DOWNLOAD PDF COMPOUNDING STERILE PREPARATIONS

Chapter 1 : Frequently Asked Questions About Pharmaceutical Compounding | American Pharmacists Ass

Compoundingâ€"Sterile Preparations,15 became official, re- placing USP chapter , Sterile Drug Products for Home Use. 20 The change from a chapter numbered above to a.

When swabbing is used in sampling, the area covered should be at least 24 cm2 but no larger than 30 cm2. Regardless of the cfu counts, corrective actions must be dictated by the identification of the microorganisms recovered. Highly pathogenic microorganisms regardless of cfu count must be immediately remedied. Environmental monitoring data must be collected and trended as a means of evaluating the overall control of the compounding environment. Any colony forming unit cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. If highly pathogenic microorganisms are detected, irrespective of the cfu count, they must be immediately remedied with the assistance of a competent microbiologist, infection control professional, or industrial hygienist. An investigation into the source of the contamination must be conducted. Once determined, the source of the problem must be eliminated, the affected area cleaned, and re-sampling performed. There are approximately 20 accepted species in this genus with the most commonly known being A. This genus has also been observed to grow on textiles, foodstuffs, fruits and painted surfaces. In the indoor environment, Aureobasidium growth is commonly found in moist places such as bathrooms and kitchens, especially on shower curtains, tile grout and windowsills. The spores are usually disseminated by wind when dry and water. Aureobasidium spores are difficult to identify on spore traps because of morphologic variation. Its most distinguishing feature is the production of primary blastospores spores produced by a budding process arising directly from pigmented, vegetative hyphae on short denticles protuberances in the hyphae. The spores may be hyaline colorless or pigmented, variable in size, one-celled, ellipsoid or ovoid, and completely encased in a slimy coat. These primary spores can give rise to secondary or tertiary spores through yeast-like budding. The conidia asexual spores adhere together to form slimy heads. The brown hyphae can differentiate to form chlamydospores resting spores or arthroconidia a spore type resulting from fragmentation of a hypha at maturity. Generally, we report irregular clumps of dark brown hyphae, dividing in more than one plane to form chlamydospores, as A. However, vegetative hyphae from other unrelated dematiaceous pigmented fungi, such as Cladosporium , may be indistinguishable from Aureobasidium when blastospores are absent. When chlamydospore-like structures are indistinguishable, we report them in the "other brown" category. Because this fungus is sticky and slimy, spores do not readily become airborne and are not commonly found on spore traps. In direct microscopic examination, it is recognizable if enough diagnostic structures have been preserved on tape lifts or swabs. In culture, Aureobasidium species grow rapidly on Malt Extract Agar MEA and, at first, produce colonies that are yeast-like and cream or pink in color. As the colony ages, a slimy exudate appears and the coloration changes to dark brown or black on the surface. As seen from the reverse side of the agar plate the colony is a pale beige. The mycelium is characterized by irregular, dichotomous two part branching, with cells sometimes rounding off and separating, and is variable in thickness. Aureobasidium colonies exhibit distinct radial, "fan-shaped" growth that makes them recognizable among other colonies. Aureobadisium pullulans has been used to produce pullulan, a biodegradable polysaccharide which, when processed, becomes a shiny and strong fiber used to package food and drugs. It has also been used industrially to remove unwanted components of raw textile materials. One of its negative economic impacts is that it has been associated with the deterioration of pears and oranges in storage or in transit. Human pathogenicity is uncommon and Aureobasidum pullulans is generally considered a contaminant and not a primary human pathogen. This article was originally published on September We use science and innovation to provide accurate data that people trust and to create solutions that save time and resources.

Chapter 2 : USP Standards for Compounding Sterile Preparations | Aureobasidium

Pharmacy technicians are an integral part of the sterile compounding process and are regularly responsible for preparation of compounded sterile products (CSPs). High risk compounded sterile products (CSPs) are often made from non-sterile components and require sterilization prior to administration to patients.

