MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

1: Microbial contamination of nonsterile pharmaceuticals in public hospital settings

"will be welcomed by all involved in parenteral www.enganchecubano.com value of this book is much more than as a guide to contamination control; it is the setting of each chapter within a wider and engaging context that makes this publication unique."-European Journal of Parenteral and Pharmaceutical Sciences be welcomed by all involved in.

In order to receive the prevailing registration rate, your registration s must be received by PDA by 5: ET on or before the date noted. Group Registration Discount Register 3 people from the same organization as a group at the same time for the Conference or Workshop and receive the 4th registration free. Other discounts cannot be applied. Special Dietary Requirements Please let us know if you have any special dietary requirement we may assist you with. Please contact us at registration pda. A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by August 16, your credit card will be charged the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference non-member fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. Emails and phone messages are not accepted. Refunds for Full Conference, Workshops and Events: After that time, no refunds or credit requests will be approved. Onsite registrants are not guaranteed to receive Conference materials until all advanced registered attendees receive them. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. For more details, contact PDA at info pda. Photo ID will be required in order to pick up badge materials on-site. This important security procedure will prevent anyone other than the registrant from picking up their badge and materials. Tape recordings are prohibited at all PDA Conferences. PDA is not affiliated or contracted with any outside hotel contracting company. The cut off date has now passed. Please contact the hotel directly to secure a room based on availability. Check in time is 4: Individual Cancellation Please be aware that obtaining and canceling hotel reservations is the responsibility of the meeting registrant. Individuals will be responsible for payment of their own cancellation fees. The cancellation policy is 6: All guest rooms and suites provide high-speed Internet, upgraded Marriott Revive bedding, coffee makers, hair dryers, iron, and an ironing board. This hotel has a smoke-free policy and no pets are allowed. Two other airports in the vicinity are both serviced by all major carriers: Dulles International, 24 miles away, and Baltimore-Washington International, 34 miles away. The 13th Annual PDA Microbiology Conference offers exciting and unique sponsorship and exhibition packages designed to strengthen brand image, increase visibility, and help you connect with industry leaders. This Conference will bring together industry experts from microbiology, manufacturing, laboratories, compliance, quality, research and development, engineering, validation, regulatory affairs as well as executives, managers, scientists, technicians and analysts. At this conference you will be exposed to high quality attendees from a variety of manufacturing companies â€" making this a must attend meeting. In addition, high profile sponsorships are available for lanyards, notepads, audience response systems, tote bags, pens, refreshment breaks, lunch and networking reception. For more information about exhibit and sponsorship opportunities, please contact:

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

2: The Cost of Microbial Control

DRUGS AND THE PHARMACEUTICAL SCIENCES Microbial Contamination Control in Parenteral Manufacturing edited by.

