory Policy Statements impacting Compounding / Pharmacy Practice -

Addressing the following topics:

- Insanitary Conditions at Compounding Facilities
- Pharmacy Compounding of Human Drugs / 503A
- 503B Outsourcing Facilities [Registration, Fees, General Facilities]
- Use of Bulk Drug Substances [503A / 503B]
- Hospital & Health System Compounding
- Compounded Products that are Essentially Copies of Approved Drug Products [503A / 503B]
- Mixing, Diluting, or Repackaging of Biological Products

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What is FDA Regulatory Guidance ?

- These Guidance Documents from FDA represent their "current" thinking and can be changed by FDA at any moment.
- From the Agency's current guidance regarding Insanitary Conditions:
  - In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required. *

* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/insanitary-conditions-compounding-facilities-guidance-industry

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Guidance vs. Regulation

The Twisted Case of the 'Deceptive' Pretzels

How FDA 'guidance' letters feed meritless lawsuits against food and beverage makers.

© 2019 WSJ [Sheldon Bradshaw & Marisa Malick]

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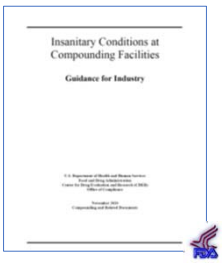
FDA's Insanitary Conditions Guidance -

- Issued first in **August 2016**, Updated in **November 2020**, it lays out FDA's focus on the following **54** key areas:
  - General Conditions
  - Aseptic Practices
  - Equipment and Facilities
  - Related to Cleaning & Disinfecting
- Drugs need not be contaminated to qualify…
- The Guidance is intended to assist local BOPs and other State Agencies
- Non-compliance will trigger Regulatory Action !



Insanitary Conditions at Compounding Facilities

Guidance for Industry

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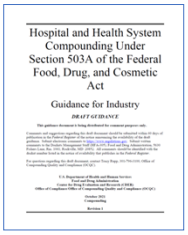
Revised FDA Hospital Guidance -

- Released by FDA on 10.6.21 this *"Guidance for Industry"* contains the following:
- The scope is for BOTH sterile and non-sterile preparations.
- Imposes a strict reliance upon a "prescription" to qualify for a 503A exemption from the FDCA. (lines 28, 80 & 192)
- Creating a distinction between a "hospital pharmacy" and a "health system pharmacy"(footnotes 2 & 12)
- FDA wants the discontinuance of any anticipatory compounding in hospitals. (line 206)
- FDA is directing hospitals to obtain compounded drug from 503Bs or to register themselves as a 503B (line 212)


Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

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Revised FDA Hospital Guidance – (cont.)

- How will FDA police this Guidance?
  - The short answer is the generally will not… DIRECTLY. (line 119)
  - They will rely on local regulatory bodies to enforce standards like USP.
  - FDA will, as always, respond to complaints (line 123)
    - Specific enforcement will be on a "case-by-case basis" (line 216)
- FDA is expecting the hospital to police this policy through –
  - The FDA's expectation that the prescriber document the "prescriber's determination of significant difference" when requesting a compounded medication! (line 275)
  - The hospital or health-system's P&T process will determine if a commercially available therapy is more suitable. (line 282)
  - FDA is tying in voluntary accreditation bodies [i.e. TJC] (line2 87)
    - Additionally, FDA is crossing over from those accreditation bodies to CMS [i.e TJC's HAP checklist] (footnote 20)

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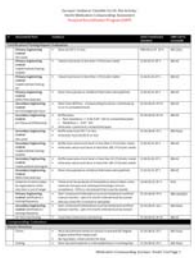
TJC Hospital Accreditation Program ("HAP") -

- This Sterile Medication Compounding Assessment Cross-walks the TJC Standard to the CMS' "Conditions-of-Participation" (CoP)
- [5-page tool]



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FDA by the Numbers – (as of 3.18.22)

TOP FDA CITATIONS FOR 503A ESTABLISHMENTS

1. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.
2. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
3. Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.
4. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.
5. There is no written testing program designed to assess the stability characteristics of drug products.

