

Update on Clinical Pharmaceutical Scientists Programs: UNIVERSITY OF MARYLAND EXPERIENCE

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Defining the Clinical Pharmaceutical Scientist

Modifications in graduate curricula are often required to adapt to changes in practice and research paradigms. A common question posed to the profession of pharmacy not long ago was: "What is a Pharm.D.?" Similarly, many of our patient care colleagues were unfamiliar with the doctor of pharmacy degree, yet the skills and capabilities of the Pharm.D., the

process of pharmaceutical care, and implementation of clinical pharmacy services are widely recognized today. We are now faced with a similar

question: "What is a clinical pharmaceutical scientist?"

In the late 1990's, the Commission on the Future of Graduate Education in the Pharmaceutical Sciences provided a series of recommendations for graduate programs to meet the demands of the phar-

maceutical industry, academia, and the Food and Drug Administration (FDA).(1) In order to increase the breadth and skills of graduates, the Commission recommended that colleges and schools of pharmacy examine Ph.D. programs in the clinical sciences as an appropriate addition to graduate program offerings. Such programs require a focus not only on drug discovery, but also drug development, and integration and practical application of the basic sciences.

The clinical pharmaceutical scientist is most often defined as a research scientist equally skilled and trained in basic science and clinical practice. Clinical pharmacy-trained researchers are uniquely qualified to maintain contact with the patient care environment (at some level) while actively engaging in research of a very basic science nature. Effective communication of research results among basic scientists, clinical researchers, and practitioners is a primary objective, as well as translation of research obtained from epidemiology and database research into clinical practice. In order to adequately prepare such clinical pharmaceutical scientists at the University

of Maryland, we have focused our current recruitment efforts on post-Pharm.D. students, preferably those with residency training experience in a clinical pharmacy specialty area, although other approaches may be utilized.

