THE FDA NEEDS YOU

Many people have little idea of how to get a job in arguably the most influential and powerful group in the pharmaceutical industry, but the US Food and Drug Administration is trying to raise awareness about career options.

"Be A Part of Discovery", exclaimed a recent advertisement that appeared in the *New York Times*, inviting suitable readers to take up the "rewarding challenge" of working for the US Food and Drug Administration's Center for Drug Evaluation and Research (CDER). The advertisement was a conscious attempt by the FDA to brighten up its image and increase awareness of the agency as a career option. A religious-like reverence for the agency that determines whether ~10–15 years of discovery and development of a new drug will be rewarded with approval in the most lucrative pharmaceutical market, combined with a previous lack of self-promotion by government departments overall, had made the pursuit of a career at CDER instantly compelling but ultimately mystifying.

In fact there's no great mystery behind getting a career at CDER. The drug approval process encompasses many subject areas (BOX 1); and CDER is looking to recruit people in the doctorate or early postdoctoral phase of their career, depending on the subject area. One of the biggest draws to working at CDER is the training. New reviewers are assigned mentors and undergo formal training and development in-house, during which they attend new reviewer and orientation workshops, and build up a solid background in food and drug law. In some cases, a new reviewer could be working on an Investigational New Drug (IND) or New Drug Application (NDA) straight away. (An IND application provides the data showing that it is reasonable to begin tests of a new drug on humans; once trials are completed, an NDA is submitted to the FDA as a request for approval to market the drug.)

Within approximately a year, depending on the employee's background, he/she could become a fully independent reviewer. Some reviewers progress to being a team leader, and the most successful can become division directors and office directors. The current Director of CDER, Janet Woodcock, began her career as a primary reviewer at FDA. The experience gained at CDER can also be a highly sellable quality for those wishing to pursue alternative employment in regulatory affairs departments in pharmaceutical companies, or in marketing or analyst firms.

Most candidates come from referrals from current or ex-FDA employees, or from external colleagues, but the agency says that it is always looking at CVs that are sent directly (EMPLOYMENT@cder.fda.gov), and the agency also posts positions on its recruitment website (http://jobsearch.usajobs.opm.gov/a9fda.asp). CDER's recruitment resources are now decentralized, which means that each office has a recruitment focal point; for example, the Office for New Drugs deals primarily with medical officers and the Office of Pharmaceutical Sciences deals mostly with chemists and clinical pharmacologists, and these offices always share applications. The FDA also advertises in big US city newspapers and at scientific meetings rather than major scientific journals, as journal classifieds have produced less of a response in recent years. Due to the added complexity of the hiring process, applications from candidates overseas are only considered in disciplines in which there is a paucity of appropriate candidates in the US, such as in clinical pharmacology, but overseas students in the US who have a working or permanent visa are always considered.

According to the Tufts Center for Drug Development, the FDA could be facing formidable pressures on recruitment[1]. User fees, which are paid by companies to review an NDA, directly fund staffing levels at the agency so that applications can be reviewed and acted on as efficiently as possible; however, the current dearth of new drugs emerging from the pipeline (see 2003 approvals: a year of innovation on page 103 of this issue) will limit funds available for new hires. In addition, maintaining staff experience as experienced staff retire or leave will increase pressure on the agency, and as companies are now expected to include more extensive data sets in approval submissions, the FDA will face the challenge of evaluating this information efficiently without slowing down the approval process, says the report. If true, it will be crucial that the agency fills its staffing gaps with the appropriate people as quickly as possible. As the recent advertisement concluded, you could help "shape the future of medicine".

1. *Outlook 2004* (Tufts Center for the Study of Drug Development, Boston, 2004).

Box 1 | **Career subject areas within the Center for Drug Evaluation and Research**

Scientists. Evaluate portions of INDs/NDAs that pertain to their particular discipline. They determine the scientific validity of manufacturers' tests, drug safety and efficacy claims. A doctorate degree in a scientific discipline with at least two years postdoctorate experience is highly desired for these positions.

Physicians. Evaluate data involving the animal testing and human clinical trials of new drugs to determine their safety and efficacy. Basic qualification is a Doctor of Medicine or Doctor of Osteopathy, and can come from various medical specialties.

Consumer Safety Officers (Project Managers). Perform management and liaison responsibilities in the review process. Must have a degree, or combination of courses in relevant scientific fields. Project management experience in the health care or pharmaceutical industries is highly desired.

Statisticians. Provide statistical support to the drug review divisions relevant to the regulatory and scientific aspects of preclinical and clinical drug development, and also approval decision processes. A doctorate degree in mathematics/statistics and clinical trial or related biomedical investigations experience is highly desired.

Source: Center for Drug Evaluation and Research. For more details, see http://www.fda.gov/cder/career/

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