Visante Webinar:

USP <795> & <797> Revisions Roundtable Discussion

December 16, 2021 – The intent of this webinar was to bring to light some of the changes to the USP Chapters <795> and <797> and highlight areas where there may be confusion and more clarity is needed. **NOTE: The comment period for this guidance ends 1/31/21. Comments can be made on the designated comment site for each chapter; for <795> (https://usp.az1.qualtrics.com/jfe/form/SV_3OBK7VUbvver6zs) and for <797> (https://usp.az1.qualtrics.com/jfe/form/SV_81VZpnzjwcQJlZA)** Visante highly recommends and encourages stakeholders to make their comments known as there are still clarifications and possible compromises to be made in each of the chapters. **Disclaimer**: This Q&A document is intended to answer questions presented during the webinar as accurately as possible. However, the views expressed in this document are the author's and not intended to provide guidance for how any health care provider, hospital or health system should conduct themselves and/or their business. The opinion's expressed by this document do not necessarily reflect the opinions of Visante inc.

Questions & Comments	Visante Answers
1. USP has stopped receiving comments on 797 revision? When do you anticipate the revised version to be subject to enforcement?	USP will continue to receive comments through January 31, 2022 (see links above for each chapter. USP has also scheduled 2 more stakeholder public comment sessions in January for each of the chapters (register for each session here).
2. Allergenic compounding requirements old vs new, will there be changes such as competency, media fill, fingertip testing?	According to the revision, before being allowed to compound allergenic extracts personnel must complete gloved fingertip and thumb sampling on both hands no fewer than 3 times then every 12 months thereafter. The same is true for media fills, they must be completed prior to compounding and every 12 months thereafter.
3. Has the beyond use date on repackaging changed from 1 year to 6 months? I have not seen this in any literature.	Under FDA guidance documents for repackaging, it is all 6 months unless the packaging material is rated as Class A or B Under USP <671> for the light

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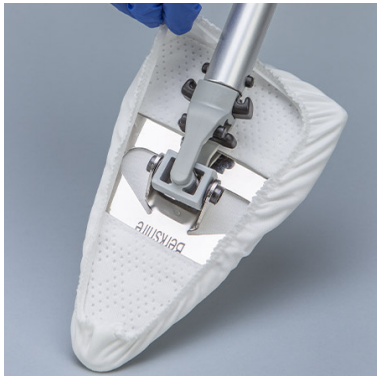
	protection and moisture barrier qualities. If the manufacturer of the packaging equipment has data that validates the packaging and rates it under class A or B then you're allowed to have 1 year dating; otherwise you must use 6 months.
4. What is everyone doing for sterile cleaning products in the PECs? We have always used sterile IPA but not all our cleaning products are sterile or all our wipers.	The revision states, "**cleaning and disinfecting supplies** used in the PEC **must be sterile** with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used. In classified areas outside of the PEC, sterile cleaning and disinfecting agents **should** be used." (emphasis added) There are products (wipers) that are specific for cleaning PECs that can be slipped over a dedicated tool which are usually wrapped in packages of 2 or 4 and are sterile. These look like miniature mops. Here are examples of what they look like. Without trying to show bias toward any product, one of these is made by Berkshire and the other is made by Contec.  
5. Do you anticipate that USP will adjust competency requirements for sites that use compounding robots for Category 3 items? It doesn't seem to make	Here is what the revision states about the use of a robotic enclosure as a PEC, "If a robotic enclosure is used as the PEC, or placed within the PEC, a