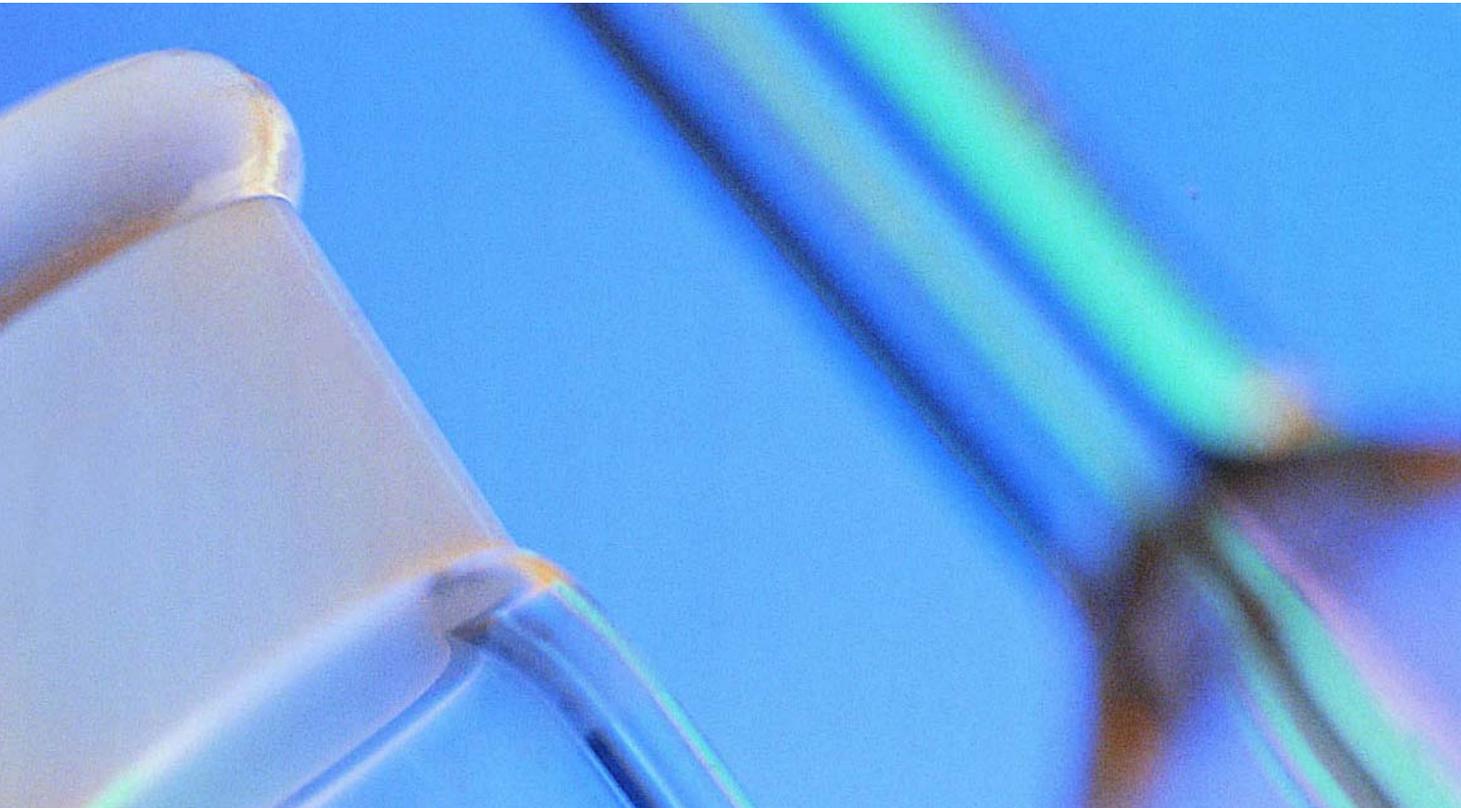
Translational Research

Development of modern clinical scientists programs must include the translational research paradigm. Today's medical and pharmaceutical research environment has changed substantially from years past with a greater emphasis placed on translational research. The term translational research itself is relatively new and refers to bridging of the gap between bench-top basic science research results and the practical use of these results in patients through daily clinical practice.

For example, translational research can be envisioned as a basic scientist's discovery of a new ligand or receptor associated with a particular disease state leading to the development of a new chemical entity to treat that disease. However, translational research can also be thought of as a two way street. The clinician may make an



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observation requiring further benchtop investigation. Differences in frequencies of a particular disease may lead to the finding of specific genetic polymorphism that predisposes the carriers of this gene within the population. Such findings could substantially alter clinical practice by improved screening guidelines and therapeutic approaches.

Thus, the clinical pharmaceutical scientists find themselves poised as an ideal candidate to perform translational research. So what makes the clinical pharmaceutical scientist different from the traditional pharmaceutical scientist? It is the formal training as a clinician, with an understating and appreciation of the complexities of therapeutics and pharmacotherapy from the caregiver's point of view. With adequate training, the clinical pharmaceutical scientist can provide a conduit between bench-top basic science researchers and clinical practitioners.

Clinical Pharmaceutical Scientist Training

A goal of the Clinical Pharmaceutical Scientist Program at the University of Maryland is to develop pharmacy-trained specialists that independently derive new knowledge through observation, study, and experimentation. Some factors that

are required for the success of such clinical sciences programs include an existing 'critical mass' of basic sciences researchers and clinical pharmacy researchers and practitioners, physician research collaborators, an academic medical teaching center, and clinical research resources such as a

General Clinical Research Center. Specific didactic requirements of our program include drug development, clinical trials design, biostatistics, pharmaceutical analysis, pharmacogenomics, regulatory, affairs and pharmacokinetics/drug metabolism. Successful completion of oral and written

Post Internship Opportunities Today

The AAPS Career Network continues to look to enhance the career services offered to undergraduate, graduate and post-doctoral students. One advantage for students is the opportunity to

broaden their horizons and their experiences through internship programs. We would like to invite your company to post available internship program information at the AAPS Online Career Network site gratis for the remainder of 2004. To date, student members have participated in internship program offerings from National Academies of Sciences, Pfizer, The Johns Hopkins University, and U.S. Pharmacopeia. Student members and affiliates of AAPS can benefit from being exposed to the various opportunities and internship programs that your company may have to offer.

