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Ensuring the Supply of Highly Qualified Pharmaceutical Scientist Specialists in Product Development and Related Technologies for Present and Future Needs - Report of the 2004 PT Section Education Committee

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ABSTRACT

The 2004 PT Section Education Committee took the first steps in addressing the charge: "How can the supply of highly qualified pharmaceutical scientist specialists in product development and related technologies that meet current and future needs be ensured?" This charge was borne out of earlier reports and current experience that suggest that: (1) graduate programs in colleges of pharmacy are increasingly failing to produce sufficient numbers of appropriately qualified specialists in product development and related pharmaceutical technologies and, (2) the pharmaceutical industry has been forced to recruit and train scientists from other disciplines. Surveys conducted by this committee of the membership (PT, PDD and BT sections) and a representative group of pharmaceutical executives validated this concern and provided insight into its nature and depth. For example, the executives reported that 50% or less of product development staff have undergraduate degrees in pharmacy and that 50% or less have advanced degrees in pharmaceutics/industrial pharmacy/pharmaceutical technology, yet entry-level PhDs in these specialties bring a better mix of skills to the product development table than their counterparts from other science disciplines, and that this advantage persist even after 4–6 years experience on the job. And the great difficulty in finding candidates with the right mix of experience and education was also made clear by the surveys. Based in part on an analysis of these surveys, this committee developed an extensive list of issues to be addressed by future PT Education committees and AAPS. Among these were: (1) Should AAPS encourage and assist in the establishment of graduate programs in product development/technology and/or tracks in academic institutions whether or not they are colleges of pharmacy?, (2) Should AAPS develop standards for and qualify such educational programs and tracks? (3) How do we and what role should AAPS play in creating awareness in colleges and universities of our needs and the incentives to develop and maintain programs that meet these needs?, and (4) How can stable funding be provided for programs in product development and technology?

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COMPOSITION OF THE COMMITTEE

The following committee of senior pharmaceutical scientists representing education, industry and FDA was assembled by the Chair.

Ajaz Hussain
James McGinity
Stephen Nail
Michael Pikal
David Savello
Joseph Schwartz
Larry Augsburger, Chair
Anil Salpekar, Ex Officio
Victor Van Beuren, AAPS Staff Liaison

CHARGE

Broadly, PT Section Chair Dr. Anil Salpekar charged this committee to seek ways to ensure the supply of highly qualified pharmaceutical scientist specialists in product development and related technologies that meet current and future needs. Further, the committee deliberations should include, but not be limited to, such issues as advocacy and support for educational programs to train such specialists.

INTRODUCTION AND BACKGROUND

Concern over the adequacy of the supply of pharmaceutical scientists is not new, having been expressed as early as 1978 in a Symposium of Teachers of Pharmacy (Pharmaceutics) held at the 25th National Meeting of the A.Ph.A. Academy of Pharmaceutical Sciences.[1] Among others, the presenters and numerous participant comments emphasized (a) the lack of financial support and its impact, (2) the potential negative impact of the growing clinical emphasis in undergraduate programs in pharmacy, (3) the types and sources of funding available, and (4) the role that could be played by cooperative programs between academia and the industry. Based on a survey of ~25 each of industrial managers and academicians, R.V. Smith[2] observed in 1981 that a great need exists for PhD pharmaceutics scientists in industry, and

that most acutely, that shortage is in the area of industrial/physical pharmacy. Based on this analysis, he noted that the following factors can be considered as contributing to this situation: (a) a shift in the interest of graduate students toward more "biological-type" sciences, (b) the movement of faculty during the previous 10 years more toward biopharmaceutics and pharmacokinetics, (c) the substantial investment in the equipment, space and faculty needed for industrial pharmacy programs has apparently been viewed as prohibitive by academic administrators, and (d) the lack of support from both federal sources and the industry itself.

A 1990 AAPS Task Force on academic pharmaceutics[3] (composed primarily of academics) observed that even though pharmaceutics has provided much of the intellectual stimulus for the development of clinical pharmacy, this did not result in pharmacy students having an enhanced interest in academic pharmaceutics per se because most students enter pharmacy school to become pharmacy practitioners. It was further noted[3] that "if the very substantial demand for pharmaceutical scientists" cannot be met by pharmacy schools, then industry and academia will turn increasingly toward other discipline areas to meet manpower needs and attempt to compensate for lack of pharmaceutical education and training in such individuals by providing in-house and commercially available training programs. It was argued that "This practice is unsound and could create a vicious cycle whereby the limited availability of newly graduated pharmaceutical scientists eventually reduces the demand for them…"[3]

In 1997, Alice Till observed that today's graduate programs are "training the majority of students for the minority of industrial opportunities."[4] Dr. Till explained that graduate programs are more and more focusing on drug discovery, and that basic research is often emphasized over applied research. This situation may be the result of specific faculty interests, funding issues or a lack of understanding of the wants and needs of industry, but the net result is that programs in industrial pharmacy or pharmaceutical manufacturing have been de-valued, and programs in material science, formulation science or process science are uncommon.[4]

More recently, Mooney,[5] in addressing the manpower needs of the pharmaceutical industry at a EUFEPS workshop, pointed out that the output from universities is not keeping up with the demands of the pharmaceutical and healthcare industries for science and engineering graduates who can "rapidly contribute to success in the business environment," and that the challenge "comes from balancing education in basic science with training in the emerging areas of science and technology." Addressing a European audience, Mooney noted that academia and industry will need to work together more synergistically, government funding should be prioritized to taken into account industry's needs, and that multi-disciplinary programs are going to be more and more important. At that same workshop, Breimer[6] also called for updated, multi-disciplinary programs, pointing to the fact that new developments in drugs (eg, new classes of mechanism-based small molecules, proteins, oligonucleotides, and others) each bring a need for new challenges to quality, production, delivery systems and formulation, among others. Both Breimer and Mooney also emphasized the need for several "softer" and/or non-disciplinary skills such as written and verbal communication skills, ability to function in interdisciplinary teams, and exposure to social and cultural skills needed for an increasingly globalized industry.

