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DOCTORAL EDUCATION FOR THE PHARMACEUTICAL INDUSTRY[1]

Robert V. Smith
Drug Dynamics Institute
College of Pharmacy
University of Texas at Austin
Austin, TX 78712

"One need not be a qualified soothsayer to recognize that the trends in the country point toward more and more governmental control over pharmaceutical industry. ....there are going to be more testing, more quality control, more requirements for current good manufacturing practices, and more demand for scientific effort to produce safe and effective drug-dosage forms than ever before. This, in turn, means a greater need for educated persons to perform the more numerous and more difficult tasks involved in meeting these requirements."

Varro E. Tyler
1978

The pharmaceutical industry is a vital employer of doctoral graduates of colleges and schools of pharmacy. In the United States, Ph.D.-level graduates complete their education at the rate of approximately 150 per year through programs administered by 43 of the 72 member schools of the American Association of Colleges of Pharmacy[2].

It is the purpose of this paper to briefly review the scope of these programs. Secondly, suggestions are offered for improving the effectiveness of U.S. doctoral-level programs and their responsiveness to the current and perceived future needs of the pharmaceutical industry.

During the development of this paper, insights and opinions were informally solicited from an about equally proportioned group of 50 industrial managers and academicians (see Acknowledgement section). Judgements were sought on the needs for doctoral-level people in industry, the types of educational experience deemed important, and the values placed on education that might be achieved in a pharmacy school *versus* that attainable in an equivalent counterpart (*e.g.* chemistry department, medical school pharmacology department). Additionally, information gained through the activities of the APhA Academy of Pharmaceutical Sciences Committee for Federal Research Support[3] was helpful in developing the author's perspectives.

In the following sections, the author addresses current industrial needs for doctoral-level pharmaceutical scientists in the areas of pharmaceutics, medicinal chemistry and pharmacognosy, pharmacology and toxicology, and pharmacy administration. In all these discussions, the necessity to develop high quality graduates is emphasized. Recognition is given to the fact that federal support to graduate and postdoctoral training is likely to decrease or remain stable (in real dollars) over the next ten to twenty years. At the same time, academicians in the United States must realize that the proportion of 18- to 24- year olds is projected to decrease 23% by 1997[4].

In the later sections of this paper, strategies are proposed for improving the effectiveness of training graduate-level pharmaceutical scientists. Many of the ideas presented are more thoroughly described in a recent work by the author[5]. Finally, suggestions are presented for closer collaboration between academic and industrial institutions.

CURRENT STATUS OF DOCTORAL PROGRAMS IN THE PHARMACEUTICAL SCIENCES

Colleges and schools of pharmacy in the United States are currently administering Ph.D. programs in pharmaceutics (industrial pharmacy, physical pharmacy and biopharmaceutics/pharmacokinetics), medicinal chemistry and pharmacognosy, pharmacology and toxicology, and pharmacy administration (socioeconomic pharmacy). The more established programs are nearly 30 years old while others have only developed real strengths in the last 10 to 15 years. In terms of grant funding and publications, about 15 schools accounted for 60% of all activity during the period 1978 through 1979[2].

Industrial Pharmacy, Physical Pharmacy and Biopharmaceutics

Programs in industrial pharmacy, physical pharmacy, and biopharmaceutics/pharmacokinetics can all be placed under the umbrella of pharmaceutics. However, in some schools of pharmacy, these areas are lumped under the title of pharmaceutical chemistry and may also embrace analytical pharmaceutical chemistry as a subspecialty. Regardless of title, the pharmaceutics Ph.D. is usually concerned with dosage form design, development, evaluation, and performance in biological systems. Programs leading to the academic doctorate generally involve advanced education in mathematics, physical and analytical chemistry, statistics, physical pharmacy, and biopharmaceutics/pharmacokinetics. Many educators acknowledge additional needs for courses in engineering and materials sciences, pharmacology, and industrial management. However, Rhodes[6] warns of potential course "overloads" because of the myriad of offerings that are of potential utility to the industrial pharmaceutics scientist.