If you currently have co-op or internship opportunities that you would be interested in having AAPS Student members fulfill, contact Ryan Williams, Career Services Specialist at 703.248.4771 or williamsr@aaps.org.





comprehensive exams is required for doctoral candidacy. In contrast to most basic pharmaceutical sciences graduate programs, evaluation of drug therapy outcomes in patients and involvement in the

design, institutional review board submission, and conduct of a prospective clinical pharmacology trial is required.

Dissertation research projects are developed to incorporate basic science methodologies that are aimed at understanding the factors and mechanism determining drug-related outcomes that can be directly measured in patients.

A number of formal training programs in Clinical Pharmaceutical Sciences are currently offered in U.S. Schools of

Pharmacy, administered through clinical departments, pharmaceutical sciences departments, or both. Like the University of Maryland, the Universities of Kentucky and Pittsburgh have Clinical Pharmaceutical Scientist Tracks that reside within the Pharmaceutical Sciences.

Students at the University of Minnesota can choose the Experimental and Clinical Pharmacology (Ph.D.) track within the Department of Experimental and Clinical Pharmacology's graduate program in Social, Administration and Clinical Pharmacy. The University of North Carolina offers a Ph.D. degree in Experimental Therapeutics that is offered jointly between the Divisions of Pharmacotherapy and Drug Delivery and Disposition.

A key aspect of each of these programs is incorporation of translational research

into disciplines such as clinical pharmacology, theory and application of biopharmaceutics, pharmacokinetics, drug metabolism and disposition, pharmacodynamics, cellular and molecular biology, and pharmacogenomics. These skills are coupled with formal training in study design and statistical methods, coupled with the integration of laboratory-based and hypothesis-driven dissertation research.

The Demand for Clinical Pharmaceutical Scientists

The short supply of clinical scientists is recognized by the National Institutes of Health (NIH). As stated by NIH Director Harold Varmus in 1997, there exists a need for "highly trained clinical researchers in order to capitalize on the many profound developments and discoveries in fundamental science and to translate them to the

University of Cincinnati College of Pharmacy Launches Master's Program in Drug Development

In September 2004, the College of Pharmacy, University of Cincinnati, Cincinnati, OH, will launch a new Master's level program in drug development. This program is being implemented to meet the need of cross-disciplinary training in scientific and regulatory aspects of drug development. This unmet and growing need is fueled by the rapid advance in scientific discoveries, shifting paradigms of pharmaceutical research, and evolving regulatory guidelines. Corporate employers and academic health centers spend significant resources for employee training at workshops/short courses and/or on-site training. The program will be made available to individuals holding post-baccalaureate degrees in pharmacy, nursing, medicine and other related biomedical sciences.

Individuals with degrees in other areas with relevant

experience may also be considered. The curriculum is particularly targeted towards fully employed professionals who are seeking advanced learning opportunities. As such, the program will be offered on a part-time basis with the didactic coursework taught during weekday evenings. It is intended that successful completion of the program will lead to improved interactions of the professionals within a team matrix, broaden the range of their activities and ultimately prepare them to become experts in global drug development. Such training should help both – the employee with advancement in career opportunities - and the employer with improved work efficiency and expanded scope of services/activities.

To implement this program, the College of Pharmacy received a generous gift as seed money from

Kendle International Inc., a global clinical research organization, headquartered in Cincinnati. The program was developed with close collaborations between the college and other units of our medical center including Cincinnati Children's Hospital Medical Center and regional pharmaceutical companies and clinical research organizations. The College of Pharmacy has over 35 faculty members with a proven record of excellence in professional and graduate education. The current specialization areas for M.S./Ph.D. programs include Biopharmaceutics & Pharmacokinetics, Pharmacology, Medicinal and Bioorganic Chemistry, Industrial Pharmacy, and Social and Administrative Sciences. The college has significant experience in offering non-traditional graduate programs, including the distance

learning M.S. program for Procter and Gamble employees working in Cincinnati and Norwich, New York.

