

Opportunities for Pharmacists at the US Food and Drug Administration

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A vast array of career opportunities for pharmacists is available, making it a worthy and marketable healthcare profession to pursue. This array of opportunities is accompanied by the need for plenty of background research to find the career path that fits a desired lifestyle. While changes in the direction of one's career can occur at any time, one should become aware of all opportunities available as a licensed pharmacist. Strategic career planning should begin as early as possible and is imperative to allow for the development of knowledge and skills for advancement and to avoid career pitfalls.

Many pharmacy students and residents are not aware of the numerous public health opportunities for pharmacists. A variety of public health opportunities for pharmacists are available at the US Food and Drug Administration (FDA). The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation. The FDA helps the public obtain accurate, science-based information needed to use medication and foods to improve and manage their health. The FDA has a complex organizational structure composed of offices and centers. The centers are composed of offices, which are further structured into divisions. This complexity attests to the FDA's substantial growth since its 1862 inception as the Bureau of Chemistry, in the US Department of Agriculture. Additional information about the FDA's history can be found at <http://www.fda.gov/oc/history/historyoffda/default.htm>. Links to charts displaying the FDA organizational structure are located at <http://www.fda.gov/opacom/7org.html>.

The FDA employs more than 300 pharmacists in more than 150 cities nationwide.

Pharmacists are employed in various positions within the FDA and have gained employment at various points in their careers. However, the majority of pharmacists hired have had at least 2 years of experience in clinical or community practice. Pharmacists are employed in the Office of the Commissioner, the Office of Regulatory Affairs, and within the six centers of the FDA.

Depending on experience and education, a pharmacist may work as a reviewer in clinical pharmacology, pharmacokinetics, pharmacology/toxicology, regulatory, or radiopharmacology. Also, pharmacists may work as regulatory health project managers, also known as consumer safety officers, in one of the offices under the Center for Drug Evaluation and Research (CDER) Office of New Drugs. The consumer safety officer position is an excellent starting

Table. Examples of Pharmacist Positions and Duties at the FDA, Center for Drug Evaluation and Research

Location	Title	General summary of duties
Office of New Drugs	Regulatory project manager/ consumer safety officer	Provide regulatory oversight and advice to multidisciplinary teams and pharmaceutical industry during the NDA approval process, coordinate the review of drug applications, serve as liaison between industry and FDA, facilitate internal FDA meetings and external meetings with industry
Office of New Drugs	Clinical analyst reviewer	Conduct reviews of clinical study protocols, review and evaluate reports and data from clinical trials submitted in INDs, NDAs, and BLAs to verify safety and efficacy of drug products. Provide advice on design of clinical studies, recommend approval of applications, and evaluate product labeling
OSE/Division of Pharmacovigilance or Division of Medication Error Prevention and Analysis	Safety evaluator	Review and evaluate spontaneous adverse event reports submitted by manufacturers, healthcare professionals, and consumers; review medication error reports; participate in risk management program development and monitor the impact of the program; participate in preapproval safety conferences between the FDA and drug sponsors and in FDA advisory committee meetings
OSE/Division of Epidemiology	Drug utilization data analyst	Analyze national drug utilization data obtained from specialized database searches as related to public health and safety concerns, collaborate with other divisions in OSE to evaluate the magnitude of adverse drug events and drug risk
Office of Medical Policy/Division of Drug Marketing, Advertising, and Communication	Regulatory review officer	Review and evaluate promotional materials for prescription drug products to ensure compliance with the federal Food, Drug, and Cosmetic Act and various regulations pertaining to the advertising of prescription drug products
Office of Training and Communications/Division of Training and Development	Director, health promotion officer	Advise and assist the director, Division of Training and Development, the Committee for Advanced Scientific Education, appropriate CDER coordinating committees, and related industry and academic organizations, scientific experts, and scientific staff throughout CDER, as well as FDA officials on the program planning, evaluation, and conduct of CDER's science-based educational activities. Prepare documents, including program management data, and correspondence related to the accreditation of CDER's continuing medical education and continuing pharmaceutical education programs. Assure compliance with criteria for administration, conduct, and evaluation of these programs
Office of Pharmaceutical Science/ Office of Generic Drugs/Division of Labeling and Program Support, Labeling Review Branch	Labeling reviewer	Verify that sponsor has submitted labeling in compliance with Code of Federal Regulations, serve as liaison between industry and FDA on issues related to label requirements, critically assess proposed labeling of approved abbreviated NDAs and supplements in terms of appearance, content, regulatory compliance, and safety
Office of Translational Sciences/ Office of Clinical Pharmacology	Clinical pharmacology reviewer/pharmacometrician	Conduct reviews of clinical pharmacology and biopharmaceuticals data and use technical tools (eg, modeling and simulation) in support of CDER's IND, NDA, and BLA review program to determine relevant clinical issues and exposure-response, drug-drug interactions, pharmacokinetics, effect of clinical pharmacology on dosing and administration, dosing regimen adjustments, and issues that impact labeling
Office of Compliance	Compliance officer	Conduct inspections of pharmaceutical manufacturing facilities to evaluate current good manufacturing practices (cGMPs) compliance, review inspection reports from other FDA investigators to determine need for regulatory or administrative action, initiate regulatory or administrative action ensuring corrected deficiencies, answer (cGMP) inquiries, provide oversight and advice to FDA staff and pharmaceutical industry on cGMPs and conducting pharmaceutical inspections, draft and review cGMP guidance documents, and train FDA field investigators