A great need exists for Ph.D.-pharmaceutics scientists in industrial firms in the United States. There are also indications that similar needs exist in Western Europe. The most acute shortages appear to be in the area industrial/physical pharmacy[6,7]. Several reasons can be cited for this state of affairs. First, there has generally been a significant shift in the interest of graduate students in recent years towards more biological-type sciences. Thus, students who elect a pharmaceutics tract are more likely to pursue specialization in biopharmaceutics or pharmacokinetics. Second, U.S. pharmaceutics faculty have moved more towards biopharmaceutics/pharmacokinetics in the last 10 years. Third, the substantial faculty-equipment-space investment necessary to develop industrial pharmacy programs has apparently been viewed as prohibitive by pharmacy and university central administrations. These problems have been exacerbated by a general lack of federal and industrial support for physical/industrial pharmacy programs and research[3,8]. The federal government has generally not favored supporting physical-industrial pharmaceutical training and research; U.S. industry has been unwilling to invest the two to five million dollars per year that has been estimated as being needed to educate sufficient numbers of Ph.D. pharmaceutics scientists[8].

There are many unmet needs for analytical pharmaceutical chemists in industry. Faculty in this sub-specialty are located in pharmaceutics or medicinal chemistry departments in U.S. colleges of pharmacy and have never represented sufficient numbers to formulate separate departmental or divisional status. Indeed, there are probably not more than ten faculty members nationwide who are clearly identified with the discipline.

The need for pharmaceutics and analytical pharmaceutical chemistry Ph.D.'s are clearly not being met by chemistry or engineering faculties. A physical chemist who might come closest to a pharmaceutics doctorate, will have great deficiencies in his/her background with respect to dosage form design and development. It is acknowledged that two of the "giants" in physical pharmacy, Professors William and Takeru Higuchi, were trained in physical chemistry. However, these two productive scientists and many of their colleagues and students have helped develop a body of knowledge over the past thirty years that underscores the need for people specifically trained in physical pharmacy.

Analytical chemistry faculty in chemistry departments in the United States have become increasingly concerned with physical and theoretical chemistry in the last 10 to 15 years. There is certainly a need for this activity to advance the state-of-the-art of analytical chemistry. Doctoral recipients in analytical chemistry, however, have become less exposed to the variety of analytical techniques and approaches that are necessary for analyses of pharmaceuticals. This is particularly true for determinations in complex milieu (e.g. dosage forms, biological fluids). As a consequence, demand for analytical pharmaceutical chemists has increased dramatically in recent years.

It is not the author's intention to underrate the need for biopharmaceutics/pharmacokinetics Ph.D.'s in industry. The demand for these people is not as great as the more traditional physical/

industrial pharmacy doctoral graduates; yet, there are still significant opportunities for the Ph.D. in biopharmaceutics/pharmacokinetics. Faculty in biopharmaceutics/pharmacokinetics, however, should be aware of one caveat. As I indicated in an earlier paper[9], faculty in the pharmaceutical sciences have no monopoly on their respective areas of research. Indeed, pharmacokinetics has become an area of study for certain pharmacology as well as pharmaceutics faculty. Certainly, the pioneering efforts of faculty such as Professors Gerhard Levy, Eino Nelson, Sidney Riegelman and John Wagner will not be forgotten. However, as the field of biopharmaceutics/pharmacokinetics advances, faculty will have to become more astute in the biological sciences to tackle the more difficult problems of this field. Indeed, the input of pharmacokinetics faculty could help to make up for deficiencies in clinical pharmacology that exist in many pharmacy-pharmacology programs (see below). At the same time, biopharmaceutics/pharmacokinetics faculty should find it mutually beneficial to form closer associations with pharmacology faculty and/or departments.

Medicinal Chemistry and Pharmacognosy

The need for doctoral-level medicinal chemists and pharmacognosists in industry has varied considerably over the past 10 to 15 years. This fact has sociological and scientific antecedents. Specifically, medicinal chemistry is viewed by many in industry as principally an extension of organic chemistry. Thus, many industrial managers seek out the best organic chemists for openings. Since there has been no lack of organic chemists, even from the best departments, some medicinal chemists coming from pharmacy schools have experienced difficulty in securing employment in industry. Consequently, some new graduates have had to take jobs in allied areas. The tendency to hire organic chemists is often perpetuated by medicinal chemical managers who themselves come out of strictly organic chemical groups.