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sense to test staff for aseptic technique 4 times per year if the robot will be completing the compounding.	dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s)." Beyond this it doesn't have any other comments or clarifications regarding compounding for specific categories. If there are no people involved in the compounding of these preparations, you would not have to do aseptic technique competency testing on personnel.
6. On repackaging, where does USP 1178 guidance to calculate BUD based on initial expiration dating on stock bottle come into play?	According to <1178>, "This chapter is intended to provide guidance to those engaged in repackaging of oral solid drug products; and the chapter provides information to any person who removes drugs from their original container–closure system (new primary package) and repackages them into a different container–closure system for sale and/or for distribution. This chapter does not apply to pharmacists engaged in dispensing prescription drugs in accordance with state practice of pharmacy." USP <1178> then explains the procedures for packaging into unit-dose and multiple-unit packaging.
7. How do (you) determine BUD when I don't have the stability or potency from the Mfr except the BUD recommendation from USP?	The USP expert committee has separated preparations into 3 different categories and the BUD are determined by how a preparation was prepared (aseptically or terminally sterilized), whether it has passed sterility testing and the storage conditions under which the preparation will be held. For Category 3 preparations you do have the option of doing your own stability study on the preparation with a stability indicating method. However, these are costly studies and many other conditions come with claiming a category 3 BUD (increased environmental monitoring, cleaning, garbing, competency

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	etc.). In the revision, please see tables 10, 11 and 12 for the different BUDs according to category.
8. Since when do you need to have a compounding record for all sterile preps? Thought this was just for anticipatory compounding?	USP <797> revision states for Master Formulation Records (MFRs), "An MFR must be created for Category 1, Category 2, Category 3 and immediate-use CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s)." For Compounding Records it states, "A compounding record must be created for all Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s)."
9. If you have a team member that floats across different infusion pharmacies, do you have them do media fill and fingertip testing at all of the different sites?	This isn't a question that would be directly answered from the chapter. However, having an understanding of the purpose of glove fingertip and thumb sampling and media fill, these are site specific, even PEC specific competencies. Our answer would be yes, they would have to have records of these being completed at each site.
10. In regard to the 797 extension of BUD with Type or Category III CSPs, why would they lessen the speciation requirements which is specific to the state of the C-PEC, and increase the Media Fill Assessment requirement which is a very broad quality assurance measure?	USPs mindset is changing to a process being driven by quality rather than testing quality into the preparations. Therefore, there is much more focus on the training and evaluation requirements of personnel as well as increased environmental monitoring requirements for assuring the processes for cleaning procedures. Having a solid, consistent process among all personnel would have a heightened level of assurance of quality for preparations rather than relying on for example finished product testing.
11. Repackaging oral dosage forms into unit doses still seems unclear to me - how can I tell the quality of the packaging used impacts the beyond-use date?	Please see the above question and answer about USP Chapter <1178> which dictates expiration dating of unit-dose packaging. <1178> refers to USP Chapter <671> Containers – Performance Testing regarding the unit-

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	dose container and closure system what requirements must be met for either Class A or Class B containers.
12. In regard to 795 as a non-sterile guidance document, why are sterility considerations overriding the stability considerations for assignment of BUDs?	It could be said that previous iterations of USP <795> were actually "behind the times" regarding the concept of water activity. For the first time water activity is mentioned in this revision and is probably long overdue. This concept has been around in food production for decades and even dates back to pre-historic times with the preservation of food through drying (i.e. beef jerky). While the amount of water activity each compound has does affect the sterility, it also affects the stability of the preparation through hydrolytic reactions.
13. FDA also includes this; what's defined as compounding. What are your thoughts on how this impacts physician clinics and even reconstitution of basic antibiotics performed at the retail pharmacy?	It appears the definitions for compounding between the FDA and USP are aligning more closely. Since the reconstitution of antibiotics is done according to the manufacturer's instructions, this would not be considered compounding and exempt from USP <795> standards.
14. How do you manage facilities management of the HEPA filters in the IV room area? Intake air flow is what I am referring to.	If I'm understanding your question correctly, you're wondering about how to increase or decrease the airflow into the cleanroom. There are many situations to account for when trying to answer this question. Is there a dedicated air handler for the cleanroom alone or is it managed by an air handler that supplies air to several areas? It's typically easier to manage the airflow if you have a dedicated system for the cleanroom only. As far as the HEPA filters themselves, they should be tested every 6 months during your room certification and changed out as necessary.