2021 Proposed USP Compounding Chapters –
Sifting Through the Confusion:

What's in, What's out, What's changed [now] and how FDA is shaping the conversation !

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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 for both 503A & 503B providers.
- List three (3) attributes (design elements) of a USP compliant compounding space for sterile or compounding.
- Discuss the impact of the FDA's Insanitary Conditions guidance document on daily practice.
- Outline three attributes of a quality compounder training program.

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DISCLOSURES -

LDT Health Solutions Inc.

- 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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GROUND RULES -

- Please ask questions at any time !
- The "management" reserves the right to defer any questions to the end of the session.

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Lets 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 January 31, 2022**.*
  - Comments should be submitted to USP at: https://usp.az1.qualtrics.com/jfe/form/SV_aWexhZowiRBbKqP
- 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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USP Timeline for Proposed Changes -

Source: US Pharmacopeial Convention – www.USP.org

USP-NF

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Let's talk compliance !

How the FDA is shaping the conversation

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

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Compounding Practice vs. Manufacturing -

Good Manufacturing Practices

- Product focused
- Production - not in "real-time"
- cGMP (21 CFR 210/211)

Pharmacy Practice (503A)

- Patient-centric
- "Real-time" provision of service
- BOP regulations

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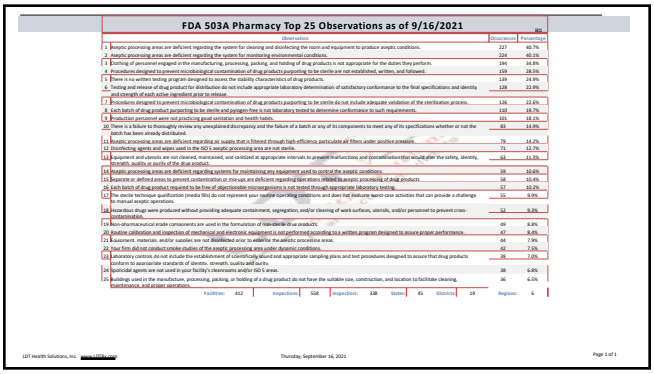

FDA 503A Pharmacy Top 25 Observations as of 9/16/2021

	Observation	Occurrences	Percentage
1	Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.	227	60.7%
2	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.	224	40.5%
3	Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.	194	34.8%
4	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.	159	28.5%
5	There is no written testing program designed to assess the stability characteristics of drug products.	139	24.9%
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.	128	22.9%
7	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.	126	22.6%
8	Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.	110	19.7%
9	Production personnel were not practicing good sanitation and health habits.	101	18.1%
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	14.9%
11	Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.	79	14.2%
12	Disinfecting agents and wipes used in the ISO 5 aseptic processing area are not sterile.	71	12.7%
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.	63	11.3%
14	Aseptic processing area are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.	59	10.6%
15	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.	58	10.4%
16	Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.	57	10.2%
17	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.	55	9.9%
18	Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.	52	9.3%
19	Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.	49	8.8%
20	Routine calibration and inspection of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.	47	8.4%
21	Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing area.	44	7.9%
22	Your firm did not conduct smoke studies of the aseptic processing area under dynamic conditions.	42	7.5%
23	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	7.0%
24	Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 areas.	38	6.8%
25	Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.	36	6.5%

Facilities: 412 | Inspections: 558 | Inspections: 338 | States: 45 | Districts: 19 | Regions: 6

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Top 5 FDA citations for **503A** Compounders -

1. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
2. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic 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 by the Numbers – **(as of 9.16.21)**

➢503B OUTSOURCING FACILITIES -

➢The most active FDA field offices are located in:
- ➢Dallas (15.5%)
- ➢Irvine [Los Angeles] (10.2%)
- ➢Tampa [Maitland] (8.9%)

• **** From LDT internal data.***

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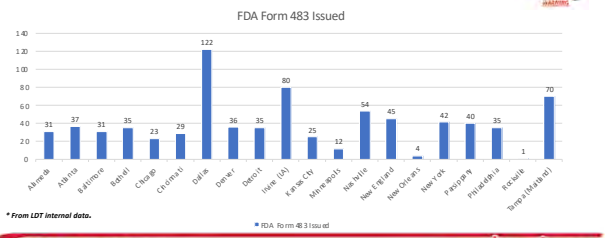
FDA by the Numbers – (as of 9.16.21)



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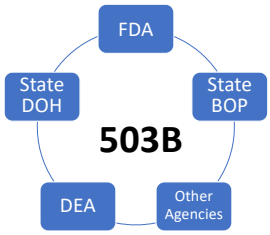
Regulatory Landscape -



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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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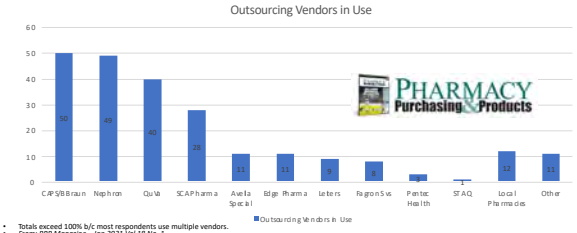
Where are Outsourced Compounded Preparations coming from ?