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FDA 503A Pharmacy Top 25 Observations as of 3/18/2022

	Observation	Occurances	Percentage
1	Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.	230	39.1%
2	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.	225	38.3%
3	Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.	194	33.0%
4	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.	160	27.2%
5	There is no written testing program designed to assess the stability characteristics of drug products.	140	23.8%
6	Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.	130	22.1%
7	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.	129	21.9%
8	Production personnel were not practicing good sanitation and health habits.	115	19.6%
9	Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.	112	19.0%
10	There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.	83	14.1%
11	Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.	79	13.4%
12	Disinfecting agents and wipes used in the ISO 5 aseptic processing area are not sterile.	75	12.8%
13	Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.	64	10.9%
14	The sterile technique qualification (media fills) do not represent your routine operating conditions and does not evaluate worst-case activities that can provide a challenge to manual aseptic operations.	63	10.7%
15	Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.	61	10.4%
16	Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.	60	10.2%
17	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.	58	9.9%
18	Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.	57	9.7%
19	Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.	52	8.8%
20	Your firm did not conduct smoke studies of the aseptic processing area under dynamic conditions.	50	8.5%
21	Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.	49	8.3%
22	Routine calibration and inspection of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.	48	8.2%
23	Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 areas.	40	6.8%
24	Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.	39	6.6%
25	Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.	37	6.3%

Facilities: 417 | Inspections: 588 | Inspectors: 347 | States: 45 | Districts: 10 | Regions: 6

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The 2021 USP Proposed Changes

How the changes to USP <795> & <797> impact practice ?

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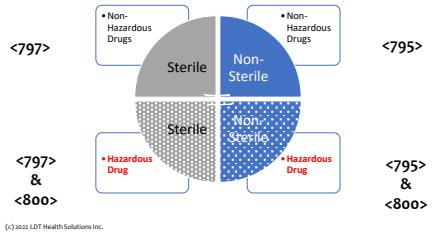
What Type(s) of Compounding is Conducted ?



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Non-Sterile Compounding <795>

2021 Proposed Chapter

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USP <795> Non-Sterile Preparations -

- Elimination of the "Categories of Compounding"
- Expanded guidance for assigning BUDs for CNSPs
- "Elaborate" on the role of water activity in determining BUDs
- Clarification of requirements for RECALL procedures
- Exclusion of the following practices:
  - Administration
  - Non-Sterile Radiopharmaceuticals *[see USP <825]*
  - Reconstitution
  - Repackaging *[see USP <1178>]*
  - Splitting Tablets

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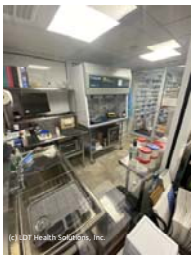
USP <795> Non-Sterile Preparations -

- Medicines intended to be Non-sterile:
  - Solid & Liquid Orals
  - Rectal Preps
  - Vaginal Preps
  - Topical Preps (Creams, Gels, & Ointments)
  - Nasal & Sinus Preps intended for local application (Nasal Sprays & Nasal Irrigations
  - Otic Preps



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USP <795> Non-Sterile Preparations -

- PRACTICES NOT SUBJECT TO THE CHAPTER:
  - **Administration** – Single-dose for a single patient when admin will begin within 4 hours.
  - **Non-Sterile Radio Pharmaceuticals** *[see USP <825>]*
  - **Reconstitution** – of a commercially available drug according to the Mft's approved labelling.
  - **Repacking** – of commercially available drug [see USP <1178>]

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USP <795> Cleaning -

Site	Minimum Frequency
Work Surfaces	Each shift, after spills, & between compounds with different components
Floors	Daily, and after spills
Walls	Every 3 months, and after spills
Ceilings	When visibly soiled or when contamination is suspected
Storage Shelving	Every 3 months, after spills, or when contamination is suspected

* From Table 1. Minimum Frequency for Cleaning and Sanitizing in Nonsterile Compounding Area(s) – Surfaces - USP <795> © 2021 USP Pharmacopeial Convention

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Sterile Compounding <797>

2021 Proposed Chapter

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USP <797> Sterile Preparations -

- Medicines intended to be Sterile:
  - Injections, including Infusions
  - Irrigations for internal body cavities (e.g., any space that does not normally communicate with the environment outside the body such as the bladder, or peritoneal cavity)
    - *Irrigations for the mouth, rectum, or sinus cavities are NOT required to be sterile!*
  - Ophthalmic Dosage forms
  - Aqueous Pulmonary Inhalation preps
  - Baths and Soaks for live organs and tissues
  - Implants

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<797> Major Revisions –

- Change in the definition of "Compounding"
- Creation of THREE Categories (I, II, and III) vs. 3 Risk Levels (L, M, and H)
- Addition of Changes in "Immediate-Use CSPs" (1hr. to 4 hrs. to begin administration)
- Changes in Personnel Qualifications
- PEC changes in terminology – RABS, ISOLATORS, IVLFZ, PHARMACEUTICAL Isolators & ROBOTIC ENCLOSURES
- SEC requirement changes
- Expansion of the role of SCA's (HD applications)
- Changes in Viable Air & Surface Monitoring (decrease in intervals for this testing)
- Changes in BUD determinations
- Refinement in the role of "QA" & "QC"
- Changes in Cleaning & Disinfection Requirements & Processes
- Changes in Compounding Documentation – Master Formula Docs & Batch Records

