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About PCCA

Do Compounded Medications Require FDA Approval?

The FDA approval process is intended for mass-produced drugs made by manufacturers. Because compounded medications are personalized for individual patients, it is not possible for each formulation to go through the FDA's drug approval process, which takes years to complete and is prohibitively expensive, often costing hundreds of millions of dollars.

About PCCA

PCCA is an independent compounding pharmacy's complete resource for fine chemicals, devices, equipment, training & support.

About PCCA

What is PCCA?



History

More than three decades ago, a physician encountered a patient who required an anti-nausea medication that was no longer commercially available. The physician challenged a Houston-area pharmacist to compound the medication, so the pharmacist consulted with his peers and procured the chemicals necessary to prepare it.

The prescription was a success, and the pharmacist realized that others in his field faced similar demands to help patients who require compounded medications. This network of pharmacists, united by a commitment to meet patient needs, was the foundation of PCCA (Professional Compounding Centers of America), which was incorporated in 1981.

Today, PCCA has become the independent compounding pharmacist's complete resource for fine chemicals, equipment, devices, flavors, ACPE-accredited training and education, pharmacy software, marketing, business and pharmacy consulting assistance. Our membership includes more than 3,900 independent community pharmacists in the United States, Canada, Australia, and other countries around the world.

Quality

PCCA offers unparalleled quality control and quality assurance.



PCCA's Quality Control department is exhaustively devoted to assuring the quality of the chemicals received, repackaged, and sold to our members. From the moment a chemical arrives to the time it ships to a member, it is monitored by Quality Control and Quality Assurance personnel. The dedicated QC lab performs as many as nine qualitative analyses on each chemical lot, and reviews the results and specifications of the Certificate of Analysis.

If the product is compromised in any way, it fails the inspection and is rejected. Inspection of incoming materials is paramount to the quality system and compliance with current Good Manufacturing Practices and Regulations.

Steps include:

- Obtaining a Certificate of Analysis for all chemicals received
- Verifying the identity of every bulk chemical received before repackaging and completing a second identity test after repackaging
- Conducting regular tests of all chemicals in inventory
- Verifying all unique identifier numbers prior to shipping.

As a distributor and repackager of both Active and Non-Active Pharmaceutical Ingredients for pharmacy compounding, PCCA is registered and inspected by the FDA and DEA. The company is licensed in the state of Texas and all other states where licensure is required.



[Click here to find out more about PCCA's quality processes.](#)

Education

PCCA provides the Comprehensive Compounding Course (C3) and Aseptic Technique compounding course in our in-house training laboratories. These hands-on courses provide pharmacists and their pharmacy technicians with a

forum for learning the latest innovations in compounding unique dosage forms. In addition, the curriculum includes discussion of quality and safety procedures, legal issues, and marketing technique.

PCCA also conducts Accreditation Council for Pharmacy Education (ACPE)-accredited continuing education programs in the form of seminars and symposiums to provide pharmacists and physicians with ongoing opportunities to earn continuing education credit, practice compounding techniques according to USP <795> and <797> standards, and learn as effective methods of building patient and practitioner relationships. These programs also provide invaluable networking sessions where colleagues share what has worked well for their compounding practices and emphasize the critical importance of the triad relationship – the patient, prescriber and pharmacist.

Find out more about PCCA's educational offerings here.

Pharmacy Consulting

When pharmacists join PCCA, they gain access a staff of more than 30 pharmacists, PhDs, and chemists who fill a variety of roles, including consulting for members, R&D, and formulation development, ready to serve their technical support needs. On average, PCCA's Pharmacy Consulting Department answers more than 600 consulting calls a day from member pharmacists who have technical questions about preparing medications for patients.

Members and consultants have access to a database of more than 8,000 proprietary formulas that have been pre-tested with PCCA's fine chemicals and are continuously reviewed and updated. PCCA's staff draws upon a library of more than 800 pharmacy and medical references. All this adds up to the most comprehensive pharmacy consulting resource in the profession.

In addition to their consulting roles, PCCA's staff pharmacists also participate in ongoing ACPE-accredited training and educational courses, helping to educate prescribers and patients regarding the benefits of compounding. PCCA also maintains close, working relationships with several universities. In fact, PCCA is a dedicated rotation site for the University of Houston's College of Pharmacy.

Our Mission

PCCA's mission is to strengthen the role, position and skills of member compounding pharmacists so they can meet the unique healthcare needs of patients through our exceptional service, highest-quality products, shared innovations and education.

One patient. One prescriber. One pharmacist. A triad relationship with a common goal: achieving a positive therapeutic outcome for the patient. And in the midst of this relationship and this common goal is PCCA, the leader in pharmacy compounding since 1981.

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Contact PCCA

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