

FDA's COMMITMENT TO PHARMACEUTICAL QUALITY



What is pharmaceutical quality?

A quality product of any kind consistently meets the expectations of the user. Drugs are no different. They must be manufactured using quality standards that ensure every dose is safe, effective, and able to provide its intended benefit.



How does FDA assure quality medicines are available to the American public?

FDA assesses all drugs before approval to assure the manufacturer is capable of meeting established quality standards. This includes evaluating data on the drug product as well as drug manufacturing processes and facilities. Beyond application assessment, FDA also inspects manufacturing facilities, monitors the state of quality of drugs on the market, encourages the use of modern manufacturing technologies, and conducts science-based research to support quality standards.



How does pharmaceutical quality impact patients and consumers?

Quality is what ensures every dose of a drug is of the appropriate strength – not too weak and not too strong – and free of contamination and defects. It is what gives patients and consumers confidence in their next dose of medicine. Problems with quality can create shortages, which may make drugs unavailable when patients need them. FDA works with manufacturers to prevent shortage risks from developing into actual shortages.



Does FDA have the same expectations for the quality of a drug made in the U.S. or abroad? Brand-name or generic?

FDA has the same expectations for quality whether a drug is made in the U.S. or abroad and whether a drug is brand-name or generic. You can have confidence knowing that all FDA-approved drugs are held to consistent quality standards regardless of the source. Drug quality requirements apply to all manufacturing facilities, domestic and foreign, and across human drug product areas: brand-name, generics, biologics, biosimilars, and over-the-counter.



What should I do if I suspect a problem with the quality of a drug?

Even when manufacturers are very vigilant, sometimes quality issues arise after drug approval. You can report suspected quality issues with a drug directly to FDA using the MedWatch system. Visit www.fda.gov/medwatch to easily find the online reporting form for health professionals.