

Editorial

Graduate Education in the Pharmaceutical Sciences: How Can It Better Meet the Needs of the Generic Pharmaceutical Industry?

With the decline in funding for academic research and the continued downsizing, restructuring and refocusing of the pharmaceutical industry, there is an ever-growing concern about employment opportunities for new graduates in the pharmaceutical sciences. The need to re-evaluate graduate education in light of the changing job market for pharmaceutical scientists has been acknowledged and is currently being addressed individually and "collectively" by academic institutions. Colleges of pharmacy are looking to external boards to advise on curricula relevant to career opportunities and the needs in today's "marketplace" for graduates. The AACP Commission on The Future of Graduate Education in the Pharmaceutical Sciences, which held its first meeting in January of this year, is taking a more global look at the supply and demand of pharmaceutical scientists, and the corresponding educational and training needs.

Not unexpectedly, identifying the needs of the pharmaceutical industry in terms of relevant training has been a major focus of these initiatives. Ensuing discussions have been based on the loose assumption that there are separate "brand" and "generic" needs. However, a quick look at the composition of the generic industry and the key functions, or departments, in a typical generic company suggests that generic needs might best be considered as a subset of brand needs. The United States generic drug industry is made up of: bulk pharmaceutical chemical manufacturers; independent generic drug product manufacturers (manufacturers of generic products only, as well as manufacturers of both generic products and new chemical entities); brand-owned generic drug product manufacturers; and contractors of services (e.g., manufacturing, bioequivalence testing, etc.). Except for drug discovery and pre-clinical/toxicology functions, the typical generic organization operates much like the brand organization. Its functions include: product research and development; analytical research and development; quality control and quality assurance; medical affairs and regulatory affairs; process development; manufacturing; marketing and sales; and, business development. A more meaningful categorization of industry needs, with respect to the qualification of future pharmaceutical scientists, might be "drug discovery" and "drug development", where the environment in which these activities takes place, brand company or generic, is irrelevant. If training needs relevant to all phases of drug development, as well as to drug discovery, are considered in graduate programs, both the brand and the generic segments of the pharmaceutical industry will be well served. At the same time, opportunities for graduates will effectively be expanded.

Graduate programs today are training the majority of students for the minority of industry opportunities. For any of several possible reasons—e.g., special interests of faculty, funding issues, confusion between wants and needs on the part of

industry—graduate programs are increasingly focusing on the relatively small drug discovery piece of the industry pie. More often the emphasis is on basic research rather than applied research. Programs further down the drug development chain, such as industrial pharmacy or pharmaceutical manufacturing, have been de-valued. Programs in material science, formulation science, or process science are rare. Yet there is a tremendous need in the industry for qualified scientists in these disciplines. At the FDA/AAPS BACPAC workshop in March, a great deal of frustration was expressed when product formulators declared that regardless of the physical property tests done to show "sameness" of a drug substance after a manufacturing change, it could not be accepted because "formulation is not a developed science". The March 1997 EUFEPS newsletter provides the results of a survey of research directors and senior managers of European pharmaceutical companies designed to "search for the problems faced when recruiting qualified personnel at the post doctorate levels in the pharmaceutical industry". Fourteen key areas and sub-areas were identified where the industry is not able to recruit adequate candidates. One of these key areas is pharmaceutical technology, which includes biopharmaceutics, drug delivery, manufacturing, and production technology. One would expect similar results for such a survey of U.S. pharmaceutical manufacturers, brand and generic.

More emphasis is also needed on the integration and practical application of the basic science and fundamental training currently provided in our graduate programs. Conferences, short courses, and tutorials as often bridge the gap between graduate school and industry as provide state of the art technology and techniques. A review of the brochures for recent offerings provides a great deal of insight into unmet industry needs.

For any area of the pharmaceutical industry—drug discovery or drug development, drug substance or drug product, brand or generic, in-house or contract—pharmaceutical scientists are needed who can problem solve on a foundation of science and practical, technical skills. The industry needs pharmaceutical scientists who can make scientifically sound decisions in a highly competitive business environment, individuals who are able to separate the "need to know" from the "nice to know" without compromising quality. In relatively smaller, less vertically integrated companies, such as independent generic companies and start-up biotechnology companies, pharmaceutical scientists need to be able to critically evaluate outsourced products (e.g., bulk pharmaceutical chemicals) and services, as well as effectively handle a broad range of responsibilities within the organization. As stated by Dr. Borchardt in his editorial in the May 1997 issue of this journal, teamwork is crucial, in both small and large organizations. Excellent written and verbal skills are also extremely important.