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USP <797> Sterile Preparations

- NOW Includes standards for these specific practices –
  - Repackaging
  - Allergenic Extracts Prescription Sets
  - Blood derived or other Biological Material (i,.e. Analogous Blood) Compounding
- NOW "redefines" – Administration and "Preparation" per "Approved Labelling" which could be out of the Scope of **USP <797>** if certain conditions are met.
- Revises the provisions for "Immediate Use" CSPs-
  - No more than **3 different sterile products**
  - Administration **must begin within 4 hours** *(previously 1 hour)* following preparation
- Replaces High / Medium /Low Risk Levels – with
  - **Category I**
  - **Category II**
  - **Category III**
- Carve out of Radiopharmaceuticals to **USP <825>**

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Cleaning of Classified Areas / SCAs -

SITE	CLEANING	DISINFECTION	SPORICIDAL
PEC [and equipment within]	Daily [When used]	Daily[When used] 70% S-IPA	Monthly(1,2) Weekly (3)
Removable work tray of PEC (if applicable)	Daily (TOP, When used] Monthly (UNDER tray)	Daily[When used] 70% S-IPA	Monthly
Pass-Through(s)	Daily [When used]	Daily [When used]	Monthly(1,2) Weekly (3)
Work surface(s) outside of PEC	Daily [When used]	Daily [When used]	Monthly(1,2) Weekly (3)
Floors	Daily [When used]	Daily [When used]	Monthly(1,2) Weekly (3)
Wall(s), Door(s), & Door Frame(s)	Monthly	Monthly	Monthly
Ceilings	Monthly	Monthly	Monthly
Storage Shelves & Bins	Monthly	Monthly	Monthly
Equipment Outside the PEC(s)	Monthly	Monthly	Monthly (1,2) Weekly (3)

* From Table 8 - Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and within the Perimeter of the SCA - USP <797> © 2021 USP Pharmacopeial Convention

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Changes in Personnel Qualifications & Training -

Skill / Competency	Frequency
Hand Hygiene & Garbing	Orientation, then annually
Basic Aseptics	Orientation, then Q6mo (Category I, II) Q 3mo (Category III)
Personnel Media Qualifications	
Fingertip & Thumb Sampling	
Return demonstration of competency	

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Is it "Compounding" or Immediate –Use ?

Preparation per Approved Labelling	Immediate-Use CSPs
NOT Compounding -	Compounding for direct and immediate administration to a patient not subject to Category I, II or III. if all of these conditions are met:
"…mixing, reconstitution or other such acts that are preformed in accordance with directions contained in approved labelling and other manufacturer directions consistent with that labelling."	• Written SOPs are followed (incl. aseptic technique) • Personnel are trained & demonstrate competency • In accordance with approved labelling or stability studies • Not greater than three (3) sterile FDA products • Any remainder from SDVs are discarded • Begin Administration within 4 hours • Conforms to specific Labelling Requirements
OUT of USP <797> Scope if: • Prepared as a single dose • For a single Patient • Approved Labelling specifies diluent, resulting strength, container closure system, and storage time.	

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Category ONE -

A PEC inside a SCA or a C-PEC inside a C-SCA

- BUD
  - 12 hours (or less) at controlled room temperature
  - 24 hours (or less) when refrigerated
  - And ONLY if compounded in accordance with applicable requirements for Category ONE CSPs in the Chapter.
  - NO Requirements for <71> & <85> testing

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Category TWO -

The Road to Category TWO always goes through an Ante-Room –

- BUDs-
  - > 12 hours at controlled room temperature
  - > 24 hours when refrigerated
  - Requirements for <71> & <85> testing based on BUD assigned – See <797> Table 11.
  - And ONLY if compounded in accordance with applicable requirements for Category II CSPs in the Chapter.

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BUD Limits for Category 2 CSPs -

CSP Characteristics		Storage Conditions		
Compounding Method	Sterility Test <71> Performed & Passed	Controlled Room Temp (20-25 C)	Refrigerator (2-8 C)	Freezer (-25 to -10 C)
Aseptically Processed CSPs	NO	From one or more non-sterile starting component(s): 1 DAY	From one or more non-sterile starting component(s): 4 DAYS	From one or more non-sterile starting component(s): 45 DAYS
		From only sterile starting component(s): 4 DAYS	From only sterile starting component(s): 10 DAYS	From only sterile starting component(s): 45 DAYS
	YES	30 DAYS	45 DAYS	60 DAYS
Terminally Sterilized CSPs	NO	14 DAYS	28 DAYS	45 DAYS
	YES	45 DAYS	60 DAYS	90 DAYS

