Q: x3 fingertip initial, this applies as x3 to annual review as well?  
A: Fingertip sampling is required annually or semi-annual according to risk level. I recommend performing gloved fingertip sampling as part of the annual or semiannual media fill.

Q: Do we need to do 'random sampling' on staff if we are using the media fill and fingertip testing together?  
A: No, there is no requirement to do any random sampling, though it might be a good idea since people behave differently when they are tested.

Q: Must surface sampling be done if you don't do any high risk compounding?  
A: Yes, surface sampling is required periodically. I recommend it be done as part of the media fill and any other times as you desire.

Q: With regard to SBOP disciplinary action for non-compliance with USP 797 - is this disciplinary action against the PIC or against the hospital or both?  
A: I don’t know the specifics of the citation yet but typically, the board of pharmacy holds the PIC responsible for complying with all applicable rules, regulations and laws. Consult your board of pharmacy rules and regulations for the responsibilities expected of the PIC.

Q: Why do 797 now recommend putting on booties first, vs. hair cover/mask, then booties? Wouldn’t it be better to do the head area garbing 1st vs. touching dirty shoes?  
A: The chapter is NOT prescriptive to the order of the dirtiest activities. The chapter says dirtiest to cleanest without any bias to what comes first. My recommended order is “head, face, and feet”.

Q: Should products be dispensed with foil seal over injection port and/or with a tamper evident cap/device in order to re-use the product (within its BUD) once dispensed to a nursing unit and returned from the unit unused?  
A: There is no requirement in USP Chapter <797> to use foil seals. Personally, I like them since it is a way to ensure some level of tamper evidence and injection port protection.

Q: Are humidity monitors required, per 797?  
A: There is no requirement to monitor for humidity per 797, though it is recommended.

Q: Regarding risk level, if you are spiking a final container with a prn adapter, and then spiking the prn adapter more than 2 times, would this be considered medium risk or low risk? (i.e. more than 2 spikes due to need to pull fluid out of bag in addition to addition of drug). To clarify, if more than 2 vials are used to add to a final container (only 1 spike of final container-i.e. one syringe required), is this still considered medium risk?  
A: The determination of risk level is ultimately the pharmacist’s responsible. If you are using a prn adapter to draw multiple doses out of a single vial to create multiple
CSPs, then I would consider those CSPs to be medium-risk level. Consult the language in the chapter that details the different risk levels.

Q: Lastly, would anything prepared on a tpn compounder (non-tpn solution) always be medium risk? thank you.
A: --In my opinion, yes.

Q: Why do the media fill tests and hand hygiene have to be once a year for high-risk and twice a year for low risk?
A: --I apologize; the requirements in the slide were incorrect (reversed). It should be annually for med/low risk and twice a year for high risk. We will correct this in the slides for follow up.

Q: What is your experience with gloving within the buffer area? Appropriate?
A: --Donning the sterile gloves can be done in the buffer area or ante area. Either location is appropriate.

Q: What is the USP guideline for vented vs. non-vented BSC (is it based on volume of chemotherapy prepared daily/weekly/monthly)?
A: --The issue with venting a BSC involves the handling of volatile hazardous drugs. Some of HDs (cyclophosphamide, cisplatin, carmustine and ifosfamide) are known to volatize (change to vapor) when prepared. HEPA filters will not stop vapors. USP Chapter <797> and the NIOSH Alert suggest the use of Class II Type B2 cabinets for operations where potentially volatile hazardous drugs are being compounded.

Q: What is the best way to put on sterile gloves? Inside the buffer room or inside the hood?
A: --Sterile gloves need to be donned aseptically and should be donned in the buffer area. I would avoid putting the glove packaging into the hood.

Q: Should we ban non sterile alcohol in the clean room?
A: --No, there are applicable for its use. Visit the USP website and review the FAQs. http://www.usp.org/audiences/pharmacist/797FAQs

Q: What is considered multiple sterile products for a medium risk compound? 3 products? 4?
A: --Within the low-risk level CSP section it states only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP. I would consider your scenario to be medium-risk level.