Interestingly, the authors of the report the 1998 Commission on the Future of Graduate Education in the Pharmaceutical Sciences[7] later observed in 2002 that the "recent dramatic increases in the federal support of biomedical research, specifically the doubling of the NIH budget, is producing an excess of PhD graduates in the biomedical sciences."[8] They suggested that this increase in graduate program enrolment is driven more by personnel needs of the academic research community and less by employment needs or even the educational needs of graduate students. It is perhaps ironic that one outcome of this situation is that the post-doctoral fellowship has become a virtually required component of higher education in such disciplines.

HYPOTHESES

Based on the personal experience of the committee and a review of the literature, the following hypotheses related to the supply of pharmaceutical scientists specializing in product development and related technologies were adopted:

Shift in Focus of Pharmacy Education

The focus of pharmacy education has been shifting away from the basic sciences. In most cases schools have been setting new priorities to conform to changes in pharmacy practice and new initiatives in health care. In many cases, graduate programs in colleges of pharmacy are focusing increasingly on drug discovery and biotechnology and other basic areas while applied programs in industrial pharmaceutics, product development and pharmaceutical technology are often devalued.

Limited Number of programs in Industrial Pharmaceutics and Related Technologies

There presently are a limited number of programs in industrial pharmaceutics, product development and pharmaceutical technology in academia, and this number is likely to diminish. When currently established faculty in these areas retire, typically they are not replaced with specialists in those same areas. The high capital cost of technology research

discourages the entry of faculty and the establishment of new programs. This situation could create a critical shortage of trained personnel for industry.

Industry Continues to Need and Value Our Graduates

Graduates are so strongly recruited that post-doctoral assignments are almost unheard of. Graduates in industrial pharmaceutics/technology are often committed to positions in the industry before all degree requirements have been completed. To meet its needs, it appears that the pharmaceutical industry has been turning more and more to scientists from other scientific areas only to train them in pharmaceutical research and development.

There is a Lack of Stable Funding for Technologically-Focused Programs

Funding is generally derived from the industry and is often short-term or project-based, thereby not providing the stability of the multiple-year grants and contracts common in federal funding. Industry funding often does not support Federal levels of overhead. Furthermore, faculty who secure such funding and their schools may not be given "full recognition" for bringing in the money because it is not "peer reviewed." This situation provides another serious disincentive for pharmacy schools and faculty to develop and nurture programs in industrial pharmaceutics/technology.

First Step

The Committee agreed that that the first step in addressing its charge should be to document the problem. It is important to find out, for example, who are the people doing technology and formulation and what their educational background is. It is also important to examine the industry's attitude, position and needs are re this issue. To that end, two surveys were created:

1) A web-based survey of the membership.

2) A focused survey directed to executives in representative sectors of the industry.

Following is a discussion of the design and implementation of these surveys and an analysis of the responses.

Membership Survey

The member survey was web-based and targeted the PT, PDD and BT sections. Of the roughly 5000 sent, there were a total of 398 responses.

Demographics

About half of responders indicated PT as their primary section membership, followed by 38.5% for PDD and 10.6% for BT. For nearly 70%, the PhD is their highest degree. Nearly 60% of responders obtained their highest degree in an area of pharmaceutics (ie, physical pharmacy, industrial pharmacy, dosage forms and drug delivery). The second most common discipline for their highest degree was chemistry (16.1%). Nearly half (47.2%) of responders hold a position that could be described as scientist/senior scientist/research fellow or equivalent. Significantly, nearly a third of respondents (29.8%) were managers, directors, section heads or their equivalent, while another 12.9% identified themselves