FDA indicates US Food and Drug Administration; IND, investigational new drug; NDA, new drug application; BLA, biological licensing application; OSE, Office of Surveillance and Epidemiology; CDER, Center for Drug Evaluation and Research.

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point for a pharmacist's career in the FDA. Pharmacists are commonly hired for these positions not only for their scientific knowledge, but also for their attention to detail, communication, and organizational skills. In addition, pharmacists may work as safety evaluators, drug utilization analysts, labeling reviewers, field inspectors, compliance officers, or on expert advisory committees and review panels. Additional information on opportunities for pharmacists at other Department of Health and Human Services (DHHS) agencies can be found at <http://www.hhs.gov/pharmacy/agencies.html#FDA>.

The Table provides a list of examples of various positions and duties performed by pharmacists for the FDA in the CDER. This list is not inclusive of all potential opportunities for pharmacists at the FDA.

Pharmacy students interested in a career at the FDA should participate in the FDA Pharmacy Student Experiential Program. This program provides an opportunity for pharmacy students in their last year of pharmacy school to learn about FDA laws, regulations, and guidance governing drugs, biologics, and devices for human use during a 4- to 6-week rotation. Participating students

may attend FDA advisory committee meetings and congressional hearings. Additionally, the program provides academic credit hours required for the Doctor of Pharmacy degree. More information about this program can be located at <http://www.fda.gov/Cder/Offices/DDI/pharmstudent.htm>.

Pharmacy students interested in a career at the FDA should participate in the FDA Pharmacy Student Experiential Program.

Pharmacy students should consider the United States Public Health Service (USPHS) extern programs as an opportunity for experiential training at various DHHS agencies, including the FDA. This program offers paid employment and other excellent benefits. There are two opportunities to participate while still in pharmacy school. The Junior Commission Officer Student Training and Extern Program (COSTEP) is available to students who are enrolled in a professional accredited school of pharmacy. Junior COSTEP allows students to serve in assignments at any time during the year for 31 to 120 days. In Senior COSTEP, students

are assisted financially during their final year of pharmacy school in return for an agreement to work for the USPHS after graduation. The student is appointed as an active-duty USPHS officer during the senior year and receives monthly pay and allowances as an Ensign (O-1) grade officer. The stu-

dent agrees to work for the program that provided the financial support for twice the time supported following graduation. For more information about COSTEP, contact the Office of Commissioned Corps Operations at 800-279-1605. Ask to speak to the Commissioned Officer Student Training and Extern Program Coordinator.

Pharmacy residents or graduating pharmacy students considering a career in public health should apply for a commission in the USPHS. The USPHS is the principal component of the DHHS. USPHS Commissioned Corps pharmacists are employed in various DHHS agencies, including the FDA. A career

in the USPHS Commissioned Corps provides both career and quality-of-life benefits. While protecting, promoting, and advancing the public health of the nation, Commissioned Corps pharmacists can enjoy benefits including an accession bonus, 30 days of paid annual leave, medical and dental benefits, access to military bases around the world, use of the GI bill to advance education, and access to the Veterans Administration loan program. Additional information on the USPHS Commissioned Corps can be found at <http://www.usphs.gov/> or contact the Office of Commissioned Corps Operations at 800-279-1605.

Licensed pharmacists seeking employment at the FDA, whether as a Commissioned Corps pharmacist or a civil servant pharmacist, should apply online at <http://jobsearch.usajobs.gov>. USAJOBS is the official job site of the United States Federal Government, and pharmacists should apply to the pharmacist recruitment bulletin, which includes pharmacists' positions for various FDA offices and centers.

References

1. US Food and Drug Administration. FDA organization. <http://www.fda.gov/opacom/7org.html>. Accessed August 12, 2008.
2. Swann JP. History of the FDA. <http://www.fda.gov/oc/history/historyoffda/default.htm>. Accessed August 12, 2008.