Q: Is wiping items with alcohol before they go into the clean room required?
A: Refer to the Suggested Standard Operating Procedures (SOPs). It is a best practice.
Q: What guidance do you have RE: pre-connecting mini-bag plus bags with drug product? Some smaller hospitals do this in patient care areas - citing immediate use. However, my training says the connecting should be done in an Iso-5 environment if one-two hours will occur prior to activation and administration. Your thoughts?
A: --I prefer to see these devices connected within an ISO Class 5 environment. Consult the manufacturer’s direction since they have studied them in a couple of different environments.

Q: What are the recommendations as far as the square footage for an ante room and cleanroom?
A: --There are no minimum facility size requirements. Any area should be adequate for the activities being performed in it and for the number of personnel working in it.

Q: We have access to a tent like device that is supposed to suffice as a clean room. This device has plastic sides and two laminar flow devices on its roof. What do you know about these type devices and do the meet the new criteria?
A: --I don’t know if your soft-wall cleanroom meets the performance criteria. Have your certifier test the room according to the CETA guidance documents (http://www.cetainternational.org/reference/CETAsepticCompoundingCertificationGuide.pdf)

Q: Do nurses using ADD-vantage products at the nursing unit (ED and Daysurgery) meet 797 standards?
A: --Refer to the Proprietary Bag and Vial System section of the revised USP Chapter <797>.

Q: Sterile Additive port seals; where should these be applied to final product, in the hood? outside the hood?
A: --USP Chapter <797> does not address if and when these seals are to be used. Personally, either location is acceptable to me.

Q: Sorry I was writing down the CDC website and didn't get the full gist of what was said on manufacturer vs. 797 so back to manufacturer's advisement on their packaging - if the manufacturer has dating less than what 797 would allow - which should be followed - e.g. ibuprofen injection says good for 30 min. after access.
A: --Follow the manufacturer’s dating unless it exceeds the BUD in USP 797.

Q: Can you comment on the caveats of automated temperature monitoring systems like Isensix. or endorse the use of automated systems
A: --I like them. Every system has its limitations. At least once a day, a temperature must be recorded regardless of the system used. It will be important to have access to the continuous data within the pharmacy to ensure that all systems are under control.

Q: Should you be testing twice a year for medium risk and once a year for high risk or vice versa?
A: --The errors in the slides were corrected in the copy provided to you. It should be annual for low and medium-risk level and semi-annual for high-risk level.

Q: Regarding BUDs, if you prepare a large volume CSP that will be administered over a period of several hours, perhaps 12 hours, must the anticipated end time for administration of the CSP fall within the BUD, or, is it OK to begin administration at the last minute of the BUD?
A: --An infusion can hang for longer than the CSP BUD.

Q: Re: Caulked ceiling tile --does the tile need to be of a certain consistency....can't be porous or should it be made of a certain product?
A: --There is specific language in the USP chapter re: tiles. It says “The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate.”

Q: Per your talk there is no Federal Regulations on 797?
A: --USP 797 is enforced by the state board of pharmacy. USP Chapter <797> is considered part of the Federal Food, Drug and Cosmetic Act. Most if not all state boards of pharmacy have language requiring compliance with all applicable federal laws. USP Chapter could be considered an applicable law.

Q: On the question regarding if all personnel need to be trained I do believe that this must also be verified with the state board of pharmacy because some say that if a pharmacist checks a CSP they must be certified as well as those that actually make the products.
A: --You should always refer to your specific state pharmacy rules and regulations re: training of personnel. All personnel responsible for supervising, managing, overseeing or checking the work of compounding personnel needs to be trained as thoroughly as the compounders. I incorrectly answered this question during the webinar.

Q: Is there critical sites that can be touch contaminated when putting Add-Vantage vials with the bag? In other words do they need to be put together in an ISO 5 environment?
A: --Refer to the manufacturer’s directions and the Proprietary Bag and Vial System section of the revised USP Chapter <797>.

Q: Is there any application of 797 to "compounding" by nurses on nursing units or at the point of care?
A: --Yes, refer to the immediate-use provision of the chapter. Anyone compounding needs to use proper aseptic technique.