- Totals exceed 100% b/c most respondents use multiple vendors.
- *From: PPP Magazine – Jan 2021 Vol 18 No. 1*

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FDA 503B Pharmacy Top 25 Observations as of 9/16/2021

	Observation	Occurrences	Percentage
1	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.	128	55.9%
2	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.	117	51.1%
3	The labels of your outsourcing facility's drug products do not include the information required by section 503B(a)(10)(A)&(B).	114	49.8%
4	Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.	111	48.5%
5	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.	108	47.2%
6	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.	73	31.9%
7	Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.	72	31.4%
8	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.	68	30.1%
9	Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.	46	20.1%
10	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.	45	19.7%
11	There is no written testing program designed to assess the stability characteristics of drug products.	36	15.7%
12	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.	33	14.4%
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.	32	14.0%
14	The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.	30	13.1%
15	Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.	29	12.7%
16	There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.	25	10.9%
17	Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices, and written procedures required by current good manufacturing practice regulations.	24	10.5%
18	Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.	24	10.5%
19	Batch production and control records do not include complete information relating to the production and control of each batch.	20	8.7%
20	Routine calibration and inspection of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.	20	8.7%
21	Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.	19	8.3%
22	The compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(1) and 503B(d)(1).	18	7.9%
23	Your outsourcing facility has not submitted a report to FDA identifying product produced during the previous six months as required by section 503B(b)(2)(A).	18	7.9%
24	Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.	18	7.9%
25	Fine limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.	17	7.4%

Facilities: 109 | Inspections: 229 | Inspections: 226 | States: 30 | Districts: 18 | Regions: 5

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Top 5 FDA citations for **503B** Compounders -

1. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions
2. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.
3. The labels of your outsourcing facility's drug products do not include the information required by section 503B(a)(10)(A)&(B).
4. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.
5. 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.

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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.

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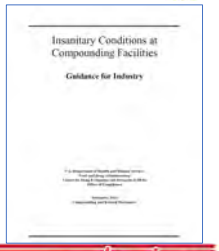
FDA's Insanitary Conditions Guidance -

- 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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The 2021 USP Proposed Changes

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

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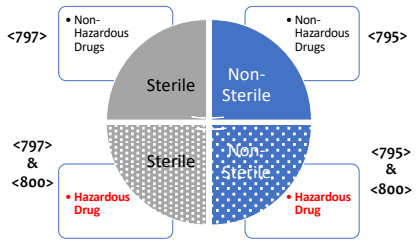
Assess Your Compounding Operation



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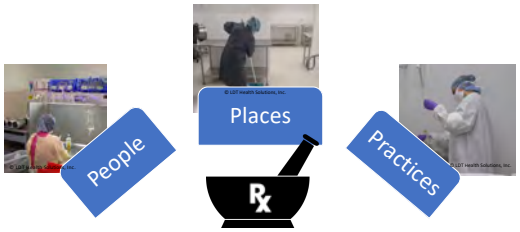
The road to compounding compliance…



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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.
- 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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QUESTIONS

LDT Health Solutions Inc.

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

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Reading List / Bibliography -

- General Chapter USP <795> <797> <800> - www.USP.org
- UPDATE - - - -
- Controlled Environmental Testing Association (CETA) – www.CETAinternational.org
- Centers for Disease Control & Prevention www.cdc.gov
- Pharmacy Purchasing and Products Magazine- www.ppmag.com
- FDA Website – www.FDA.gov
  - Drug Quality & Safety Act -
    http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm
  - Guidance – Pharmacy Compounding -
    http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377964.pdf
  - Guidance – Hospital & Health System Compounding-
    http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM486581.pdf
- OSHA / NIOSH Resources –
  - HD Drug list - http://www.cdc.gov/niosh/docs/2016-161/default.html
  - NIOSH Drug Alert- http://www.cdc.gov/niosh/docs/2004-165/default.html
  - Workplace Solutions – PPEs- http://www.cdc.gov/niosh/docs/wp-solutions/2009-106/pdfs/2009-106.pdf
  - DONNING & DOFFING – (videos) http://www.cdc.gov/vhf/ebola/hcp/ppe-training/
  - CSTD- (Draft for comment) - http://www.cdc.gov/niosh/docket/review/docket288/default.html

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Quality Process-

Courtesy of LDT Health Solutions, Inc.

- Personnel are capable and qualified to perform their assigned duties.
- Ingredients used in compounding have their expected identity, quality, and purity .
- Critical processes are validated to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
- The engineering controls and production environment is suitable for its intended purpose (addressing such matters as environmental cleanliness, control, monitoring, staff attire, and the setting of action limits, as appropriate).
- There is assurance that processes are always carried out as intended or specified and are under control.
- Appropriate stability evaluation is performed or determined from the literature for establishing reliable expiration dating to ensure that finished preparations have the expected potency, purity, quality and characteristics at least until the labeled expiration date.
- Appropriate release checks or testing procedures are performed to ensure that finished CSPs have their expected potency, purity, quality and characteristics at least until the labeled beyond use date.
- Preparation conditions and procedures are adequate for preventing mix-ups.
- There are adequate procedures and records for investigating the product, correcting failures or problems in preparation, testing, or in the preparation itself.

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