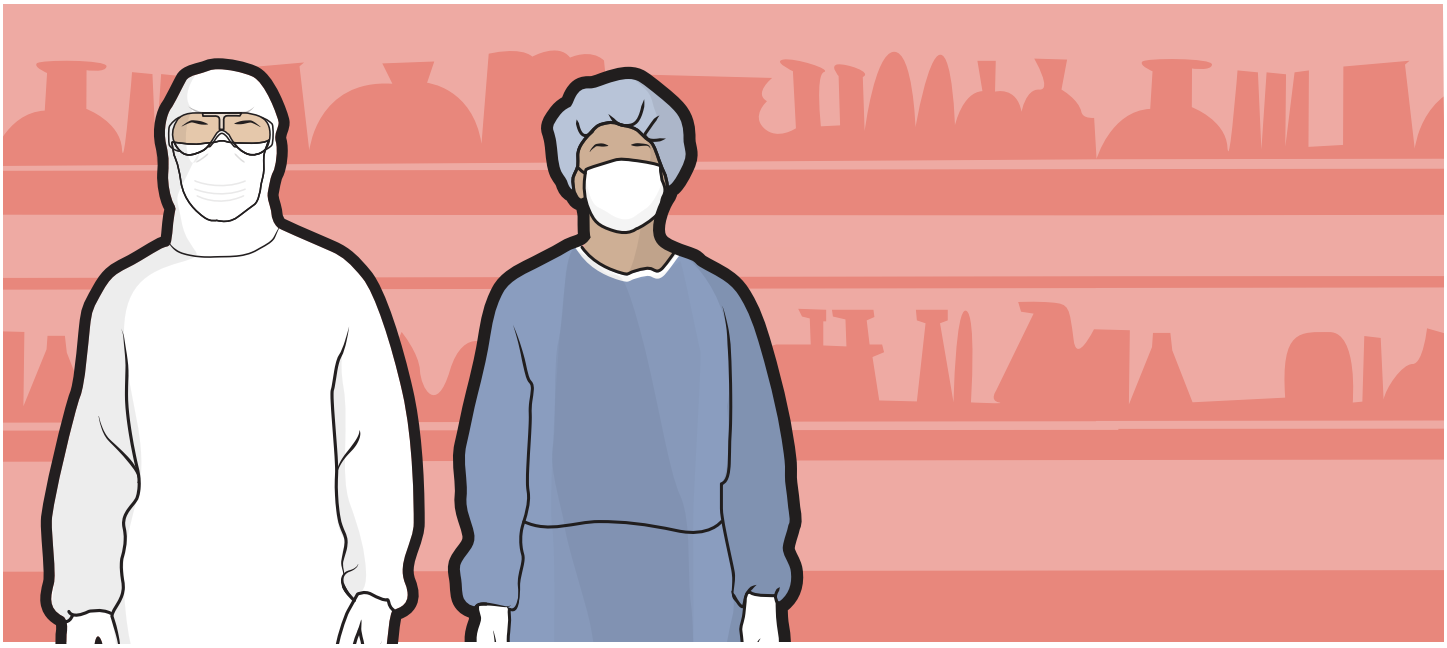
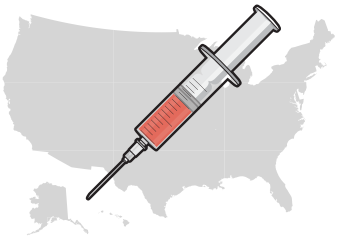
A fact sheet from THE PEW CHARITABLE TRUSTS | July 2015



Pharmaceutical Compounding: Quality standards for different scales



751 infected | **64** deaths

In 2012-13, the U.S. experienced a nationwide **outbreak of fungal meningitis** linked to **contaminated injections** made by a compounding pharmacy. Patients in 20 states were affected.

When compounded drugs are created in large volumes and shipped across the country, as was the case with injections linked to the national meningitis outbreak, producers should meet some of the same quality assurance requirements as do drug manufacturers. The standard pharmacy compounding controls are not enough. A federal law passed in 2013 establishes a new category of compounding "outsourcing facilities" that will meet these higher standards, providing a safer source of compounded drugs made and purchased at larger scales. In response to the law, state policymakers may need to revisit regulations on compounding that goes beyond traditional pharmacy practice.

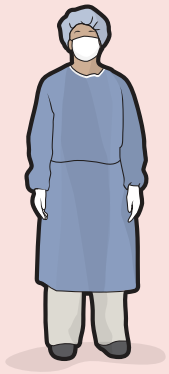
Good Manufacturing Practice*

Quality standards that drug manufacturers and "outsourcing facilities" must follow when making sterile drugs

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

USP 797*

Quality standards that traditional compounding pharmacies must follow when 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.

*Quality standards—what are the differences?

Drug manufacturers are required to meet Good Manufacturing Practices—rigorous requirements enforced by FDA that describe a full set of quality systems for the manufacture, processing, and packing of pharmaceutical products.

Under the Drug Quality and Security Act of 2013, **large-scale compounders that voluntarily register with FDA as "outsourcing facilities" must meet many of the same quality standards as drug manufacturers.**

Pharmacies compounding sterile drugs should follow the U.S. Pharmacopeial Convention, Chapter 797—a standardized compounding quality system that, while appropriate for traditional compounding, is not adequate to ensure the safety of large-scale sterile compounding practices.

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 Kastango, E., and K. 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.

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