S, sensitive; ZI, zones of inhibition. Discussion The study findings have shown that all tested samples were microbiologically contaminated. The isolated aerobic bacteria were mainly Bacillus spp, while the fungal contaminants comprised Candida spp and Aspergillus spp. Our findings are consistent with those of previous studies, which found that the majority of microbial contaminants in nonsterile pharmaceuticals are Bacillus spp, C. This calls for more stringent measures to prevent possible detrimental effects. This is an indication of improper handling of pharmaceutical products in our hospital pharmacies, as already reported elsewhere. The presence of potentially pathogenic opportunistic microbes, including Aspergillus spp and C. However, when Klebsiella moves outside the gut, it can cause a serious infection. Thus, its presence in the assayed samples is also an indication of unhygienic conditions, and may have originated from pharmaceutical personnel. Such a finding would have elucidated the magnitude of pharmaceutical contamination- related microbial infections in Tanzania. Klebsiella, Bacillus, and Candida spp are the predominant contaminants. Of the identified microbial contaminants, Bacillus spp were resistant to augmentin and cloxacillin. Poor handling of the pharmaceutical products during dispensing or repackaging might have contributed to the observed high rate of microbial contamination. Education on personal hygiene and proper handling of medicines in dispensers cannot be overemphasized, since these are essential for prevention and control of microbial contamination of pharmaceuticals and other medicine-derived infections. Acknowledgments The authors acknowledge the assistance of the pharmacy department at the hospital where the study was conducted and are grateful for the partial funding received from the Ministry of Science, Technology and Higher Education. Footnotes The authors report no conflicts of interest in this work. Blackwell Scientific Publications; The Science of Dosage Form Design. Surface contamination in some common available dosage forms. Aspects of microbial contamination of tablets dispensed in hospitals and community pharmacies in Benin City, Nigeria. Trop J Pharm Res. Microbiological assessment of commercially available quinine syrups and water for injections in Dar es Salaam, Tanzania. Tests for specified microorganisms. Cambridge University Press; Denyer S, Baird R, editors. Guide to Microbiological Control in Pharmaceuticals. Microbiology â€" A Human Perspective. Genitourinary Infections and Antimicrobial Medications. Am J Infect Control. Prevalence of extended spectrum lactamase producing Klebsiella pneumoniae in a tertiary care hospital. Ind J Med Microbiol. Microbiological contamination and preservation of pharmaceutical preparations. The Science of Dosage from Design. Quality of chlorine-based antiseptics and disinfectants circulating in Dar es Salaam, Tanzania. Poor preservation efficacy versus quality and safety of pediatric extemporaneous liquids. JB Lippincott Co; Clinical Laboratories Standards Institute. Clinical Laboratories Standards Institute; Fluconazole disk diffusion susceptibility testing of candida species. Microbiological quality of pharmaceutical raw materials. Antibiotic therapy for Klebsiella pneumoniae bacteremia: Implications of production of extended-spectrum beta-lactamases. Beta-lactamase mediated resistance in hospital acquired urinary tract infection. Prevalence of community-occurring extended spectrum beta-lactamase-producing enterobacteriaceae in Brazil. Guarner F, Malagelada JR. Gut flora in health and disease. Contaminated cough syrup kills 22 in Panama. Assessment of the microbiological quality and wash treatments of lettuce served in university restaurants. Int J Food Microbiol. AIDS and economic welfare in peasant agriculture:

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

3: Microbial Contamination Control in Parenteral Manufacturing : Kevin L. Williams :

This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments.

Elizabeth Kerrigan Introduction Microbial contamination of parenteral products is one of the most serious issues currently facing the pharmaceutical industry. Injectable drugs, which are administered directly into the circulatory system, bypass a number of innate human immune defenses associated with the gastrointestinal system. Therefore, to ensure the sterility of each of these products prior to patient administration, pharmaceutical companies must adhere to strict government regulations regarding quality control. Maintaining and following a robust quality control program is integral to quality standards and meeting regulatory requirements. Adding to these pressing concerns are compounding pharmacies that function inappropriately as drug manufacturing companies, but are not legally required to adhere to federal drug manufacturing regulations. Rather, they function under more lenient state policies that govern their operation, but do not enforce quality control analysis. This lack of regulation and oversight has led to several significant microbial outbreaks, which have resulted in multiple deaths from use of contaminated parenteral steroids, cardioplegia solutions, and intravenous drugs. These events highlight the importance of effective pharmaceutical sterility procedures as well as the need for updated regulatory control policies governing the operation of compounding pharmacies. In this article, we will discuss current practices and issues associated with pharmaceutical quality control analysis, how these can affect patient health and safety, and what could be done to remedy the issue. Pharmaceutical Manufacturing Companies Pharmaceutical manufacturing companies are licensed facilities that develop, produce, and market drugs. When appropriately followed, these processes prevent product adulteration and microbial contamination. They are intended to assure the proper design, monitoring, and control of all manufacturing procedures to confirm the sterility and quality of products. This includes establishing a reputable management system, obtaining high quality raw materials, upholding controlled operating procedures, identifying product deviations, and maintaining reliable laboratories [1]. To monitor compliance of pharmaceutical companies with cGMP regulations, the FDA routinely performs facility inspections and reviews publically generated product reports. Companies not in compliance with cGMPs are issued a warning and may become subject to regulatory actions. Although the FDA cannot force a company to recall a drug when compliance is not met, violations can be legally addressed and a court order can be granted allowing the seizure and disposal of drugs [1]. However, patient health is still at risk when these pharmaceutical products are not immediately removed from the market. To reduce these risks, it is the responsibility of the pharmaceutical and health care industries to voluntarily cease the production, distribution, sale, or use of all known non-compliant products. These methods are based on the observation of media turbidity due to the growth of contaminating microorganisms through either direct transfer-immersion sterility testing or membrane filtration [2, 3]. However, these analyses only measure the probable, not actual, sterility of a product lot. Thus, the product administered to the patient is not directly tested for sterility [3]. This presents a major limitation in current sterility testing as it assumes that a small sample is representative of an entire lot. Therefore, these tests can only offer sterility control and assurance; and cannot guarantee product sterility. To fully ensure product sterility, pharmaceutical manufacturing procedures should incorporate sterility protocols, such as filtration procedures, in addition to endproduct microbial contaminant testing. To supplement USP sterility testing methods, members of the pharmaceutical community often implement RMMs for the routine examination of microbial limit testing , bioburden assessment, environmental testing , raw materials testing , process water testing, sterility testing, and in-process testing. RMMs employed include growthand viability-based technologies, molecular methods, endotoxin testing , and rapid air monitoring. However, although these processes offer an enhancement over conventional microbial detection practices,