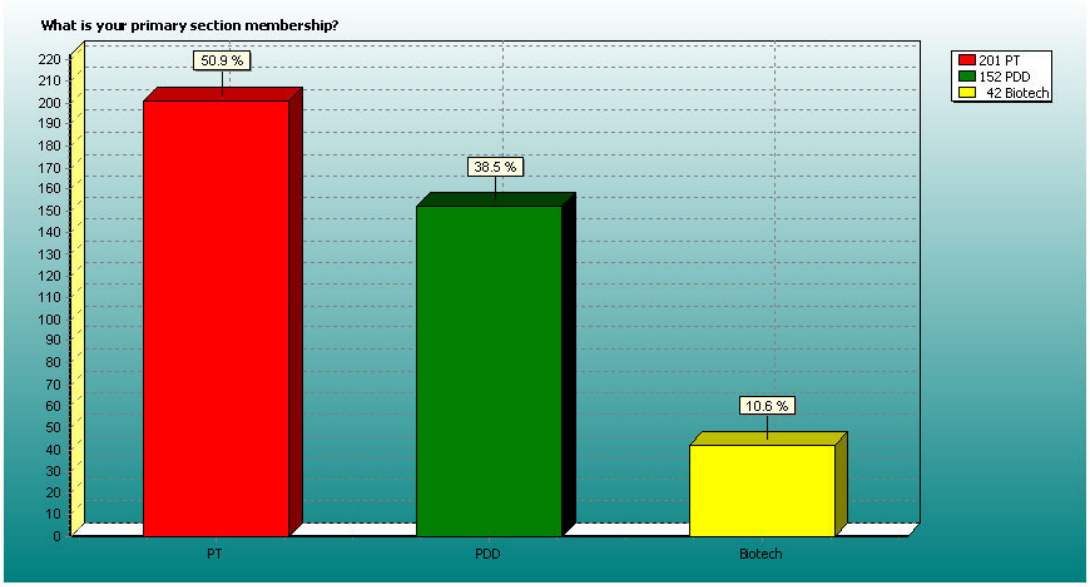

Figure 1. Primary section membership.

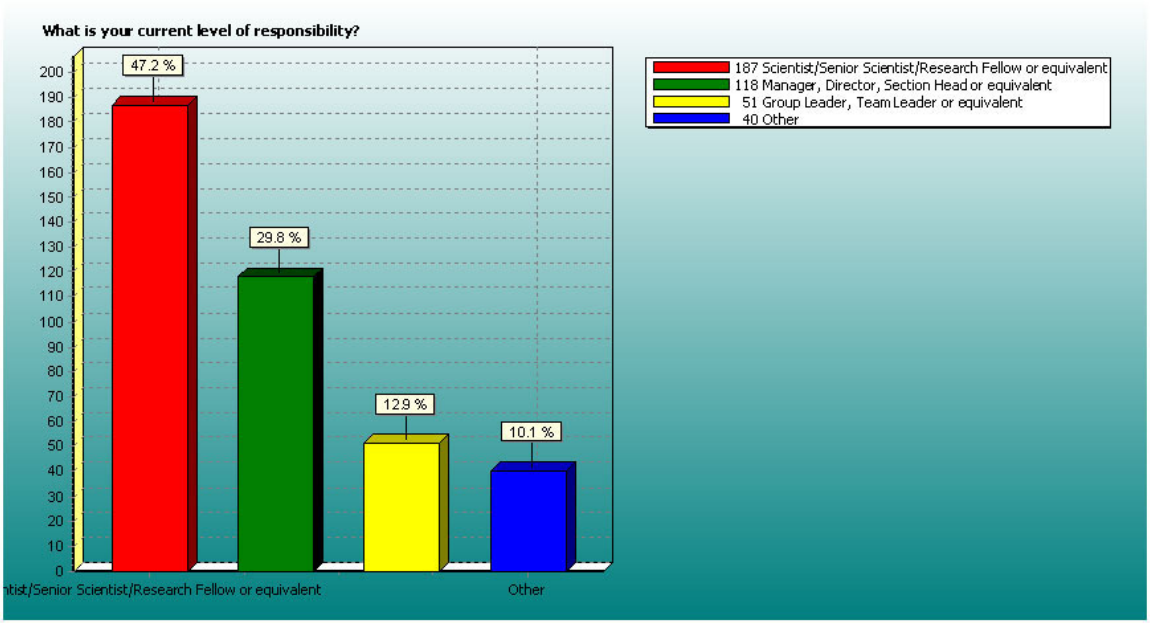

Figure 2. Current level of responsibility.

as group leaders, team leaders or the equivalent. The demographics are presented in more detail in Figures 1, 2, and 3.

Interestingly, 68.3% have only held their current position for 5 years or less (Figure 4) although, more than half (53%) have been in the pharmaceutical industry for 11 years or more (Figure 5).

Responses to Membership Survey Targeting the PT, PDD and BT Sections to Document the Industry's Attitude, Position, and Needs (Tables 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12).

Executive Survey

Although the *Member Survey* was clearly informative, the PT Education Committee considered that a focused survey directed to pharmaceutical executives would provide an additional perspective to the problem. A list of more than 50 executives was compiled from the suggestions of the committee. They were presidents (10%), vice presidents (40%), various levels of directors (42%) and others (8%). The Executive Survey was a hardcopy questionnaire sent with a postage paid return envelop. Fourteen responses have been received to date for a 27% return rate.

