A fact sheet from THE PEW CHARITABLE TRUSTS | July 2015

Pharmaceutical Compounding: Quality Standards for Different Types of Risk

This fact sheet was updated in March 2018 to improve clarity.

Overview

Different types of drug compounding carry different risks, which can be mitigated by applying appropriate quality standards—requirements for how drugs are made and stored to prevent dangerous contamination or other problems.

For traditional pharmacies that dispense drugs one prescription at a time, the United States Pharmacopeia (USP) developed standards to minimize risks. Its standards for sterile compounding are called USP <797>, and most states require traditional pharmacies to follow them.

For outsourcing facilities that compound stock supplies of drugs, which pose a greater safety risk because of their typically longer shelf life and larger batch sizes, the Food and Drug Administration requires quality standards similar to the Current Good Manufacturing Practices (CGMP) that apply to drug manufacturers.

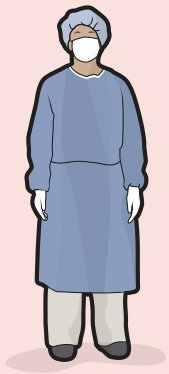
Current Good Manufacturing Practices

Quality standards that apply to outsourcing facilities making sterile drugs

Personnel must be **completely covered with sterile gowning** (no exposed skin).

USP <797>

Quality standards that most states apply to traditional pharmacies making sterile drugs



Gowning required, but **only gloves must be sterile**. Neck and face may be uncovered.

Human skin can carry many kinds of bacteria and fungi, making the people who produce sterile drugs the greatest potential source of contamination.

Manufacturers **must test** nonsterile ingredients to be used in sterile drugs for pre-existing contamination.

Compounding pharmacies are **not required to test** for contaminants in nonsterile ingredients.

Contaminants in nonsterile ingredients can end up in a finished drug. Advance testing allows producers to reject highly contaminated materials.

Daily monitoring for contamination is required in the manufacturing space, including during or immediately after production.

Monitoring for contamination is **less frequent**. Air particulate levels are checked twice yearly.

Contamination in production environments can cause contamination in a drug. Frequent checks for contaminants in the air and on surfaces and personnel can help prevent this.

References

1 U.S. Food and Drug Administration, "Current Good Manufacturing Practice for Finished Pharmaceuticals," Code of Federal Regulations, Title 21 Part 211, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211.

2 U.S. Food and Drug Administration, "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice," http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070342.pdf.

3 U.S. Pharmacopeial Convention, "Chapter 797: Pharmaceutical Compounding—Sterile Preparations."

4 Eric S. Kastango and Kate Douglass, "Quality Standards for Large Scale Sterile Compounding Facilities," Clinical IQ LLC (May 2014), http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/05/21/ensuring-the-safety-of-compounded-drugs.

For further information, please visit:

pewhealth.org/drugsafety

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