much of the pharmaceutical industry has been reluctant to adopt RMMs. Their unwillingness is primarily centered around a reluctance to adopt new methods due to perceived increased cost, lack of expertise, or fear of the unknown [5]. By combining these sterility practices, pharmaceutical companies can ensure that quality control procedures and products are kept at the highest standards. Another quality control method employed by pharmaceutical manufacturing companies is the addition of antimicrobial preservatives. These substances are added to products to protect them from the growth of microorganisms that are introduced during the manufacturing process or through multiple withdrawals of the product from its container. For these preservatives to be effective, the stability of the preservative, interactions with the parenteral drug product, the minimal inhibitory concentration, and optimum pH for antimicrobial activity must all be considered [6, 7]. When properly performed, the AET provides a general gauge of antimicrobial effectiveness at levels that are non-toxic to the consumer. However, this analysis does not guarantee that a preservative system will never allow the growth of a contaminant in a product [8]. Overall, the quality control methods used by pharmaceutical manufacturing companies, in addition to strict FDA regulatory oversight, ensure that manufactured parenteral drug products are sterile prior to administration. However, associated regulatory procedures should be updated or modified to truly guarantee the sterility of all products. For example, when cGMP compliance is not met, products should be removed from the market immediately upon discovery and a recall issued to ensure they are not used. Additionally, sterility testing methods and protocols used to test preservative efficacy should be updated to include more sensitive assays. Maintaining high standards in manufacturing and quality practices provide customer assurance that a product is indeed safe to use. Pharmaceutical Compounding Companies Compounding pharmacies are companies that combine or process FDA approved drug products to produce individualized medications to fit the unique needs of a single patient. They are often called upon when patients require limited dose strength, a unique or specialty formulation, or allergenfree medication. Presently, compounding facilities are predominantly regulated by individual state Pharmacy Boards with oversight by the FDA. Section a of the FDCA defines the purpose of drug compounding and what practices compounding pharmacists must follow. Furthermore, this law clarifies that compounded products must be prepared in limited amounts and should not be produced when commercially available drug products exist. However, due to the limited volume of compounded products produced in each lot, this law exempts legitimately prescribed and prepared compounded drugs from review, approval, adverse event reporting, and placement of storage and labeling requirements on product vials [9]. Problems arise when compounding pharmacies function outside the FDCA regulations by operating as drug manufacturers. By functioning in this inappropriate capacity, compounding companies risk producing large quantities of adulterated drugs that are not manufactured under cGMPs, not properly controlled for quality, and are not FDA-approved. Thus, the sterility of compounded products received by patients cannot be guaranteed. This standard details sterility testing procedures including sampling the air, preparation surfaces, and gloved fingers for viable microbial particulates. In these particular tests, any colony forming unit counts that exceed the respective action level require identification of the source of contamination and subsequent re-evaluation of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency. Because of the continued regulatory leniency over quality control and sterility testing procedures, there have been multiple microbial outbreaks associated with compounded parenteral products. A recent example includes numerous hospitalizations and deaths attributed to contaminated parenteral steroids produced by the New England Compounding Center NECC [10]. Patients who received the tainted steroid product were documented to have primarily suffered from fungal meningitis as well as strokes, spinal osteomyelitis, epidural abscesses, or fungal infections associated with peripheral joints [10, 11]. In addition to this recent outbreak, there have been other past incidences of contaminated compounded parenteral drugs resulting in patient sickness and death. These include tainted cardioplegia solutions produced in by Central Admixture Pharmacy Services Inc. Regardless of the increasing number of hospitalizations and deaths associated with contaminated parenteral drugs, regulations governing the quality control of pharmaceutical compounding have yet to be legally