Q: Is there a brand of "sterile" alcohol?
A: --No, there are a number of manufacturers of sterile alcohol.
Q: Is it okay for both sides of the pass thru window between the clean and ante room to be open at the same time?
A: --Ideally, no. If it is, the time should be brief to avoid depressurizing the buffer area.

Q: Is it necessary to use sterile alcohol within the hood or glove box?
A: Yes. Please refer to the FAQs on the USP website.
http://www.usp.org/audiences/pharmacist/797FAQs

Q: Is it appropriate for pharmacists to perform their own Plate surface testing or should we outsource a professional to accomplish this task?
A: --Pharmacists can perform their own surface testing in accordance with USP Chapter <797>.

Q: Is fingertip sampling a required or suggested monitoring procedure?
A: --It is a required procedure.

Q: Is fingertip sampling applicable when using a barrier isolator chamber like the Germfree model?
A: Yes

Q: In terms of BUDs on IV labeling, what language do you best feel should go on a pharmacy information system label? For example, because we have several different levels of 797 compliance in our facility, we are considering putting 3 dates on our IV labeling: Prep date/time, Infuse before date/time, & expiration date/time.
A: --If you put all three on the label, how will you avoid confusion? Choose one and be consistent.

Q: We are in the process of building a new facility. We are trying to build our new clean room to meet and potentially exceed USP 797 expectations. Where do you see USP 797 standards going in the future? Do you see them becoming even stricter?
A: --Personally, I do not believe the facility requirements will become stricter. Currently, the revised chapter is consistent with requirements from the FDA of manufacturers and what is required of pharmacies in Europe, Asia and Australia.

Q: What about training for pharmacists that might only compound during a code blue scenario...do they need training?
A: --They do, especially in aseptic technique.

Q: In our nursing home we have been using 28 day BUD for all of our insulin vials. A recent audit by a Medicare D PDM told us we cannot refill insulin sooner than 30 day unless the ordered dose would use up the vial in less time. Do you feel the BUD for insulin vial should be 28 or 30 days?
A: --The chapter is very specific regarding the storage of MDVs. Refer to manufacturer’s package insert for specific storage recommendations.

Q: If you have a BSC do you need to gown up?
A: Absolutely. There is specific language in the chapter that full garb is required when working in any primary engineering control (e.g., LAFW, BSC, CAI or CACI) unless otherwise stated by the manufacturer.

Q: If you cannot remove rings from fingers, will adequate hand washing and sterile gloves be acceptable?
A: It is not for me to say. Acceptable to whom? You might have to justify why rings are being worn.

Q: If you are using a barrier isolator that is located in a low traffic area (but do not have a cleanroom) is the risk level low risk or low risk w/ < 12 hr BUD?
A: There is specific language in the chapter regarding placement of isolators. Please refer to the chapter and to the FAQs published on the USP website: http://www.usp.org/audiences/pharmacist/797FAQs for more information.

Q: If my certifier is International Air Filtration Certifiers Association (IAFCA) certified. Is that as good as NSF?
A: I am not aware of the qualifications of IAFCA.

Q: If I have an MIC, do I need a Class 7 buffer room around it?
A: The USP chapter has specific language regarding the placement of isolators. See the Placement of Primary Engineering Controls section of the USP chapter.

Q: I work in cancer center and we are required to use 2 chemotherapy gloves per NIOSH but at this time Kendall does not offer sterile chemotherapy gloves.
A: You can wear a pair of sterile gloves over nonsterile chemo gloves. Covidien now manufacturers sterile chemo gloves.

Q: Hand washing - Are we suppose to use a regular soap hand washing up to the elbows then apply surgical antibacterial soap once in the clean room every time entering the room?
A: You can use either an antimicrobial soap or plain soap followed with an application of a persistent antimicrobial surgical scrub. These scrubs typically contain chlorhexidine and isopropyl alcohol and different than the type of soap used during the initial washing.

Q: I thought that low and medium risk level is annually and high-risk level is semi-annually?
A: They were reversed but have been corrected in the slides, I apologize for the inconvenience.