Pankaj B. Desai, Ph.D., Associate Professor of Biopharmaceutics and Pharmacokinetics, will serve as the director of the M.S. program in drug development. A panel of experts from the UC Medical Center and regional industries have been assembled to participate in the curriculum, which includes courses such as: Global Drug Development, Pre-clinical Product Development, Regulatory Affairs I (pre-clinical) and II (clinical), Clinical Trials Design I, II and III, Project Management, Drug Delivery Devices, Pharmacovigilance, and Pharmacoeconomics. For further information visit the UC College of Pharmacy website at <http://pharmacy.uc.edu>.

clinical setting...they are highly interactive with basic, clinical, and epidemiological researchers in related disciplines".(2)

In accordance with the NIH directive, a primary focus of most clinical pharmaceutical scientist programs is translational research. This research paradigm is further being encouraged by the NIH through enhanced funding initiatives. Tenure-track academic positions are widely available for clinical scientists, especially those with research initiatives consistent with the NIH roadmap, often requiring extramural funding to support independent research programs.

Additionally, the pharmaceutical industry continues to place increasing demand on clinical trials, with clinical development consisting of nearly \$300 million or one-third of the total drug development cost. Graduates from the clinical scientist programs are well positioned for careers in the pharmaceutical industry, which is often highly integrated and globalized. Researchers with training in clinical trials, biopharmaceutics, pharmacokinetics, and pharmacodynamics are ideally suited to design, implement, analyze, and interpret all aspects of the clinical trials performed in the Phase I clinical trial program. Other divisions within the pharmaceutical industry would benefit from the knowledge base of the clinical pharmaceutical scientist, including Regulatory Affairs, Pharmacokinetics, Project Planning, and Clinical Research. Clinical Scientists are also being recruited by the FDA based on their broad understanding of the drug development process. For example, the background of a pharmacist with the understanding of medicinal chemistry and pharmacotherapy with formal training in phase I clinical trial design, implementation, and data analysis, places the clinical scientist in an ideal position to review NDAs and ANDAs. Partnerships between industry and clinical sciences graduate programs can provide an experiential component to the trainee's experience.

Summary

The concept, definition, and role of the clinical pharmaceutical scientist have evolved over the past two decades. It is now recognized that clinical scientists have a responsibility to effectively communicate basic biopharmaceutical research

AAPS Members Can Access Science's Next Wave

Science's Next Wave, www.nextwave.org, is the weekly online publication that focuses on career development for scientists—from undergraduates to faculty and career scientists. Next Wave is a global site that includes information on academic, industry, and non-traditional career paths, highlighted by a multitude of first-person perspectives. For undergraduates, Next Wave includes articles on how to prepare for the GRE and transitioning from a 2-year to a 4-year college or from undergraduate to graduate school. For graduate students, our articles include how to find the perfect advisor and writing your first 'First Author' paper. Our

Postdoc Network provides postdocs, their mentors, and their institutions with the resources that they need to improve the postdoctoral experience.

For those following an academic career path, our Career Development Center has practical advice on professional issues such as negotiating a job offer and setting up your first lab. If students and postdocs are moving into the non-academic job market, Next Wave features nuts and bolts career advice, such as job market trends and how to present your weaknesses during an interview. And for the faculty in our audience, we provide practical advice on academic career issues such as women in the

tenure pipeline and mentoring your students.

Lastly, our most recent section is our Minority Scientists' Network, which addresses the problem of recruiting and retaining minority scientist students and focuses not only on students, but also on mentors and administrators.

In addition, each month Science's Next Wave focuses on a special topic that scientists will find useful in planning their next career moves, whether they be alternative avenues for their hard-earned talents or simply to gain new insights into the worlds of academe and industry. An online archive of feature articles also can be accessed.



with clinical practitioners and investigators. Further development of graduate programs in clinical pharmaceutical sciences are needed to provide a critical mass of faculty, trainees, and independent researchers to maintain the momentum of the translational research paradigm. ↻

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