Appropriate coursework and research laboratory training, themselves, are not enough to adequately prepare graduates for the pharmaceutical industry. The environment in which these are provided must foster the skills delineated above, as well. How this might be accomplished will be a major challenge for academic institutions.

Over the last 20 years, there has been a general "inflation" of perceived degree requirements for positions in the pharmaceutical industry and the industry, itself, has been a major contributor to this inflation. For any given function in the industry there seems to be a strong correlation between educational level required (masters, doctoral, post-doctoral) and size and/

or maturity of the organization. As we continue to re-evaluate graduate programs in the pharmaceutical sciences with respect to meeting the needs of the pharmaceutical industry, we should also be taking a hard look at the degree required to meet these needs. Perhaps it's time for both industry and academia to re-evaluate the "terminal" degree as well as program content.

Alice E. Till, Ph.D.

*Generic Pharmaceutical Industry Association
1620 I Street N.W., Suite 800
Washington DC 20006*

News from the National Institute of General Medical Sciences (NIGMS)¹

HOW DOES THE NIGMS SUPPORT PROGRAM PROJECT GRANTS? WHERE IS CURRENT INFORMATION AVAILABLE ABOUT THIS MECHANISM?

The program project (PO1) research grant mechanism is designed to support research where the funding of several projects as a group offers significant scientific advantages over support of these same projects as individual research grants. Successful program projects bring scientists together (who might not otherwise collaborate) to apply complementary approaches to a well-defined problem.

A program project grant usually consists of three to five individual projects from different investigators. The scientist designated as the principal investigator has responsibility for the overall scientific leadership and fiscal management of the grant. The principal investigator, and each individual project leader, must demonstrate in the written application that the grant will be much more effective if funded as a program than if funded as independent research projects. Successful program projects establish effective collaborations, particularly in emerging areas of research, that extend beyond the duration of the program itself. Hence, a program project generally has a finite lifetime, and justification is required for the renewal of support beyond the initial funding period. Since it is not unusual for principal investigators on individual research grants to share techniques, information, and methods, it is not sufficient that the projects be unified by a common theme. Program project grants can support essential shared core facilities, e.g., major equipment, although the need of a group of investigators for a major piece of instrumentation or core facility does not itself provide sufficient justification for a program project grant. Program project grants are not intended to be vehicles for departmental support, or for research support of a senior investigator and several postdoctoral and research associate-level scientists. The program project and each individual project should represent a significant effort on the part of the participating scientists and be distinct from other funded efforts. Investigators can also participate as associate members, and have full use of any core facilities and contribute to the overall collegiality of the program, but derive no financial support.

The program project grant application should be structured as a series of separate but related project proposals. There is an upper limit of \$4,000,000 (exclusive of any subcontractual F & A costs) that can be requested in a competing program

project application to the NIGMS. If justified, additional funds can be requested for major pieces of instrumentation. An introductory section must contain justification for the program project grant mechanism and describe the goals that are not readily attainable through individual research grants. There should be a description of the objectives of the program as a whole, the relationship of the individual research projects to the entire program project, and the special benefits to be achieved by funding as a program project grant.

The individual projects, as well as the program project grant as a whole, must meet the same standards of scientific merit as regular research grants. Final review and recommendations by the National Advisory General Medical Sciences Council will also take into account the relevance of the program to the interests and mission of NIGMS. It is possible that funding for some individual projects or core components recommended by the initial review group may be deleted by Council or by NIGMS staff prior to award of a grant, based upon the lesser scientific merit of certain components or their lack of cohesion with the rest of the program project.

NIGMS supports research in the broad scientific areas of its divisions: Pharmacology, Physiology, and Biological Chemistry; Cell Biology and Biophysics; and Genetics and Developmental Biology. NIGMS's policies regarding program projects are described in the announcement SUPPORT OF PROGRAM PROJECT GRANTS, NIH Guide to Grants and Contracts, Volume 25, Number 10, March 29, 1996, which is available on the NIGMS home page at <http://www.nih.gov/nigms> under the headings Funding Info, then Program Announcements. Program project grants are investigator-initiated, but because of budgetary constraints, they may be restricted to areas of special interest to the individual divisions within NIGMS. Potential applicants are urged to contact NIGMS program staff listed in the program announcement for advice in the appropriate scientific areas, and for guidance in preparation of the application.

Future topics for this column: exploratory grants for high risk/high impact research, training grants at the NIGMS, and your suggestions

Rochelle M. Long, Ph.D.

Program Director

Pharmacological, and Physiological Sciences

(PPS) Branch Division of Pharmacology, Physiology, and Biological Chemistry (PPBC) NIGMS, NIH

¹ Send comments on this column to: longr@gml.nigms.nih.gov.