PCS
PROCESS CONTROL SOLUTIONS

CASE STUDY

Custom Gruenberg Pharamceutical Oven:
FDA / GMP Compliant

When it comes to purpose-built custom dry heat sterilizers and dryers designed to meet FDA and GMP standards, very few companies consider it a core competency. However, PCS and Gruenberg have extensive experience in this area and can guide you through the process of defining the ideal equipment to meet the unique requirements of your project. Below is an example of one such successful project.

Current Good Manufacturing Practice Regulations:

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMP. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

U.S. Food and Drug Administration. (n.d.). Current good manufacturing practice (CGMP) regulations. Retrieved from https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

Situation:
A global supplier of disinfection solutions for the medical device sector is developing a new product that must meet FDA standards. They require equipment capable of performing the sterilization step in the manufacturing process. The product's novel formulation demands precise sterilization to ensure safety without compromising the product or posing risks to users.

Problem:
The product is solvent-based and heat-sensitive, requiring a low, uniform heat source. The sterilization cycle must include rapid temperature transitions to maintain strict exposure limits. The equipment must also be installed in a clean GMP manufacturing area, with space at a premium, necessitating a compact design. As the product's size range evolves, the equipment must be flexible to accommodate future changes.

Solution:
The required equipment does not exist in a standard form, so Gruenberg engineers developed a custom solution. The proposed dry heat sterilizer features a stainless-steel interior and exterior, Class A design, MSA solvent detectors for safety, HEPA filtration, tunable duct walls with VFD for uniformity, a versatile tray design to fit various applicator sizes, and a stand-alone chiller for rapid cooldown rates.

Conclusion:
Despite the challenges of the COVID pandemic, the Gruenberg team successfully designed, built, tested, and installed the equipment on time. TPS was able to host a customer-attended Factory Acceptance Test at the New Columbia, PA facility, ensuring a successful solution deployment.

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