updated; however, it is not from a lack of trying. In the past decade, there have been several efforts to establish additional FDA oversight on pharmacy compounding. One example includes an attempt in to introduce the Safe Drug Compounding Act, which would have provided the FDA with authority to restrict when doctors could order injectable drugs from compounding pharmacists, limit interstate distribution of compounded drugs, and establish requirements for sterile compounding. Moreover, those opposed claim that the FDA does not have the right to impose a ban on traditional compounding practices, as the FDA Modernization act of , which amended the FDCA, was created to ensure the continued availability of compounded drug products [9]. Though it is unlikely that the FDA will be able to legally enforce some of the aforementioned quality control regulations, the safety concerns associated with compounded parenteral products must be addressed and minimized. First, all compounding pharmacies that are functioning outside of FDCA regulations and operating as manufacturing companies should be required to register with the FDA and operate under FDA regulated cGMPs and sterility testing procedures. This will ensure that any pharmaceutical facility that manufactures a drug is regulated by a minimal set of quality control standards. Second, compounding companies should be required to report any adverse drug problems, such as microbial contamination or calculation errors, with the FDA. This would ensure that all patients who had been exposed to the product would be immediately notified and assisted. Lastly, all clinical health care facilities that purchase and distribute compounded medications should be required to provide a disclaimer to their patients. This warning would warrant that patients are well informed of the risks associated with compounded medications, which may lead to more individuals to immediately seek help upon use of a contaminated product. Conclusion Though it is the responsibility and ethical obligation of each pharmaceutical facility to produce parenteral medications of confirmed sterility, companies may fall short of their obligations. Over the past decade, failure of regulatory compliance has resulted in numerous hospitalizations and deaths attributed to contaminated products. In response to these outbreaks, both the enforcement of and the quality control regulations that pharmaceutical companies currently operate under must be scrutinized and updated. Currently, registered pharmaceutical manufacturers operate under strict FDA regulatory control. In contrast, compounding pharmaceutical companies are minimally regulated, do not require drug approval, and are not legally required to report the production of an adulterated parenteral drug. Additionally, many of these compounding companies regularly operate outside the boundaries of the FDCA by functioning inappropriately as a drug manufacturer. Because of lax oversight regarding product preparation and sterility, the quality of the drug supply is diminished. Thus, it is essential that the policies governing the sterility, operation, and production of all pharmaceutical products be addressed. Only with updated, effective regulations, procedures, and robust manufacturing and quality practices can patients be assured of the sterility of their medications. United States Pharmacopeial Convention. Larrimore, Parenteral Quality Control: Third, Revised and Expanded ed, ed. The Need for a New Microbiology Curriculum. J Pharm Sci, Shi, Antimicrobial preservative use in parenteral products: Eur J Parent Pharm Sci, Federal Food, Drug, and Cosmetic Act. Recall of Certain Injectable Drugs. She received her Ph.

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

4: 13th Annual PDA Global Conference on Pharmaceutical Microbiology

This reference surveys emerging trends, concepts and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction and validation of new parenteral facilities; and the monitoring of clean environments.