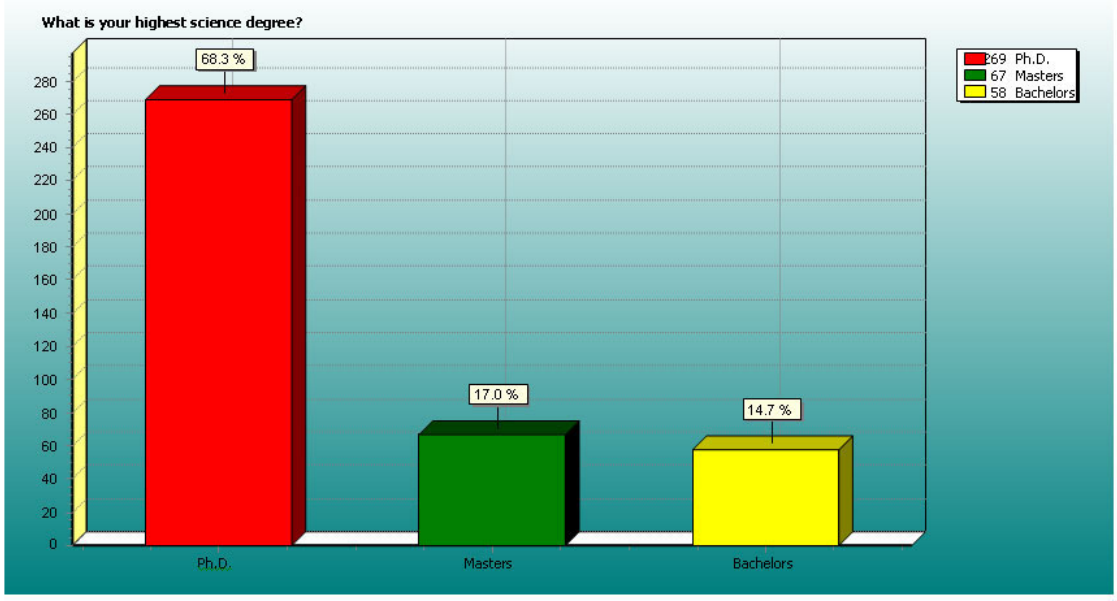

Figure 3. Highest science degree obtained.

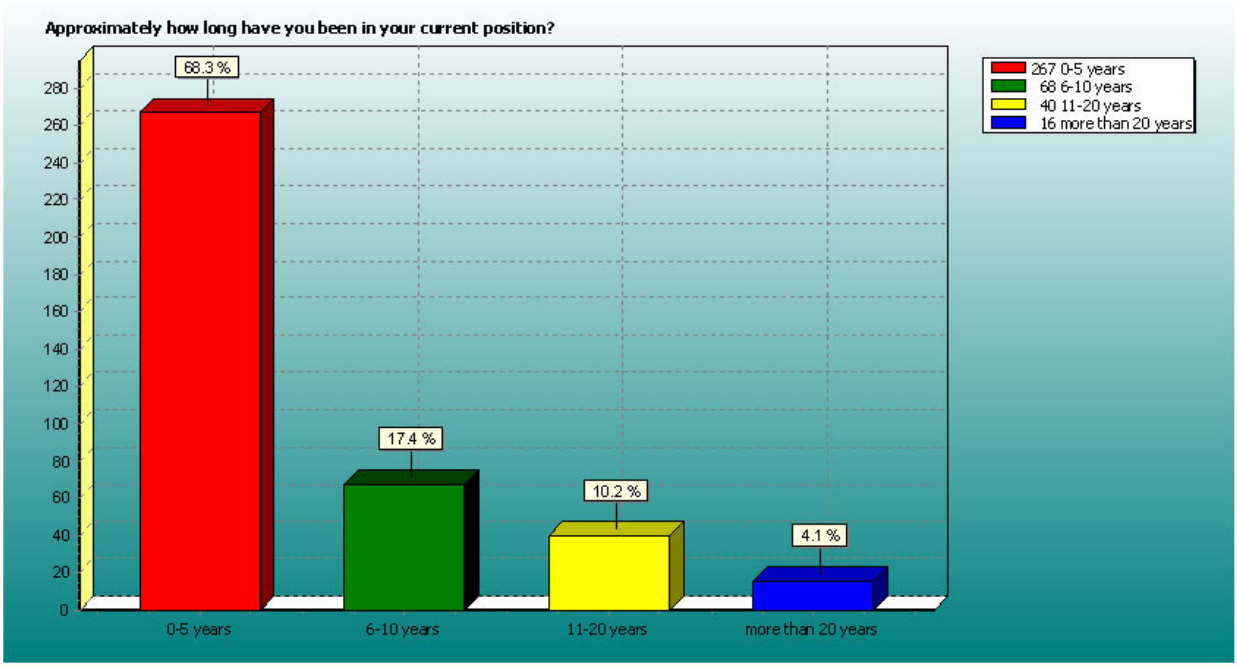

Figure 4. Length employed in current position.

Demographics

More than 90% consider PT their primary section. All respondents have been in the pharmaceutical industry for 11 or more years, of which 57% have been in this industry for more than 20 years. The highest degree of respondents was either a PhD (86%) or a Masters degree (14%) and is most likely (86%) to be in pharmaceutics (defined as physical pharmacy, industrial pharmacy, product development).

Questions and Responses

1. What percentage of staff engaged in product development activities in your firm or division has an undergraduate degree in pharmacy regardless of what discipline their advanced degree(s) are:

- ***7(50%)*** 0%-10%
- ***4(29%)*** 11%-25%

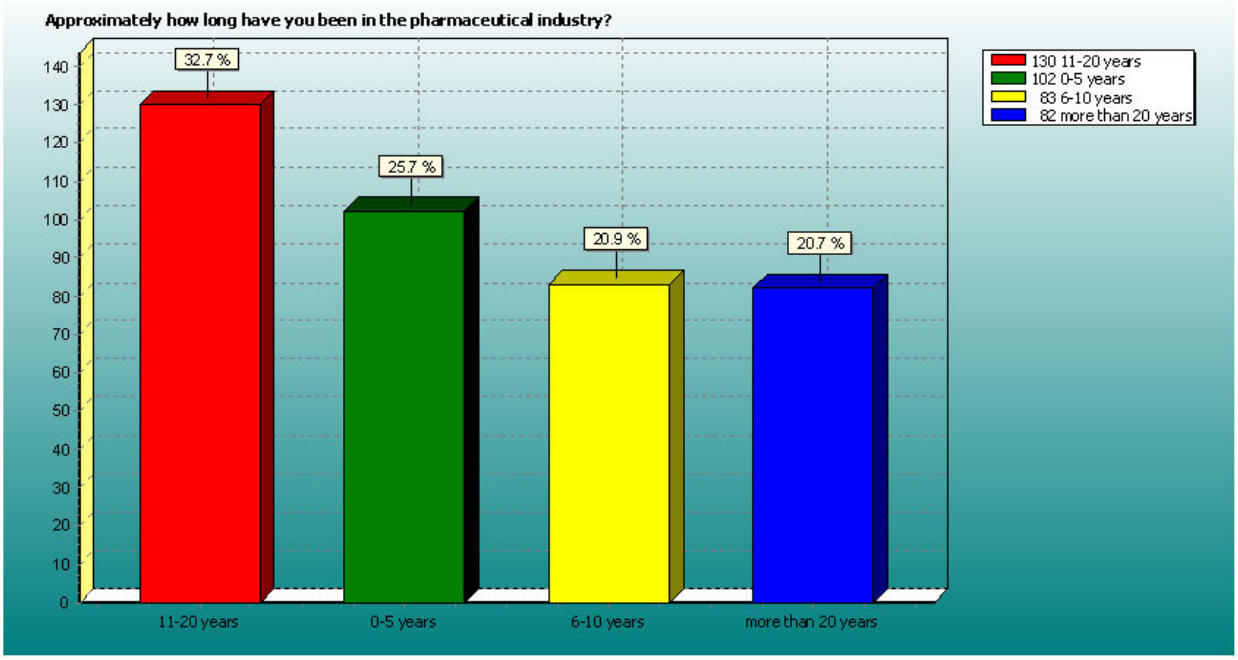

Figure 5. Length of service in the pharmaceutical industry.

Table 1. Opinion Results that the Currently Available Education/ Training of Entry-level PhD Pharmaceutical Scientists is Adequate Preparation for Positions in Product Development Groups in the Pharmaceutical Industry*

Response	Count	Percent
Strongly agree	21	5.3%
Agree	179	45.1%
No Opinion	63	15.9%
Disagree	115	29.0%
Strongly Disagree	19	4.8%

*About half (50.4%) of respondents agreed with this statement; whereas, about one-third (33.8%) did not agree, the remainder expressing no opinion.

- ***1(7%)*** 26%-50%
- ***2(14%)*** 51%-75%
- ***0%*** >75%

2. What percentage of staff engaged in product development activities in your firm or division has an advanced degree in pharmaceutics/industrial pharmacy/pharmaceutical technology?

- ***7(50%)*** 0%-10%
- ***4(29%)*** 11%-25%
- ***2(14%)*** 26%-50%
- ***1(7%)*** 51%-75%
- ***0%*** >75%

3. What percentage of staff engaged in product development activities in your firm or division only has an entry level or advanced degree in an engineering field?

- ***9(64%)*** 0%-10%
- ***4(29%)*** 11%-25%
- ***0(0%)*** 26%-50%
- ***1(7%)*** 51%-75%
- ***0%*** >75%

Table 2. Opinion Results that Entry-level Scientists Should have a Strong Background in Preformulation and Materials Science as Well as Unit Operations in Manufacture of Pharmaceutical Products as Part of their Phd Program*

Response	Count	Percent
Strongly agree	141	35.6%
Agree	173	43.7%
No Opinion	27	6.8%
Disagree	48	12.1%
Strongly Disagree	7	1.8%

*Nearly 80% (79.3%) agree with this proposition; only 14% disagreed, the remainder expressing no opinion.

Table 3. Opinion Results that a Strong Background in Basic Science is Sufficient Background for an Entry Level Scientist Since Materials Science, Processing and Product Development Experiences can be Picked up on the Job*

Response	Count	Percent
Strongly agree	31	7.8%
Agree	129	32.7%
No Opinion	42	10.6%
Disagree	163	41.3%
Strongly Disagree	30	7.6%

*Respondants displayed substantial ambivalence on this question, with approximately half (50.5%) in agreement and nearly half (48.9%) in disagreement, the remainder expressing no opinion.

4. What percentage of staff engaged in product development activities in your firm or division only has an entry or advanced degree in other science fields (physical chemistry, physics, organic chemistry, biochemistry, etc.)

- ***3(21%)*** 0%-10%
- ***4(29%)*** 11%-25%
- ***4(29%)*** 26%-50%
- ***2(14%)*** 51%-75%
- ***1(7%)*** >75%

5. On scale of 0 to 4 (0 = more qualified candidates than openings; 4 = cannot fill current positions), how would you rate the level of difficulty in finding qualified people to fill product development positions?

- ***0(0%)*** 1
- ***4(29%)*** 2
- ***7(50%)*** 3
- ***3(21%)*** 4

Respondants were also asked to elaborate on their answer by making written comments. Following is a representative list of their comments: *(1) Direct formulation expertise coupled with communication skills are hard to find;(2) Difficult to find "formulation" candidates; (3) Pharmacy and pharmaceutics almost impossible – especially those with some*

Table 4. Opinion Results that an Entry Level Pharmaceutical Scientist Should have a Working Knowledge of Patents, SOPs, INDs, NDAs, and ANDAs as Part of His/Her Graduate Education*

Response	Count	Percent
Strongly agree	44	11.1%
Agree	168	42.5%
No Opinion	57	14.4%
Disagree	118	29.9%
Strongly Disagree	8	2.0%

*Most respondents (53.6%) were in agreement with this proposition.