Find articles by Michael R. This article has been cited by other articles in PMC. Abstract Significant patient safety incidents related to sterile drug compounding have occurred for many years. Previous guidelines have focused on ensuring sterility, but serious compounding errors have occurred as well. National efforts are needed to identify and reduce the potential for such errors and their causative factors. In response, the Institute for Safe Medication Practices ISMP convened in October a summit of 60 invited experts in the field for the purpose of establishing by consensus guidelines, safe practices, and standard operating procedures needed to ensure the safe preparation of compounded sterile preparations, especially intravenous admixtures. The resulting guidelines were categorized into 14 core processes: They were also classified into 3 levels: The guidelines presented in this article were felt to be applicable to any health care organization that prepares sterile compounded products. The consensus of the group was that adherence to these guidelines will improve the safety of sterile product compounding and reduce harmful errors in patients receiving these products. Incorporation of these guidelines into sterile compounding practices of health care organizations is an important component of improving patient safety. Yet, a recent survey has shown that only 18 states directly require compliance with this standard, 6 only In , there were 4 serious incidents of contaminated pharmacy-prepared sterile products resulting in harm to more than patients. Serious compounding errors have also been reported. Through analysis of the medication error reports it receives, as well as the on-site medication risk assessment it conducts for hospitals, ISMP has identified several additional risks for sterile compounded products. Lack of standardized concentrations. Despite The Joint Commission requirement for the use of a limited number of standardized concentrations MM. Many hospitals do not effectively use the formulary process to ensure standardization of sterile products. Lack of use of current technology solutions. In , one hospital was able to implement extensive sterile processing automation reducing the number of sterile medications that needed to be prepared by human hands in the hospital to 4. A survey 7 showed only 2. The survey also revealed that only 3. Lack of adequate space often does not allow adequate segregation to prevent mix-ups. This may be due, in part, to the absence of specific practice guidelines related to product preparation checks, but inadequate training in schools of pharmacy may be responsible as well. Stakeholders More than 60 invitees agreed to attend the summit see Appendix. Those who participated came from a variety of backgrounds, including medication safety officers, experts in IV safety technology, pharmacy technicians, pharmacists, nurses, health care consumers, and representatives of the medical product vendor community. Based on the pre-summit survey, one-third of responding participants represented hospitals with to beds and half were from hospitals with over beds. All participants were volunteers and received no compensation other than travel and meeting expense reimbursement. The meeting was sponsored and conducted by ISMP, an independent, nonprofit charitable organization that works closely with health care practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping health care practitioners keep patients safe, leading efforts to improve the medication use process. Summit Attendees were surveyed prior to the summit to gather information about their facilities, the preparations they compounded, standard admixture practices, quality control mechanisms, use of automated processes, and software used related to compounded sterile preparations CSPs. Participants were asked to review and comment on a compendium of ISMP-recommended best practices sent to all attendees prior to the summit. Otherwise they were accepted for inclusion in the guidelines. A literature review was also conducted to identify additional published admixture-related errors. Reports highlighted fatal medication errors associated with IV compounding in pharmacies, often involving infants or children. At the summit, participants were asked a variety of questions regarding best practices when applied to preparation of 1 simple compounded

sterile preparations CSPs; those with 1 or 2 ingredients, such as patient-controlled analgesia infusions, single electrolyte infusions, bolus doses, or maintenance IV infusions with no more than 2 ingredients , 2 complex CSPs those with more than 2 ingredients, such as parenteral nutrition [PN], cardioplegia solutions, or dialysis solutions , 3 pediatric and neonatal preparations, and 4 chemotherapy. The summit focused on establishing by consensus guidelines, safe practices, and standard operating procedures SOPs needed to ensure the safe preparation of CSPs, especially IV admixtures. The summit comprehensively reviewed current methods used to prepare CSPs, identified manual and automated safeguards that help provide assurance that the proper preparation is dispensed for administration, addressed barriers that could inhibit safe practices, and sought to identify and standardize critical quality control practices needed for preparing and verifying the quality and safety of the final CSP. The goals for the summit were to: Review currently employed quality control measures used to ensure the correct preparation of CSPs. Identify quality control practices that should be standardized for incorporation into the manual process to ensure the correct preparation of CSPs. Describe current and emerging technologies that assist the preparation of CSPs and how these technologies are utilized. Identify the minimum safeguards that must be in place to prepare and dispense CSPs. Recommend best practice guidelines to ensure the safe preparation of CSPs by pharmacies. Guidelines The summit resulted in a set of guidelines and safe practices that were agreed upon by consensus to ensure the safe preparation of CSPs Table 1.

Chapter 3 : Sterile Preparations & Injectables | Buderer Drug Co.

General Chapter Pharmaceutical Compounding - Sterile Preparations Previous Next Millions of medications are compounded each year in the US to meet the unique needs of patients.