Poor water solubility is an increasingly common issue in pharmaceutical development. When these drugs are introduced through traditional dosage forms such as oral solid dose they fail to dissolve and have limited bioavailability. As a result, insoluble drugs delivered through conventional forms have limited therapeutic effect and often fail. Though not as straightforward, there are multiple techniques available to increase the solubility of drugs and improve their delivery. Micronization and nanomilling are processes by which a drug is milled or ground down to decrease particle size. As the particle size decreases, the surface area-to-volume ratio increases. This allows for greater interaction with water, which improves solubility and dissolution rate. Particle size reduction is an efficient, reproducible process that allows large quantities of drug to be solubilized at once. For some drugs, poor solubility is a direct result of a stable crystalline form that water cannot efficiently penetrate. The amorphous form of drug is often more soluble because less energy is required for dissolution. As a result, solid dispersions were developed that distribute the drug in a carrier polymer such as HPMC, preventing it from crystallizing. These amorphous solid dispersions can be produced via hot melt extrusion HME or spray drying SD processes. There are a wide variety of encapsulation technologies used in drug delivery, including lipid- and polymer-based systems. And the use of particle-based formulations allows drugs to be encapsulated in a highly soluble form. These technologies offer many attractive attributes for drug delivery, including improved bioavailability, delivery of high doses, protection of the drug from harsh environments, targeted biodistribution of drug, and sustained release of therapeutics. The underlying technologies behind most encapsulated products include: Over fifty of these drug products have been approved by the FDA and many more are in clinical development. In addition to the above techniques, there are other methods to solubilize drugs, usually involving some combination of pH modification, salt forms, co-solvent systems, surfactants, or complexation with an excipient like cyclodextrin depending on the physicochemical properties of the API. What Makes Them Complex? It is critical to have experience formulating and processing these form factors to understand these uncommon drug-excipient interactions and to have the unique analytical expertise to investigate properties such as particle size or encapsulation efficiency. Implantable drug-eluting systems e. For instance, they can provide localized, site-specific drug delivery, improving the effectiveness of treatment and minimizing side effects. Drug-eluting systems can also be tailored to provided extended release of a drug. These long-acting dosage forms can improve patient compliance because they require fewer doctor visits and dosages than traditional therapies. Drug-eluting systems are combinations of drug and polymer wherein the polymer acts as a vehicle to deliver the drug. There are two categories of drug-eluting systems: Biodegradable drug-eluting systems also referred to as bioabsorbable use biocompatible materials such as Poly Lactic-co-Glycolic Acid PLGA to deliver drugs decompose in the body over time. Examples of biodegradable drug-eluting systems include: Biodurable drug-eluting devices can be designed as matrix, reservoir, or osmotic systems to deliver drugs via diffusion or osmosis. Other examples of biodurable drug-eluting systems include subcutaneous implants, osmotic pumps, and refillable ophthalmic implants. The function of drug-eluting systems is heavily dependent on drug-polymer interactions, so polymer selection is a critical part of the formulation process. The selected polymer or polymer blend must provide the desired release profile, drug stability, and compatibility for the application. Additional analytical methods must often be developed to assess drug content, state, and uniformity within a polymer. Drug-eluting systems also employ unique routes of administration; therefore, drug release must be modeled differently than traditional dosage forms like oral or parenteral. And since device manufacturing through HME or injection molding often involves elevated temperatures, the thermal