Table 5. Opinion Results that there is a Current Shortage of Entry-level Scientists with an Appropriate Background in Product Development and Pharmaceutical Technology*

Response	Count	Percent
Strongly agree	69	17.5%
Agree	161	40.8%
No Opinion	111	28.1%
Disagree	49	12.4%
Strongly Disagree	5	1.3%

*Nearly 60% (58.3%) agreed that this shortage exists; whereas, only 13.7% disagreed, the remainder expressing no opinion.

industry experience; (4) Will extend offers only to 25%-40% of those interviewed. Lack of knowledge of industrial processes/processing; (5) Typical time to fill vacancies: 9 months; (6) Concept of product development is novel to executive team. Product development not recognized let alone understood; (7) Difficulties encountered by the coordination of education and experience; (8) Difficult to find the right level and mix of education and experience needed; (9) It is difficult to get persons with experience in mixed skill sets in today's job with demanding multi-tasking.

6. How do you recruit for product development positions? Check all that apply.

10 Contact recruitment firms ("Head-hunters")

6 Contact professors/departments at colleges of pharmacy

3 Contact professors/departments at other colleges

14 AAPS placement service

11 Other (Please describe briefly): Internet jib boards, referral from community, in-house recruiter and journal, newspaper ads, Web site, contact vendors of equipment and excipients for referrals, go deep into network.

7. When you recruit for product development positions, what percentage of positions require a technical background in *Biology and Drug Delivery*?

- ***4(29%)*** 0%-10%
- ***2(14%)*** 11%-25%
- ***6(43%)*** 26%-50%
- ***2(14%)*** 51%-75% >75%

8. When you recruit for product development positions, what percentage of positions require a technical background in *Physical science and Pharmaceutical Technology?*

- ***1(7%)*** 0%-10%
- ***7(50%)*** 11%-25%
- ***3(21%)*** 26%-50%
- ***3(21%)*** 51%-75% >75%

9. Assuming 0–2 yrs experience, how would you compare a PhD in industrial pharmacy, pharmaceutical technology or related area to graduates of other science disciplines you have seen in the following attributes. [Please place an X in the appropriate box.] (Table 13 and Figure 6.)

10. Assuming 4–6 yrs experience, how would you compare a PhD in industrial pharmacy, pharmaceutical technology or related area to graduates of other science disciplines you have seen in the following attributes. [Please place an X in the appropriate box.] (Table 14 and Figure 7.)

Table 6. Opinion Results that there is no Shortage of Suitably Trained Pharmaceutical Scientists due to the Current Abundance of Experienced Pharmaceutical Scientists Seeking Employment*

Response	Count	Percent
Strongly agree	12	3.0%
Agree	79	19.9%
No Opinion	137	34.6%
Disagree	145	36.6%
Strongly Disagree	23	5.8%

*Approximately 3/4 (77%) of the respondents either disagreed or had no opinion on this proposition.

Table 7. Opinion Results that due to a Shortage of Funds Available to Pharmaceutics Faculty to Train Students for the Pharmaceutical Industry, the Pharmaceutical Industry should be Responsible for Providing Funding to University Professors to Continue the Supply of Future Scientists to the Industry*

Response	Count	Percent
Strongly agree	54	13.7%
Agree	138	35.0%
No Opinion	93	23.6%
Disagree	90	22.8%
Strongly Disagree	19	4.8%

*Nearly half (48.7%) agreed that the industry should fund university professors; whereas, about a quarter (27.6%) disagreed with that proposition, the remaining expressing no opinion.

Table 8. Opinion Results: I Would Prefer to Hire Phd Level Chemists and Chemical Engineers and have them Learn on the Job to Fill Current Voids and Needs for Scientists in Product Development and Pharmaceutical Technology*

Response	Count	Percent
Strongly agree	22	5.6%
Agree	97	24.5%
No Opinion	84	21.2%
Disagree	141	35.6%
Strongly Disagree	52	13.1%

*Nearly half (48.7%) of respondents disagreed; whereas 30% agreed with this proposition, the remaining expressing no opinion.

Table 9. Opinion Results that an Adequate Supply of Suitably Trained Entry-level Pharmaceutical Scientists is not a Problem, but my Firm Spends More Time and Resources than it should in Sponsoring Permanent Residency Status*

Response	Count	Percent
Strongly agree	12	3.1%
Agree	37	9.4%
No Opinion	194	49.4%
Disagree	113	28.8%
Strongly Disagree	37	9.4%

*Nearly half of respondents had no opinion on this question, although more than a third (38.2%) either disagreed or strongly disagreed with the proposition.

SUMMARY ANALYSIS

Desired Background and Experience for Entry-Level Pharmaceutical Scientists in Product Development Groups

Taken as a whole, both surveys support the idea that entry-level product development scientists should bring to the position a good basic sciences background, but, in particular, be strong in preformulation, materials science and unit operations. Bringing the appropriate background to the job is preferable to having a good basic science background and picking up these additional skills on the job. A working knowledge of patents, SOPs, INDs, NDAs and ANDAs should also be a part of the entry level pharmaceutical scientist. About half of members surveyed opined that currently available education/training of entry-level PhD pharmaceutical scientists is adequate preparation for product development.

Who Is Doing Product Development?

Executives report that 50% or less of product development staff have undergraduate degrees in pharmacy and that 50% or less have advanced degrees in pharmaceutics/industrial pharmacy/pharmaceutical technology. According to more than 90% of executives, no more than 25% of their product development staff have either undergraduate or graduate degrees in an engineering field, but up to 75% of staff have entry level or advanced degrees in other science fields (eg, physical chemistry, physics, organic chemistry, biochemistry, etc).