Partly because of the competition from organic (and bioorganic) chemical groups, some U.S. medicinal chemistry departments have developed excellence within their ranks. This is reflected in part by the relatively high measure of success medicinal chemists have had in attracting extramural grant funds from the federal government[10]. On the other hand, a number of mediocre medicinal chemistry programs still exist in the United States. This has not helped the image and potential employment opportunities for many young medicinal chemists.

This is an appropriate point to emphasize a strongly held personal opinion. That is, quality graduates regardless of their specialization will always find gainful employment in industry. Thus, the medicinal chemist with an outstanding foundation in organic chemistry, spectroscopy, and pharmacology will usually succeed. However, as with all good doctoral students, exceptional research skills must be developed (see below). Additionally, postdoctoral experience with a well recognized organic chemist or pharmaceutical scientist may be necessary for the Ph.D.-medicinal chemist to create the necessary competitive edge for a position in industry.

There are limited industrial opportunities for traditional pharmacognosy Ph.D.'s. However, certain pharmacognosy faculty members and departments have become more oriented towards organic and bioorganic chemistry in recent years. When expertise in these areas is coupled with background and experience in separations methods and microbiology, graduate pharmacognosists result that have expanded industrial opportunities. In this regard, microbial chemistry represents an outstanding field for training doctoral candidates who may ultimately find industrial employment in the ever widening field of antibiotics and antimicrobial research, and recombinant engineering.

The few U.S. medicinal chemistry-pharmacognosy departments that have developed good programs in drug metabolism and pharmaceutical analysis generally find little difficulty in placing their doctoral graduates. Success in these areas will be perpetuated by collaboration with selected pharmaceutics and biochemical pharmacology faculty members. So-called drug metabolism specialists will have to develop abilities in pharmacokinetics and pharmacodynamics. People trained in pharmaceutical analysis should have an understanding of the challenges that arise during the assay of bulk drugs, drugs in dosage forms, and drugs and metabolites in biological fluids. Thus, background in traditionally defined pharmaceutics areas are appropriate for the pharmaceutical analysis student who is "housed" in a medicinal chemistry department.

Pharmacology and Toxicology

Many U.S. colleges and schools of pharmacy do not have pharmacology departments[11]. Of the ones that do, a relatively small proportion have developed high quality graduate programs. Some schools with pharmacology departments have not invested heavily enough in quality faculty and facilities. First-rate graduate programs will include advanced study in various aspects of pharmacology including toxicology; physiology, pathology, biochemistry, statistics, and computer science. A number of industrial managers emphasize the importance of the latter two areas because of the significant amounts of data that require processing during development of New Drug Applications.

Medical school pharmacology programs have certain advantages over their counterparts in pharmacy schools. Not least of all are lightened teaching loads which permit more time for faculty to develop as effective researchers. Also, as noted earlier, medical school pharmacology programs are able to develop clinical pharmacology sections that are essentially non-existent in pharmacy departments. However, pharmacy-pharmacology programs have the opportunity to enrich their students' programs through collaborative efforts with medicinal chemists and pharmaceutics faculty and students. Such collaborative efforts serve as an outstanding model for the type of cooperation that is required during drug developmental work in industry.

I have had the occasion to visit with students in a number of medical school pharmacology programs over the past two years. During these encounters, I was struck by the relative naivete of the doctoral students regarding the overall process of drug development. Indeed, the opinion of at least one industrial manager in pharmacology[12] was confirmed. That is, many graduates of doctoral-level pharmacology programs are too narrow in outlook.

Industrial opportunities for Ph.D. level pharmacologists appear to be excellent at the present time. This is especially true in the sub-specialty of toxicology where a yearly need of 200 or more Ph.D.-level toxicologists is predicted for several years to come[13].

Pharmacy Administration

Graduate programs stressing business and socioeconomic aspects of pharmacy are frequently referred to by the unfortunately ambiguous title of Pharmacy Administration. There are few quality pharmacy administration programs in the U.S. Furthermore, one educator in the area[14] bemoans the fact that the good programs can hardly meet requirements for pharmacy administration faculty no less fulfill the perceived needs in industry.

Opportunities for pharmacy administration graduates would appear to be in the areas of market research, corporate development and planning, research administration, sales management, industrial relations, and public/professional relations[15]. Because of extensive opportunities in these groups in the U.S. pharmaceutical industry, there is little reason to believe that quality pharmacy administration graduates wouldn't be accepted in industrial positions.