stability of the drug in the polymer must be determined early on. The complexity of drug-eluting systems stems from these unique considerations that follow throughout the formulation process. Sterile Products Why Use Them? The FDA requires certain types of drug products to be provided as a sterile dosage forms to avoid the possibility of microbial degradation or infection occurring because of their use. This includes several types of drug products, including injectables small or large volume parenteral products , ophthalmic drugs, otic dosage forms, and implantable products. Sterility of finished dosage forms can be assured via different processesâ€"either terminal sterilization or aseptic manufacturing. The terminal sterilization process usually involves filling and sealing product containers under high quality environmental conditions designed to minimize microbial and particulate contamination of the product. This minimization of upstream bioburden the number of microorganisms on a surface reduces the challenge to the subsequent sterilization. The product is then subjected to a validated sterilization process e. Products that cannot be terminally sterilized due to factors such as API degradation must be aseptically manufactured. Aseptic processing presents a higher risk of microbial contamination than terminal sterilization. In an aseptic filling process, the drug product, containers and closures are sterilized separately and then brought together under an extremely high quality environmental condition designed to reduce the possibility of a non-sterile unit. Any manual or mechanical manipulation of the sterilized drug, containers, or closures prior to or during aseptic filling and assembly poses the risk of microbial contamination. The manufacture of sterile products is subject to special requirements in order to minimize risks of microbiological, particulate, and pyrogen contamination. Much depends on the skill, training, and attitudes of the personnel involved. Quality Assurance is particularly important, and sterile product manufacturers must follow established and validated methods of preparation and procedure. Here are just some of the requirements that must be accounted for during sterile operations: Cleanroom Architecture â€" Cleanrooms are rooms designed, maintained, and controlled to prevent particle and microbiological contamination of drug products. Air cleanliness in cleanrooms is maintained using tools like High Efficiency Particulate Air HEPA filters, room pressurization sequences, and air change rates. For handling of sterile products, critical areas ISO 5, Grade A must be identified to provide the highest level of control to maintain sterility. Air Filtration â€" In addition to the HEPA filters used in cleanrooms, there are many other filtration mechanisms to remove particles from gases and liquids used in pharmaceutical manufacturing. These filters are essential for providing effective contamination control. These processes must be validated as part of the overall sterilization validation strategy. Personnel â€" Personnel pose the greatest risk to the sterility of finished dosage forms. As operator activities increase, the risk to finished product sterility also increases. To ensure product sterility, it is critical for operators to use proper aseptic technique at all times and employ proper application and use of cleanroom gowning materials. These drugs produce an effect on the body even at low concentrations. Controlled substances such as opioids have high addiction potential and require strict documentation and interaction with the DEA. However, many of these drugs are essential for treating conditions such as acute pain or CNS disorders. Potent compounds are typically categorized based on therapeutic class and an acceptable daily exposure limit ADE , a dose that is unlikely to cause an adverse effect if an individual is exposed, by any route, at or below this dose every day for a lifetime. The list is divided into five schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. Schedule I controlled substances have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Most pharmaceutically relevant substances fall into schedules II-V. Examples of schedule II drugs include fentanyl, amphetamine, and pentobarbital. Schedule V drugs often contain limited quantities of certain narcotics, like a cough preparation containing a low dose of codeine. Both classes of compounds come with increased risk profiles and require extra paperwork and enhanced containment. Before an HPAPI is introduced to a facility, a thorough literature search on hazards and a handling strategy must be completed. There are facility requirements, including physical systems to shield controlled substances from the external

environment. Employees are also subjected to regular scrutiny from the DEA, who can audit a facility and its operations at any point to maintain licenses to manufacture, store, and distribute controlled drugs. There are similarities in the level of preparation and protocols that are required for HPAPI and controlled substance handling. Both necessitate specialized training, planning, and facilities, and in some cases, drugs may even fall into both categories. Any company looking to develop products with these drugs must be willing and able to address the added responsibilities that accompany them. Conclusion This is the first entry in the Particle Sciences Blog. In this post, we provided an overview of complex drug products, including definitions and a discussion of the unique expertise that these products demand. We look forward to sharing our expertise and educating others in the exciting world of complex drug delivery.

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

5: Microbial Contamination Control in Parenteral Manufacturing: 1st Edition (Hardback) - Routledge

be welcomed by all involved in parenteral www.enganchecubano.com value of this book is much more than as a guide to contamination control; it is the setting of each chapter within a wider and engaging context that makes this publication unique."-European Journal of Parenteral and Pharmaceutical Sciences.