Table 10. Opinion Results that Pharmaceutics Graduate Students Entering Product Development Groups in the Pharmaceutical Industry Need to have a Strong Background in Product Development and Drug Delivery Since Current Pressures on Industrial Scientists do not Allow Time to Mentor and Train Entry Level Pharmaceutics Graduates*

Response	Count	Percent
Strongly agree	49	12.4%
Agree	210	53.0%
No Opinion	52	13.1%
Disagree	84	21.2%
Strongly Disagree	1	0.3%

*Respondents agree in large measure (65.4%) that pharmaceutics graduate students entering product development groups in the pharmaceutical industry need to have a strong background in product development and drug delivery.

Table 11. Opinion Results that Fewer Colleges of Pharmacy in the United States Focus on the Product Development/Technology Needs of the Industry*

Response	Count	Percent
Strongly agree	88	22.3%
Agree	177	44.8%
No Opinion	108	27.3%
Disagree	16	4.1%
Strongly Disagree	6	1.5%

*Nearly 70% (67.1%) either strongly agree or agree with this proposition.

Availability of Entry-Level Scientists with Appropriate Backgrounds in Product Development and Pharmaceutical Technology

Most members surveyed supported that there is not only a shortage of entry-level scientists with appropriate background in product development and pharmaceutical technology, but also a lack of suitably experienced pharmaceutical scientists seeking employment. This situation was most obvious in the survey of executives, 70% of whom reported that the level of difficulty in filling such positions 3 or higher on a 4-point scale (4 = greatest difficulty). Most executives observed that there was substantial difficulty in finding the right mix of experience and education. According to the executives, when recruiting for product development positions, less than half the positions require a technical background in biology and drug delivery; whereas, ~90% require a technical background in physical science and pharmaceutical technology. The executives report and most members agree that firms go to extraordinary efforts to recruit for product development, using every means available, including going "deep" into the network.

Table 12. A Decline in United States-Trained Scientists will Result in the Exportation of Product Development Activities to Foreign Countries*

Response	Count	Percent
Strongly agree	75	18.9%
Agree	137	34.6%
No Opinion	94	23.7%
Disagree	76	19.2%
Strongly Disagree	14	3.5%

*More than half (53.5%) of respondents were in agreement with this proposition.

Table 13. Survey Results of Pharmaceutical Executives on PhDs with 0–2 years Experience in Industrial Pharmacy, Pharmaceutical Technology, or Related Areas Compared with PhDs in Other Science Disciplines

	Much better than graduates of other science disciplines	Somewhat better than graduates of other science disciplines	About equivalent to graduates of other science disciplines	Somewhat worse than graduates of other science disciplines	Much worse than graduates of other science disciplines
Basic science skills	*3 (21%)*	*2 (14%)*	*4 (29%)*	*5 (36%)*	*0*
Knowledge of dosage forms and drug delivery	*9 (64%)*	*3 (21%)*	*2 (14%)*	*0*	*0*
Formulation skills	*9 (64%)*	*3 (21%)*	*2 (14%)*	*0*	*0*
Knowledge of pharmaceutical manufacturing unit processes	*7 (50%)*	*4 (29%)*	*2 (14%)*	*1 (7%)*	*0*
Problem solving skills	*3 (21%)*	*4 (29%)*	*6 (43%)*	*1 (7%)*	*0*

Comparison of a PhD in Industrial Pharmacy, Pharmaceutical Technology or Related Area to Graduates of Other Science Disciplines

The majority of the members surveyed who expressed an opinion indicated that they would not prefer to hire PhD level chemists and chemical engineers and have them learn on the job to fill current voids and needs for scientists in product development and pharmaceutical technology.

Entry-level PhDs in industrial pharmacy, pharmaceutical technology or related areas bring a better mix of skills to the product development table than their counterparts from other science disciplines, and this advantage persist even after 4–6 years experience on the job. Assuming 0–2 years experience, 80% or more of the executives felt that a PhD in industrial pharmacy, pharmaceutical technology or related area to graduates was much better or somewhat better than graduates of other science disciplines in knowledge of dosage forms and drug delivery, formulation skills, and knowledge of manufacturing unit processes. About 50% opined that their problem solving skills were somewhat better or much better than that of graduates of other sciences, and 43% felt that they were about equivalent in problem solving skills. About 64% felt that their basic science