Compounding is the creation of a pharmaceutical preparationâ€"a drugâ€"by a licensed pharmacist to meet the unique needs of an individual patient either human or animal when a commercially available drug does not meet those needs. A patient may not be able to tolerate the commercially available drug, the exact preparation needed may not be commercially available, or a patient may require a drug that is currently in shortage or discontinued. Customize strength or dosage. Flavor a medication to make it more palatable for a child or a pet. Reformulate the drug to exclude an unwanted, nonessential ingredient, such as lactose, gluten, or a dye to which a patient is allergic. Change the form of the medication for patients who, for example, have difficulty swallowing or experience stomach upset when taking oral medication. Compounding does not include making copies of commercially available drug products, as this is not allowed by law. How is pharmaceutical compounding different from drug manufacturing? Pharmaceutical compounding is performed or supervised by a pharmacist licensed by a state board of pharmacy see question below on legal oversight of compounding versus manufacturing. Manufacturing is the mass production of drug products that have been approved by the Food and Drug Administration FDA. These products are sold to pharmacies, health care practitioners, or others who are authorized under state and federal law to resell them. What is a compounding pharmacy? While most pharmacies offer some level of compounding, most compounding is done in pharmacies that have made the investment in equipment and training to do so safely and efficiently. The preparations offered by these compounding pharmacies can be nonsterile ointments, creams, liquids, or capsules that are used in areas of the body where absolute sterility is not necessary or sterile usually intended for the eye, or injection into body tissues or the blood. All licensed pharmacists learn during their training and education to perform basic compounding. In addition, most pharmacies have some compounding tools, such as a mortar and pestle for grinding materials, graduated cylinders for measuring liquids, balances for weighing solids, spatulas for mixing materials, and ointment slabs on which to work. With such tools and through applying their knowledge, all pharmacists routinely prepare nonsterile compounded preparations when requested by prescribers. Of the approximately 56, community-based pharmacies in the United States, about 7, pharmacies specialize in compounding services. This means the pharmacists in those facilities spend most or all of their time compounding special preparations for patients. Preparations made in these pharmacies are more likely to include both sterile and nonsterile dosage forms. Compounding also takes place in hospital pharmacies and at other health care facilities. Who regulates compounding pharmacies? Do compounding pharmacies follow the same regulations as drug manufacturers? Why or why not? The practice of compounding is regulated by state boards of pharmacy. Community and hospital compounding pharmacists are allowed exemptions to the Federal Food, Drug, and Cosmetic Act of if they comply with the regulations outlined in Section A. All pharmacists and pharmacies engaged in compounding are subject to oversight by both federal and state authorities. Pharmacists engaged in compounding are expected to follow applicable standards and regulations for the types of preparations that are compounded. Controlled substances include narcotics such as hydrocodone, amphetamines, and similar drugs, and drugs such as those used for anxiety and sleep disorders. This private, nonprofit organization defines the chemical purity of drugs and also issues practice standards. USP develops standards for the identity, quality, strength, and purity of medicines, dietary supplements, and food ingredients that may be used in compounding preparations. These standards in particular are relevant to compounding pharmacists. It provides guidance on preventing microbial contamination and other variances in compounded sterile preparations, regardless of setting e. It describes categories of compounding simple, moderate, complex , defines concepts such as beyond-use date and stability, and provides criteria for compounding pharmacists to follow in preparing various drug preparations. This standard aims to promote worker safety pharmacists, pharmacy technicians, veterinarians, veterinary technicians, and many others , patient safety, and environmental protection. This standard was published on February 1, , but will not be

officially implemented until July 1, Compliance with these and other USP guidelines is considered the minimum standard of practice in pharmacy. Pharmacy Compounding Accreditation Pharmacy Compounding Accreditation is a service of the Accreditation Council for Health Care ACHC that assesses the nonsterile and sterile pharmacy compounding process as defined by a specific set of standards that concentrate on the quality and consistency of medications produced. How would patients know if their medication is compounded? Knowing that, should they take any precautions, or do anything differently? A patient can receive compounded drugs from a typical community pharmacy or a specialty compounding pharmacy, or compounded drugs can be administered by doctors or other health professionals in clinics or medical offices. Patients should ask the person administering a medication or the pharmacist dispensing a prescription whether it was prepared in a compounding pharmacy or manufactured by a drug company. Does a compounding pharmacist have special training? Compounding is a central activity to the practice of pharmacy. Pharmacists who practice in the 7, pharmacies that specialize in compounding services have generally had advanced training in compounding after they graduated from pharmacy school. No state currently requires a particular type of training, and no nationally recognized specialty exists for pharmaceutical compounding. Specialized training in pharmacy compounding processes is available through several of the active pharmaceutical ingredient API suppliers serving the needs of the compounding pharmacy community. When is a compounding pharmacy necessary? A health care provider will prescribe a compounded drug only when commercially available drug products do not meet your needs. If you do not understand why you have been prescribed a special formulation, ask your prescriber. If you are concerned about taking a compounded drug and you and your prescriber agree that you can tolerate the commercially available drug, you may also ask if there is any evidence that your outcome will be better on the compounded formulation. Where is more information about compounding available? APhA has made available on this website the introductory chapter of a leading book it publishes on compounding pharmacy. The FDA and CDC websites provide up-to-date information, lists of affected facilities and states, treatment guidelines, FAQ statements and other resources to assist health care providers and the public in addressing this issue. What caused the meningitis outbreak, and how could it have been prevented? A number of things went wrong with these preparations. Because the compounded preparation was a suspension with visible particles rather than a solution a dispersion of the drug at the molecule level , the liquid could not be filtered in a way that would have removed bacteria and fungi. Because the preparation was being injected directly into the spine, no preservative or other additives that might have prevented fungal growth could be added. The Compounding Quality Act of was a direct outcome of increased regulation over compounding. The first section, Title I , is concerned with compounding. Title II deals with Track and Trace rules. The Act also created a new entity, called Outsourcing Facilities. The Board of Pharmaceutical Specialties is developing a specialty designation for sterile compounding.