COMPOUNDING PHARMACIES

MARKET OVERVIEW

Compounding pharmacies from an inspection perspective are classified as sterile or non-sterile facilities, some do both. Sterile processing facilities produce prescriptive custom medication mixtures that are ingested, infused, injected or applied topically to include the eyes.

Compounding pharmacies range in size from single clean room to multi clean room processing facilities. They can be stand alone or part of a larger health care facility such as a hospital. Larger hospitals have compounding operations, which are a very profitable activity in the hospital infrastructure.

Compounding pharmacies are at the moment unregulated in comparison to pharmaceutical manufacturing companies such as Merck or Pfizer. These companies come under direct supervision of the FDA. The basic difference is that compounding pharmacies make specific drug mixtures predicated on a direct unique prescriptive request from a physician or veterinarian, while pharmaceutical companies manufacture large batches of prescription drugs for general public consumption.

The operational regulations in place for "all" compounding pharmacies (to include hospitals), which as noted are minimal compared to pharmaceutical manufacturing companies, are written by United States Pharmacopeia (USP), a quasi-governmental organization founded in 1820 (http://www.usp.org/about-usp). Its drug standards are employed in over 140 Countries. USP works hand in hand with the FDA, State Pharmacy Regulatory Boards and The Joint Commission (JCAH0). USP **only writes** regulations. Enforcement is the responsibility of the FDA and respective State Pharmacy Regulatory Boards. Inspections by either entity can occur at any time and are unannounced. However, the FDA and State Pharmacy Boards typically do not play well together and their inspection efforts are usually not coordinated.

Of particular concern to the industry recently are newly minted regulations from USP, specifically Chapter 800, which promulgates a whole new set of standards to protect employees in these facilities in relation to general safety, surface and air quality and associated control protocols. Air and surface disinfection requirements are a major part of these new regulations. They stipulate air and surface parameters, but cannot and do not specifically recommend products or procedures to achieve these enhanced standards. These unknowns are what is causing major concern in the industry, as when an inspection team does walk through the door they don't know what the inspectors

are looking for in relation to policies and procedures, let alone disinfection chemicals or other disinfection technologies.ie: are they good enough to satisfy the inspectors predicated on the vagueness of the new regulations.

That, conjunctive with the unfortunate fungal meningitis out break at The New England Compounding Pharmacy that produced in excess of 14,000 doses of contaminated steroidal injections resulting in multiple deaths and injuries have accelerated this scrutiny from the FDA, State Pharmacy Boards and USP. Direct regulation of the industry is inexorable and inevitable. Most compounding pharmacies currently employ manual disinfection cleaning techniques using a variety of disinfection bactericides, sporicides, virucides and fungicides. Studies have shown that even the best terminal manual cleaning protocols only achieve a 40-60% reduction in residual bio-burden.

Consequently, forward thinking, innovative compounding operations are strategically reacting to this increased regulatory and inspection activity by implementing comprehensive decontamination protocols to preempt outbreaks or chronic contamination problems at their facilities, as well as pragmatically and consistently reducing overall facility bio-burden. Touchless, total room disinfection systems such as the Sanosil Halo Disinfection System that offer a consistent and comprehensive disinfection capability with a 99.9999% kill on all known pathogens on all exposed surfaces can insure that all of these new regulations regarding surface disinfection are met or exceeded. An insurance policy for the facility operator so to speak.

The Sanosil Halo Hydrogen Peroxide Disinfection System, which can be used for room/area or equipment decontamination is lightweight, portable, colorless, odorless, quiet, eco-friendly, effective, and economical. The Halo Disinfection System assures a homogeneous mist of ionized particles that migrates to areas that regular cleaning can't or don't reach, to include high touch areas around doors, behind window treatments, and even under desks, chairs and rails. The Halo Disinfection System will kill 99.9999 % of all bacteria, viruses, fungi, spores and mold on pre-cleaned hard surfaces, without harming sensitive electronics, surfaces or substrates. The Sanosil Disinfecting Solution can be sprayed or fogged**, NO WIPE.**

The Sanosil Halo Disinfection System is EPA Registered, No. 84526 -1,6. For additional information, please refer to our website at http://www.safetynetamerica.com or view the industrial video at http://sanosilinternational.com/halo-disinfection-system.

Compounding pharmacy user references are available upon request.