STRATEGIES FOR EFFECTIVELY EDUCATING DOCTORAL-LEVEL PHARMACEUTICAL SCIENTISTS FOR INDUSTRY

Two elements are of paramount importance in educating Ph.D.-level pharmaceutical scientists for the pharmaceutical industry. First, there is no substitute for quality. Pharmacy schools must recruit the best faculty and students, provide them with sufficient basic resources (e.g. equipment, support staff), and allow for sufficient time for faculty to build exceptional programs. There is an element of personal indignation in these admonishments. It is my belief that academic pharmacy and significant numbers of pharmacy administrators have for too long considered research and graduate education as dispensable activities. This is deplorable! The pharmaceutical sciences have become well established over the past 30 years. Academicians in the pharmaceutical sciences should be proud of this fact. The recent serious shortages of quality pharmaceutical scientists in industry and academia should attest to the importance of graduate education and research. Pharmaceutical science faculty should emulate medical school faculty and administrations who view their research roles as essential to the health (sic) of society.

The second most important criterion that should be sought in developing and implementing quality graduate programs in the pharmaceutical sciences is an emphasis on research and research skills. Nothing is more important to the industrial manager than hiring creative individuals who are effective problem solvers. This fact has been stated aptly by Dr. Jane Sheridan[16] who proposes that industrial scientists ...."understand what is meant by defining the dimensions of a project, by controlling their plan when their data is unexpected, by recognizing what are the pertinent parts and what are irrelevant side-tracks and lastly, knowing when the problem is either solved or cannot be solved by currently available resources." In the sections that follow, the themes of quality and importance of research acumen are stressed.

Disciplinary vs. Interdisciplinary Training

In graduate education, it is important for the beginning student to work mostly within a discipline. Of even greater significance is the weaving of research and research training throughout the student's graduate career[5]. This notion is illustrated by the diagram labeled A, in Figure 1. Note that this model contrasts with a second model, B, which involves two years of intensive course work prior to beginning research. I favor model A because it emphasizes research as the "heart" of the student's program. Also, it maximizes time allocated to research and problem solving activities.

The major professor has to be more priority conscious in helping the student choose course work in the model-A system because there is less time allotted for this activity; however, this liability is worth accepting for the sake of devoting greater overall time to research activities. An additional "hidden" benefit of model A is

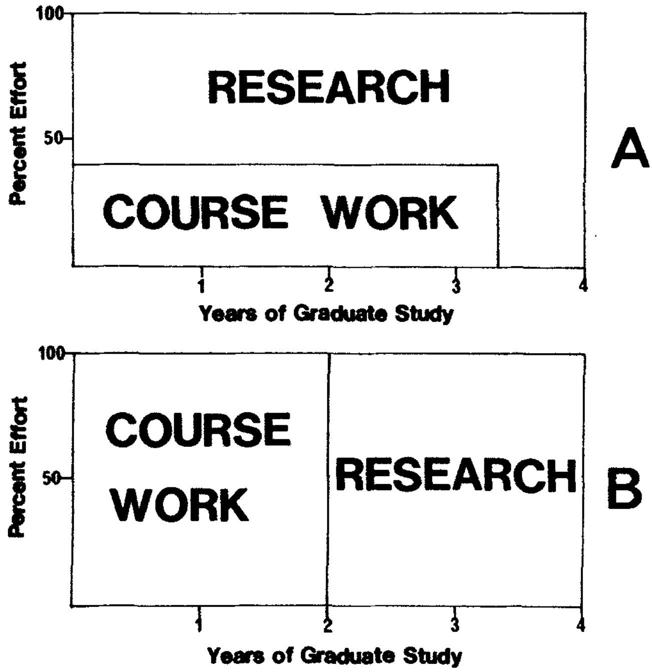

FIGURE 1.

Diagrammatic representations of models for graduate study. Approximate formal course equivalents: A, 25 to 30 semester hours (≅ 40% of years 0 through 3.3); B, 42 to 48 semester hours (50% of years 0 through 4).

related to students taking modest amounts of course work almost entirely throughout their graduate career. That is, students must learn to budget their time, a management-type activity that will be of great benefit to the future industrial scientist.