* From Table 11 - BUDs for Category 2 CSPs USP <797> © 2021 USP Pharmacopeial Convention

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Category THREE -

- Category THREE starts with an ISO-classed cleanroom suite, including an ANTE.
- Then, Comply with ALL requirements for Category TWO CSPs, **AND -**
- **Fulfill ALL the additional Category THREE burdens for:**
  - **Sterile Garb**
  - **Use of Sporicidal Disinfectant Agents**
  - **Increased Frequency of Environmental Monitoring**
  - **Stability Determinations (USP Method)**
- **Undergo Sterility testing [<71>].**
  - **Supplemented by Endotoxin testing [<85>] if applicable.**

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BUD Limits for Category 3 CSPs -

CSP Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temp (20-25 C)	Refrigerator (2-8 C)	Freezer (-25 C to – 10 C)
Aseptically processed, Sterility tested <71>, and passing all applicable tests for Category THREE CSPs	60 DAYS	90 DAYS	120 DAYS
Terminally sterilized, Sterility tested <71>, and passing all applicable tests for Category THREE CSPs	90 DAYS	120 DAYS	180 DAYS

* From Table 11 - BUDs for Category 2 CSPs USP <797> © 2021 USP Pharmacopeial Convention

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Summary & Conclusions -

- Full Compliance to the Proposed 2021 USP Compounding Chapters will require a multi-pronged approach.
- Although an FDA guidance is non-binding, the probability that the Local BOP and other standards organizations may incorporate all or part of these documents into local regulation should encourage pharmacists & technicians to engage them in an active conversation before statues, rules, or regulations change without discussion.
- Considerations to FDA Guidance, CETA standards, and Local BOP regulations & requirements will be necessary to assure that compliance gaps are eliminated.
- Patient Safety is the Primary Objective !

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TEN take-a-ways for Compounding Compliance -

1. Do you have **written policies & procedures** in place to reflect how you actually compound in your pharmacy ?
2. Do those policies include a clear & complete **Environmental monitoring program** to address the proper documentation of your control over the compounding spaces?
3. Do you have policy, training records, and other resources for all **equipment** used in the compounding process? DO you document this training ?
4. Assure that the gowning gloving & garbing supplies as well as the **PPE** in-use complies with USP, BOP, & OSHA statutes and guidance.
5. Review the **cleaners, cleansers and disinfectants** in use. Do you have the a proper sporicidal agent in use as part of your cleaning processes ?

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TEN take-a-ways for Compounding Compliance -

6. Have you completed your assessment of risk for all **HD drugs** & API at your site, whether you compound or not !
7. Have you reviewed FDA's **Insanitary Conditions Guidan**ce document?
8. Do you routinely **review the logs & completed documents** that demonstrate your compliance (for completeness, appropriateness, & compliance)?
9. Has the information and data used to determine your site's **Beyond-Use dates** been verified & documented ?
10. Have you considered outside resources to assist ?

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QUESTIONS

- Many Thanks !
- LSDiorio@LDTRx.com
- www.LDTRx.com

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Learning assessment questions

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Question 1 -

- **TRUE or FALSE : Compliance to USP General Chapter <800> exempts a Pharmacy from the rigors of complying with USP <797> ?**
- FALSE – The current Official versions of both are enforceable & applicable!

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Question 2 -

- **FDA Guidance Documents are:**
- (a) Published by FDA to share their current thinking of a particular subject.
- (b) Legally enforceable.
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Question 3 -

- **Regarding the proposed changes to USP <795> and USP <797>, which of the following is FALSE:**
- (a) The comment period to submit to USP for consideration ended March 17, 2022.
- (b) The current Official Chapters (USP <795> & <797>) are in place and should be considered as the current reference standard for practice.
- (c) You must make changes to your standard operating procedures before March 17, 2022 in order to be in compliance with USP.
- (d) Compliance to the USP Compounding Chapters is considered by the Centers for Medicare & Medicaid Services (CMS) for program participation.
- (c) is FALSE

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Question 4 -

- **Under the proposed USP General Chapter <797>, which of the following is FALSE:**
- (a) There is a limit to the batch size of CSPs that can be prepared.
- (b) An Ante Room is required to maximize the ability of a pharmacy to assign the longest possible beyond-use date (BUD) to a compounded sterile prep (CSP).
- (c) "Gloveboxes", "Isolators" or other restricted access barrier devices ("RABs") are no longer usable under any circumstances for sterile compounding.
- (d) Changes in the frequency of environmental monitoring of your compounding rooms will be needed under the proposed chapter.

- (c) is FALSE

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