Q: I have seen that some facilities are adopting hang times of 48 hrs for IV solutions prepared by the Pharmacy. Does USP 797 address hang time, or where is this found?
A: USP Chapter 797 does not address hang times. Typically, the hang times for IV solutions is based on CDC recommendations or institution-specific policies.
Q: I disagree... All staff, especially Pharmacists needs to be trained if they want to verify what a technician compounds. How else are they supposed to verify if they don't know how it is supposed to be made according to USP 797?
A: --I agree. After I answered the question, I realized my error. Pharmacists need to be trained as thoroughly as the technicians.

Q: How often is viable environmental monitoring required?
A: --There are specific requirements for air, surface and gloved fingertip monitoring in the chapter.

Q: How does USP 797 affect preparation of sterile products in the OR suites by Anesthesia?
A: --USP 797 is applicable to all personnel in all locations where CSPs are handled, prepared, and stored.

Q: How do I ensure medication accuracy if labels or paper in general are not allowed in the cleanroom?
A: --USP Chapter <797> does not prohibit labels or paper in the cleanroom.

Q: How about the cleaning supplies for floors and counters? We had a sales rep come in marketing "sterile" cleaning products (not sterile alcohol).
A: --Sterile germicidal detergents are not required for the floors and counters.

Q: Do the products (disinfectants, etc) used to do the cleaning of the IV room needs to be "sterile"?
A: --Use of sterile 70% alcohol is required in the ISO Class 5 area, vial stoppers or septa, ampule necks and gloved hands. Please refer to the chapter and to the FAQs published on the USP website: http://www.usp.org/audiences/pharmacist/797FAQs for more information.

Q: Is there a list of items that are not to be included in the ante room? Can you keep drugs/supplies in ante area?
A: --There isn’t a list. You should limit the items in the ante and buffer area to those necessary for compounding. These areas are specialized areas of activity and should be set up as a warehouse.

Q: For single dose bottles, e.g. Foscavir or Magnesium that could deliver multiple doses during the day, if the bottle is sealed or has a closed spike and is removed from the hood, what is the expiration? 1hr or 6hr?
A: --There is specific language on the use of single doses within an ISO Class 5 environment and ambient air. Please refer to the chapter and to the FAQs published on the USP website: http://www.usp.org/audiences/pharmacist/797FAQs for more information.

Q: For relief pharmacists in hospital, can you use fingertip testing from other hospital pharmacies?
A: --No. All personnel need to be trained according to your procedures and their training records reflect documentation.

Q: Do injectable syringes that are drawn up on a patient-specific basis (i.e., such as peds IV doses) fall under USP 797 requirements?  
A: --If these drawn-up doses are stored, then USP 797 applies.

Q: For annual fingertip testing, how many times (1 vs. 3) should each person be tested?  
A: --Each person must complete a set of 3 gloved fingertip samples with zero CFUs followed by either annual or semi-annual testing. Refer to the USP Chapter for additional information.

Q: Eric, I understand that 797 does not address infusion (hang) times, just time from start of compounding to time of the beginning of the administration (BUD), do you have any guidance on preparations such as OnQ or implantable pumps. Should we be preparing these "long-term" infusions with a higher degree of process quality? If so, where can the RPh go to find it?  
A: --ISMP just published specific handling and compounding recommendations re: OnQ pumps. I believe that these devices need to be prepared in the pharmacy under optimal conditions.

Q: Eric- our clean room consists of iso class 8 ante room, iso class 7 iv filling room (both positive pressure) and iso class 7 chemo room (negative pressure). Are we compliant, I thought I heard you say you need an ISO class 7 ante room if you have a chemo compounding area?  
A: --If you enter an ISO Class 7 chemo room or iv filling room from a common ante area, the air cleanliness classification of the ante area needs to be ISO Class 7. This requirement can be found in the USP Chapter.

Q: Eric - Can you elaborate on USP 797 as a standard and SBOP ability to impose disciplinary actions if state is not mandating?  
A: --This question is best addressed by your state board of pharmacy. If there is no state rule and regulation mandating compliance then I don’t see how disciplinary actions can be imposed.

Q: Epidurals that we make are made from sterile products. High risk??  
A: --No. Refer to the USP Chapter <797> for the definition of each risk level.