While the author acknowledges the importance of training within a discipline, the student must be aware of interdisciplinary work from the beginning of his/her graduate career. Especially for the prospective industrial scientist, serious exposure to interdisciplinary work should occur toward the end of his/her graduate education. This proposal is diagrammatically presented in Figure 2. The reader should also note that the diagram in Figure 2 suggests that the postdoctoral fellow receive a "heavy dose" of interdisciplinary training as a prelude to accepting an industrial position. To clarify what the author means by interdisciplinary research, the following definition is provided[5].

> "Interdisciplinary research involves the joint, coordinated, and continuously integrated efforts of investigators from different disciplinary backgrounds. These people work together to produce results which are so tightly woven that individual contributions are not easily identified. In chemical-biological interdisciplinary studies, for example, the chemist will perform biological experiments; the biologist will do some chemical work." In contrast . . . ."Multidisciplinary research results from experts in different disciplines working separately on various aspects of a primary objective. The synthesis of results is done primarily by the research manager."

The author stresses the value of interdisciplinary work in graduate and postdoctoral studies because of the unique cross-disciplinary character of drug developmental investigations in industry. Again quoting Dr. Sheridan[16],

> "The real value of the pharmacy-trained employee is that they appreciate the end use of our products, they understand the interdisciplinary complexities

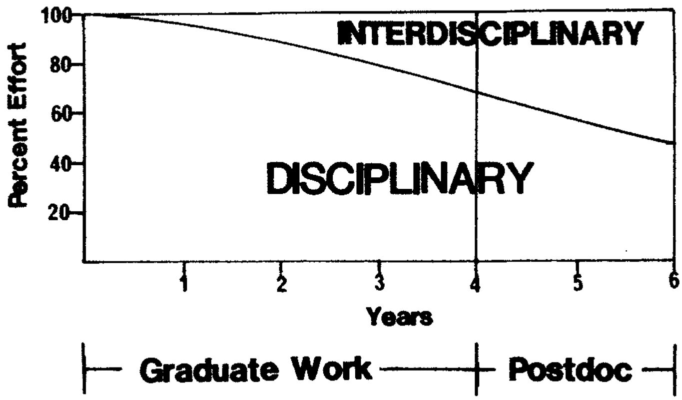

FIGURE 2.

Diagrammatic representation of recommended blend of disciplinary and interdisciplinary work in graduate and postdoctoral studies in the pharmaceutical sciences.

of our products, and hence can take a broad spectrum approach to the projects they are given to work on."

The espousal of the merits of interdisciplinary work is hardly unique to Dr. Sheridan[16] or this author[5]. The Nobel Laureate and long-time director of the University of California at Berkeley's Laboratory of Chemical Biodynamics, Professor Melvin Calvin, recently has been quoted as saying about his laboratory ......

"Here physicists, chemists, and biologists really live together. They aren't just placed together, they work and think together.

"'Team' isn't the right word. You don't decide, 'we're going to have a team' -- at least I don't. You look at the problems, what has to be done, and who can do it.

> Pretty soon, people start getting together. Each has his own central problem, but each contributes to the others. They're willing to take the trouble to participate in their neighbors' concerns. Really participate, not just advise. That's an important distinction"[17].

Interestingly, other progressive academicians and scientists outside of pharmacy have also begun to appreciate the value of interdisciplinary efforts. The eminent biochemist, Professor Esmond E. Snell has recently written the following . . .

> "knowledge, unlike universities, cannot be segmented along departmental lines . . . progress at the frontier of knowledge is most rapid when a variety of investigational techniques is applied ..... Departmental structures, while useful and necessary for administrative and instructional purposes, reflect the historical development of a subject area and cannot anticipate future needs in it. If too rigidly or jealously maintained, they can inhibit the very development they seek to promote. An important function of administration at all levels should be to ensure that rules and regulations do not impede interdisciplinary cooperation in either the teaching or research function of the University. Only the forward-looking actions of individual faculty members can ensure that such cooperation actually occurs"[18].

Dr. Philip Handler, President of the National Academy of Sciences, has recently written the following . . . .

> "Twenty years ago the major scientific and societal problems still fell reasonably neatly into the old disciplinary compartments of physics, chemistry, geo-

logy, and biology, etc., although biochemistry itself was something of an awkwardness. But that facile compartmentation no longer is, or seems, quite so relevant. The very success of science has created new sets of problems which cannot be quite so neatly encompassed. The biosocial problem of population control, the environmental crisis, the information explosion, the energy problem, the future of developing nations, even the relationship between brain and mind, the genesis of life, or the etiology of cancer can no longer be managed by a single classical discipline. And so, what scientists, from their disciplinary standpoint, deem as scientific progress, may now seem questionable or irrelevant to the public at large"[19].

