

In the past, Compounding Was Pharmacy! Throughout history, pharmacists compounded drugs for patients when they were prescribed by physicians. In the early 1900s, however, the pharmaceutical industry began manufacturing most drugs and dosage forms for patients and the need for compounding diminished. Since the late 1900s, however, a lot has changed and the pharmaceutical industry no longer supplies all the medications needed by patients, and pharmacy compounding has experienced tremendous growth. It has not, however, been without its detractors. True, there have been some difficulties along the way, but recently great strides have been made to enhance quality pharmacy compounding, including the following.

PHARMACY COMPOUNDING ACCREDITATION BOARD

A consortium of eight national pharmacy organizations have worked together to establish the Pharmacy Compounding Accreditation Board. This Board begins the process of accrediting compounding pharmacies in the spring of 2005. The accreditation standards are quite rigid and require documentation of a quality operation. Although voluntary, there are potentially some distinct advantages to becoming an accredited compounding pharmacy.

U.S. PHARMACOPEIA-NATIONAL FORMULARY

Beginning in 1985 at the U.S. Pharmacopeial Convention, a resolution regarding pharmacy compounding was passed, and this has been followed by resolutions at the 1990, 1995, 2000, and the 2005 conventions concerning increased efforts in establishing pharmacy compounding standards and especially efforts related to special populations (pediatrics). In recent years, two enforceable general chapters have been implemented, including *USP* Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations, and *USP* Chapter <797> Pharmaceutical Compounding—Sterile Preparations. In addition, two additional *USP* informational chapters are in effect, including, *USP* Chapter <1075> Good Compounding Practices, and *USP* Chapter <1160> Pharmaceutical Calculations in Prescription Compounding. A new chapter on Quality Control in Pharmacy Compounding is being prepared. In addition to the General Chapters, the *USP-NF* currently contains approximately 200 monographs related to pharmacy compounded preparations. The U.S. Pharmacopeial Convention has recently hired additional laboratory staff to establish beyond-use dates for new monographs for the *USP-NF*.

US PHARMACOPEIA-PHARMACISTS PHARMACOPEIA

The *U.S. Pharmacopeia* was originally developed for pharmacists. However, the emphasis of the current *USP-NF* is directed towards the pharmaceutical industry. The *USP-Pharmacists Pharmacopeia* will be launched in the summer of 2005. This set of compounding standards can be enforced by the State Boards of Pharmacy, as well as the US Food and Drug Administration. The *USP-Pharmacists Pharmacopeia* will be divided into two sections. Section one contains monographs for compounding substances and excipients and monograph standards for compounded preparations, as well as general chapters related to compounding standards. Section two contains supportive information for quality pharmacy compounding. This compendium will be continually revised and updated.

AMERICAN COUNCIL ON PHARMACEUTICAL EDUCATION (ACPE)

The ACPE has requested performance outcomes related to pharmacy compounding. These will be presented to ACPE this spring for consideration for implementation in the curriculum of accredited Colleges of Pharmacy throughout the U.S. ACPE standards are required for accreditation of Colleges of Pharmacy.

AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY (AACP)-TEACHERS OF PHARMACEUTICS

The Teachers of Pharmaceutics section of AACP is surveying its membership to determine the current status of pharmaceutics and compounding in the curriculum. The in-depth survey is designed to identify course content that is either taught as separate, free-standing courses, or as an integrated component of other courses.

PHARMACY COMPOUNDING EDUCATIONAL PROGRAMS

Many pharmacy compounding support companies, as well as the *International Journal of Pharmaceutical Compounding*, provide programs and information on pharmacy compounding. In addition, there are several books as well as websites available (www.ijpc.com; www.compoundingtoday.com) that provide information to support pharmacists in all practice sites (community, hospital, home healthcare, etc.) in pharmacy compounding.

LABORATORY SUPPORT

Analytical support is provided by several laboratories throughout the U.S., many of which are FDA-registered and -inspected. Potency analysis, sterility and endotoxin testing is now commonplace. In addition to outsourcing to these laboratories, some pharmacies (community as well as hospital) use in-house testing as appropriate.