Q: Does use of Bacteriostatic NS or sterile water for reconstitution of sterile products (primarily SDV's) affect beyond use dating?  
A: --Refer to package insert for specific storage direction of these reconstituted vials.

Q: Does the pharmacist need to check the final product in an ISO 5 or can it be in the ante-area?  
A: --USP Chapter 797 does not address this issue. The answer will depend on your state board of pharmacy laws.
Q: Can supplies (drugs, syringes) be kept in the ante-room?
A: --There is nothing in the chapter to prohibit this activity. The ante room should NOT become a warehouse of supplies. I would limit the amount of supplies to 2-3 days worth of inventory.

Q: Does the daily cleaning need to be performed if there is no compounding for the day?
A: --The chapter is silent on this issue. If you can be sure no one enters the area after it is cleaned and all of the environment conditions are maintained, then cleaning should not be required on non-compounding days.

Q: Do you need to wear non-sterile gloves under the sterile gloves for the compounding of CSP’s?
A: --No.

Q: Do you need to do gloved fingertip sampling inside of a LFGI not located within a cleanroom?
A: --Yes. Using an isolator does not exempt you from any of the USP Chapter <797> requirements.

Q: Do you know of a video or step by step procedure on donning sterile gloves correctly?
A: --If you Google “donning sterile gloves”, you will find lots of videos. Consult with your hospital’s OR personnel to see how they train their personnel.

Q: chemo gloves? Can you wear non sterile under a pair of regular sterile gloves?
A: --Yes. Covidien manufacturer’s a sterile chemo glove.

Q: Can you use non-sterile gloves and sterilize with sterile alcohol prior to compounding?
A: --No, you are required to use sterile gloves.

Q: BUD: We have been told before that the BUD was the date at which the administration of the product should begin. Pharmacies use dates such as "begin use by" on the label. Is this correct?
A: --Have you read USP Chapter <797>? If your language complies with the chapter, then it can be used.

Q: BUD vs. Expiration date. For example, a high risk compound with known stability of 30 days that has a BUD of 24 hr, should 2 dates be put on the product? A BUD "begin infusion by" date and a true expiration date.
A: --Chemical stability is different than microbial sterility, which is what the USP Chapter <797> BUDs are based on. How do you prevent the two dates from being confusing to the end-user?

Q: Are topical meds compounded for wound care considered high risk?
A: --Depends on how the topical meds are prepared.
Q: High risk for wounds from non-sterile products to be used for instillation in a wound?
A: --Any CSP prepared from non-sterile components is considered high-risk. Irrigations for wounds are required by the FDA to be sterile. Please refer to: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071324.pdf

Q: Are the red spots on the USA map areas where there is no state board involvement?
A: --The red dots are state boards of pharmacy that have NO regulations re: sterile compounding.

Q: Are single dose antibiotic vials when reconstituted in a iso 5 hood have a BUD of 6 hours or longer if noted in the package insert?
A: --No more than 6 hours.

Q: Are gasked ceiling tiles acceptable in 797?
A: --No. Refer to the chapter more specific language.

Q: Are caulked removal tiles necessary or can the ceiling be a hard surface closed ceiling?
A: --The ceiling can be a hard surface.

Q: Fingertip testing: Doesn't 797 state no personnel shall compound until 3 passing tests? The debate = This is prohibitive if strictly applied; i.e. - would this not require a facility to shut down until at least one appropriate personnel passes so compounding can resume?
A: --USP Chapter <797> is a standard. If your state requires compliance then it is incumbent upon you to get personnel through the 3 passed tests. It is not a difficult task to complete. Contact me via email if you are having difficulties in meeting this requirement.

Q: We have 60+ RPh. Not all of them go in the IV room and actually compound CSPs, but they check the final product. Do they all have to have a media fill and fingertip or just those who directly compound CSPs?
A: --You should always refer to your specific state pharmacy rules and regulations re: training of personnel. All personnel (pharmacists) responsible for supervising, managing, overseeing or checking the work of compounding personnel needs to be trained as thoroughly as the compounders. I incorrectly answered the question during the webinar.