The reader should not misconstrue what has been argued above. Interdisciplinary work does not substitute for a strong disciplinary effort in the better part of the graduate student's academic career. However, a research advisor who promotes interdisciplinary activities is serving his/her students well. One mechanism for accomplishing this objective is to arrange for joint group research meetings with a colleague in a complementary discipline. Additional ideas for accomplishing interdisciplinary work have recently been described by the author[5].

Management and Communicative Skills

Many industrial managers emphasize the need for managerial and exceptional communicative skills in prospective employees. Courses in management and scientific writing are often available for graduate students, however, the objectives of these offerings should be reinforced by the major professor. Indeed, a good case can be made for improved management skills in professorial research managers[5]. The effective research manager in turn serves as an outstanding model for the student. More specific mechanisms that aid the graduate or postdoctoral student include requirements for written monthly reports and oral presentations at group research meetings, regularly planned individual research conferences between student and professorial advisor, and mandatory participation in organized journal clubs and departmental or collegiate seminars[5]. Communicative skills are further enhanced by encouraging presentation at regional and national meetings of scientific organizations, and by planned joint review of manuscripts prepared by members of the research group or submitted to the major professor as referee[5].

Improving Academic-Industrial Interactions

Since the pharmaceutical industry will be a prime benefactor of improved graduate programs in the pharmaceutical sciences, it seems sensible that the industry should be willing to be of tangible assistance. At this point, it is important to note that few departments or universities have the resources to fully finance high-quality graduate and research programs in the pharmaceutical sciences[5]. Indeed, it is estimated that it takes between $50,000 and $75,000 to educate a single Ph.D.-level pharmaceutical scientist. This level of funding is just not available through higher education institutions. Of greatest benefit are industrially sponsored fellowship programs that can be established and supported by unrestricted grants to academic institutions. For the modest sum of $10,000 per year, a fellowship can be established in the name of a company to support the education of a doctoral level student for one year. Two such programs are currently established in the Drug Dynamics Institute (DDI) at the University of Texas at Austin. One supports students in pharmaceutics while the second sponsors students in pharmaceutical analysis. The value of the grants is maximized since students can be paid stipends (usually about $500/month) that are tax free because stipulations can be set to satisfy the regulations enumerated in IRS ruling 60-378[20].

The predoctoral fellowship programs administered through the DDI also provide for summer industrial internship experiences. That is, a fellow can spend a summer in the sponsor's firm where he/she is expected to work in several different areas. These are enriching experiences that have been very favorably received and appreciated by students. While no obligation to the sponsoring firm is accrued by the fellow, the company does have an early opportunity to attempt to recruit the student following graduation.

Other academic-industrial cooperative programs could be of benefit in training increasing numbers of high quality pharmaceutical scientists. For schools in close proximity to pharmaceutical firms, joint educational programs can be established where the graduate student performs much of his/her research in the cooperating company. If carefully planned and monitored, such programs can lead to quality graduates. Additional bipartisan efforts can include adjunct faculty appointments, truly joint research efforts, and two-way sabbatical programs. Academia and industrial firms should look imaginatively at all these options. Industry should be generous in giving both moral and financial support!

SUMMARY AND CONCLUSIONS

Current U.S. industrial needs for Ph.D.-level graduates in pharmaceutics, medicinal chemistry and pharmacognosy, pharmacology and toxicology, and pharmacy administration have been reviewed. The greatest demands appear to be in the areas of physical pharmacy, industrial pharmacy, analytical pharmaceutical chemistry, biopharmaceutics/pharmacokinetics, and pharmacology/toxicology in that order. Some strategies have been presented for educating Ph.D.-level scientists for industrial positions. The attainment of quality in students and programs is stressed along with extraordinary emphasis on research and research skills. A varying proportion of disciplinary and interdisciplinary research activities is proposed for graduate level education and some suggestions for effective collaborative efforts are provided. Several suggestions have been made for improving managerial and communicative skills in graduate students and their professorial advisors. Finally, proposals have been offered for closer interactions between academia and industry.

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