The Cost of Microbial Control by: Microbial controls can be found throughout the manufacturing process including, but not limited to, raw materials, equipment, cleanroom environments, finished product manufacturing, and storage and shipping processes. Bioburden control programs are also essential for both sterile and nonsterile manufacturing. Many similarities exist between bioburden control and contamination controlâ€”in fact, the terms are frequently used interchangeablyâ€”however, the differences can result in ineffective or excessive control programs for sterile and nonsterile products. Nonsterile products are allowed to possess certain types and levels of bioburden within the manufacturing process and in the final product. The challenge for a nonsterile manufacturer, therefore, is identifying how to control bioburden and achieve microbial contamination control without implementing sterile manufacturing requirements. In contrast, sterile products must be devoid of microorganisms, yet are produced in manufacturing facilities that possess a microbiome that can never be removed entirely. For a sterile manufacturer, the challenge is identifying effective controls with an appropriate level of redundancy that ultimately assure product sterility. But why is bioburden and microbial control so critical? Failure to adequately control bioburden or microbial contamination has the potential to significantly impact patients receiving sterile or nonsterile products. Consequently, ensuring that the manufacturing environment and processes are well controlled is essential. The costs of resolving product quality problems and cGMP compliance issues arising from poor microbial control or recurring microbial contamination should eclipse concerns about operational costs. Naturally, a recall due to microbial contamination presents a financial drain for a manufacturer. Moreover, the most prevalent reason for recalls of over-the-counter drugs and personal care products was contamination of nonsterile product with objectionable microorganisms 2. Robust processes that assure product quality, especially in terms of bioburden and contamination control, rather than a heavy reliance on testing microbial enumeration, sterility, etc. FDA advised drug manufacturers that Burkholderia cepacia complex poses a contamination risk in nonsterile and water-based drug products. The Agency reminded manufacturers of the importance of developing effective microbial contamination control and root cause investigation strategies to avoid adverse events or quality problems 4. Over the past few years, numerous repeated recalls of high profile products, including sterile large volume parenterals, small volume parenterals and nonsterile dosage forms, have occurred 5. These two elements are among the top ten most-observed deficiencies by the U. FDA since 7. Bioburden and microbial contamination control is technically challenging with the potential for significant adverse patient impact and financial implications for the manufacturer. With this in mind, how can pharmaceutical microbiologists become more informed in order to ensure their microbial control processes and systems are sufficient? The goal of the conference is to solve microbiological challenges and sustain success through a culture of collaboration. Several case studies on effective root cause investigation and collaboration between departments and suppliers to address recurring microbial contamination will be presented in this session moderated by Edward Tidswell, PhD, Executive Director, Microbiology QA. The pharmaceutical industry is facing pressure to continuously challenge and improve its manufacturing processes to achieve regulatory compliance and produce high quality product. New technologies to improve microbial control, support root cause investigation and provide faster response are expected to become available over the next few years. Thus, the conference will also present innovative, next-generation microbiological methods and regulatory updates to ensure companies are up to date on the best methods to ensure microbial safety for patients. Sutton, S, and Jimenez, L.

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

6: What are Complex Drug Products? | Particle Sciences

Historical and emerging themes in parenteral manufacturing contamination control / Kevin L. Williams --Microbial contamination hazard analysis in sterile product manufacturing / Simon Rusmin --Overview of modern parenteral products and processes / Arvind K. Bansal --The role of USP in the microbiological assessment of parenteral manufacturing.

7: Microbial Contamination Control in Parenteral Manufacturing - CRC Press Book

Microbial Contamination Hazard Analysis In Sterile Product Manufacturing. Overview Of Modern Parenteral Processes. The Role Of USP In The Microbiological Assessment Of Parenteral Manufacturing.

MICROBIAL CONTAMINATION IN PARENTERAL MANUFACTURING (DRUGS AND THE PHARMACEUTICAL SCIENCES) pdf

Technology Executives World and Other Places (Signed Edition) Digital image processing ebook Facts about clouds Reel 601. December 15-31, 1892 Envy, and other works Green grass grew all around Some concluding thoughts and suggestions. Toyota financial services business credit application 8k high resolution camera system seminar report How to survive a bachelor party (The bachelor Wendy Merrill New market leader intermediate practice file 24 Flower Quilt Blocks Ancient coin collecting MCSE Windows NT server 4 for dummies Legally Safe Mental Health Practice The Gambling Times guide to harness racing FireWire(R System Architecture Movie industry book The story of civilization will durant Guide to the reptiles and batrachians exhibited in the Department of zoology of the British museum (Natur Adventure (1870-1875) Statements by Orthodox, Conservative and Reform rabbis on the architecture of the synagogue. 189th Quartermaster Gas Supply Company Support Battery Self-regulation in a / Updike, Rabbit, and the myth of American exceptionalism Donald J. Greiner Umikers management skills seventh edition Crohns and colitis diet guide includes 175 recipes Listening for the visually impaired Study of heredity of insanity in the light of the Mendelian theory Grass seed in June The Holy Grail And The Medieval Magician Essentials of health economics Hyperbolic Differential Polynomials The British brothers All the best in South America, east coast: Venezuela, Surinam, Brazil, Paraguay, Uruguay, Argentina. Interview questions for mechanical design engineer freshers The movement and the sixties terry anderson Show; Dont Tell! Isolation of Biotechnological Organisms from Nature