WORK SURFACE SAMPLING

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joint annual conference, raise important questions about pharmacy workplace safety and the effectiveness of routine pharmacy cleaning and decontamination procedures.

Strategies for the protection of pharmacy employees against the carcinogenic, mutagenic, and reprotoxic effects of antineoplastic drugs have been implemented and improved during the last decades, but contamination of personnel and the workplace with these compounds still occurs. Regular monitoring of antineoplastic drug contamination in pharmacies may be a useful means of determining the effectiveness of decontamination strategies and provide input for the development of

thresholds and guidelines for the safe handling of antineoplastic and other hazardous drugs.

As part of an effort to achieve compliance with workplace safety regulations recently implemented in Germany, researchers from the Institute of Energy and Environmental Technology, Duisburg, identified the antineoplastic drugs most commonly handled by pharmacies in that country. For 17 of the 25 most frequently handled compounds, sampling and analytical methods for routine contamination monitoring have been established and validated.

The identification of suitable sampling strategies for these drugs included the selection of media to be monitored (eg, ambient air, work surfaces, textiles), sampling techniques and locations, and the timing and frequency of sampling.

For the remaining eight drugs (Table), a program of workplace surface wipe sampling and testing (Monitoring Effect Study of Wipe Sampling in Pharmacies [MEWIP]) was developed and implemented in 130 pharmacies (78 hospital and 52 public pharmacies) in Germany in 2006. The goals of the MEWIP program were to establish the feasibility of wipe sample monitoring, baseline levels of work surface contamination, and the long-term effects of routine ambient monitoring on pharmacy contamination levels.

The participating pharmacies were divided into two groups: the monitoring group (55 pharmacies) performed work surface wipe sampling every 3 months and received the results of contamination testing (and thus had the opportunity to take targeted actions to decrease contamination levels), and the control group (75 pharmacies) performed sam-

pling only at baseline and the conclusion of the 15-month program.

The designated pharmacy work surface sampling locations were the floor in front of the most intensively used safety cabinet, the most intensively used countertop, and the refrigerator door and handle. Wipe samples were obtained using standardized materials and procedures and were taken from 900 cm² areas by pharmacy personnel at the end of the work day but before cleaning of the respective surfaces.

A total of 1272 wipe samples were obtained during the course of the program, resulting in 10,176 measured values. Overall, 61% of the sampled surfaces revealed contamination with at least one of the eight investigated drugs, reported T.K. Kiffmeyer and colleagues.

The highest percentage of contaminated wipe samples (73%) came from the pharmacy floors. Contamination with at least one drug was detected in 61% of the samples from countertops and 49% of the samples from refrigerator doors.

Cyclophosphamide was the drug most frequently detected (37% of the surfaces), followed by gemcitabine (32%), 5-fluorouracil (31%), and ifosfamide (21%). The four remaining drugs were detected on a maximum of only 5% of the work surfaces sampled.

Little correlation was observed between work surface contamination levels and the responses to questionnaires regarding pharmacy work practices. In particular, the levels of work surface contamination were not influenced by the amounts of drug processed or the frequency of cleaning of the respective work surface.

In contrast, a significant correlation was observed between the level of contamination and the procedures for the disinfection of drug vials before they are put into the safety cabinets. Spraying of disinfectant (eg, isopropanol) onto the drug vials resulted in higher levels of cyclophosphamide contamination on all work surfaces sampled than wiping the vials or using no disinfection.

A tendency towards higher levels of contamination was observed in pharmacies where the air from the safety cabinet was recirculated into the work room. This configuration was observed in only 21% of the pharmacies studied.

No significant decreases in the proportion of contaminated work surfaces were observed in either group during the course of the 15-month program. The overall contamination load decreased in the monitoring group during the study.

Most of the MEWIP participants expressed satisfaction with the wipe sampling and monitoring procedures, and two thirds of the pharmacies reported planning consequences based on the monitoring results. Most of the participants agreed to accept or consider ongoing contamination monitoring.

The researchers said that safe work surface contamination thresholds have not been established for most antineoplastic drugs. They noted that absolute work surface contamination levels may be less important than levels relative to those in other facilities and changes in levels over time or in response to revised cleaning or decontamination procedures.

—DSM

Table. Antineoplastic Drugs Investigated in the MEWIP Study

Cyclophosphamide
Etoposide
5-Fluorouracil
Ifosfamide
Gemcitabine
Methotrexate
Paclitaxel
Docetaxel

MEWIP indicates Monitoring Effect Study of Wipe Sampling in Pharmacies.