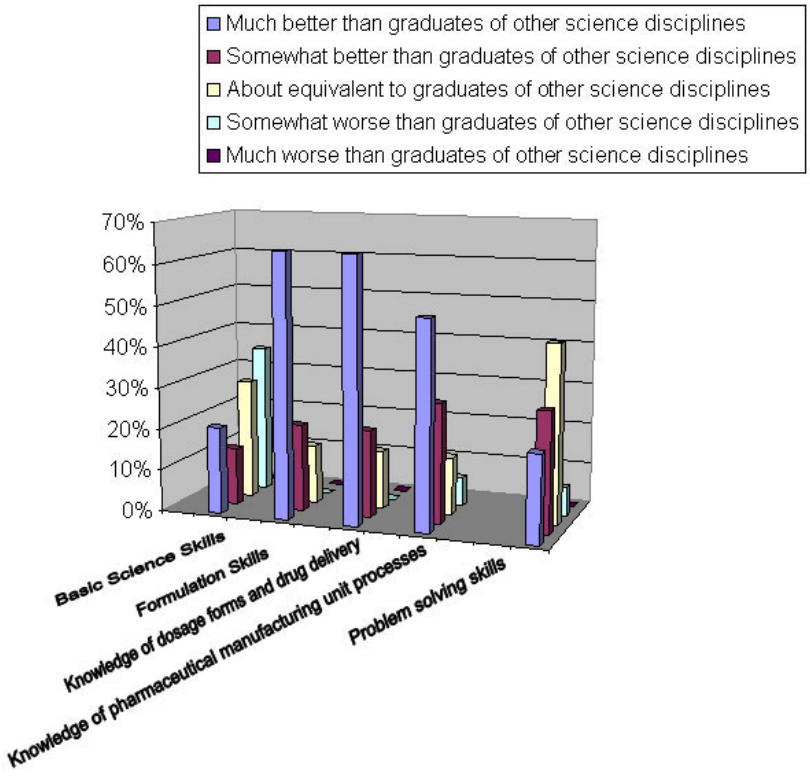

Figure 6. How pharmaceutical executive respondants compared a PhD in industrial pharmacy, pharmaceutical technology or related areas with 0-2 years experience to graduates of other science disciplines they have seen with the same level of experience.

Table 14. Survey Results of Pharmaceutical Executives on PhDs with 4–6 years Experience in Industrial Pharmacy, Pharmaceutical Technology, or Related Areas Compared with PhDs in Other Science Disciplines

	Much better than graduates of other science disciplines	Somewhat better than graduates of other science disciplines	About equivalent to graduates of other science disciplines	Somewhat worse than graduates of other science disciplines	Much worse than graduates of other science disciplines
Basic science skills	*3 (21%)*	*4 (29%)*	*4 (29%)*	*3 (21%)*	*0*
Knowledge of dosage forms and drug delivery	*8 (57%)*	*5 (36%)*	*1 (7%)*	*0*	*0*
Formulation skills	*10 (71%)*	*3 (21%)*	*1 (7%)*	*0*	*0*
Knowledge of pharmaceutical manufacturing unit processes	*6 (43%)*	*5 (36%)*	*2 (14%)*	*0*	*0*
Problem solving skills	*4 (29%)*	*4 (29%)*	*6 (43%)*	*0*	*0*

skills were equal to or better than those of graduates of other science disciplines.

Assuming 4–6 years experience, 90% or more of the executives felt that a PhD in industrial pharmacy, pharmaceutical technology or related area to graduates was much better or somewhat better than graduates of other science disciplines in knowledge of dosage forms and drug delivery and formulation skills, and 79% felt that their knowledge of manufacturing unit processes was somewhat better or much better than graduates of other science disciplines. About 50% opined that their problem solving skills were somewhat better or much better than that of graduates of other sciences, and 43% felt that they were about equivalent in problem solving skills. 100% felt that their problem solving skills were equal to or better than those of graduates of other science disciplines; whereas, 79% felt that their basic science skills were about equal to or better than those of graduates of other science disciplines.

What Sources and/or Solutions to the Problem Are Revealed in the Surveys?

These questions were only superficially addressed, and only in the member survey. Members broadly recognized that fewer United States colleges of pharmacy focus on product development. Those expressing an opinion (>75%), agreed (2 to 1) that the pharmaceutical industry should assume greater responsibility in funding university professors to continue the supply of future scientists to the industry. Concern was expressed by a 2 to 1 majority of the >75% of members who expressed an opinion that a decline in United States trained scientists will result in the exportation of product development to foreign countries.

What Do AACP Faculty/PhD Productivity Data Teach Us?

It is interesting to reflect on the above conclusions in light of recent statistical data from AACP.[9] Below are two graphs

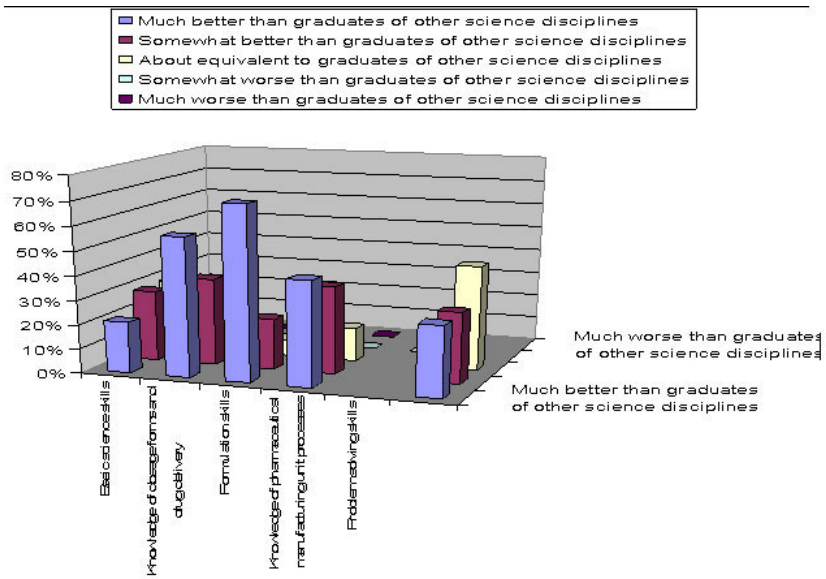

Figure 7. How pharmaceutical executive respondants compared a PhD in industrial pharmacy, pharmaceutical technology or related areas with 4-6 years experience to graduates of other science disciplines they have seen with the same level of experience.

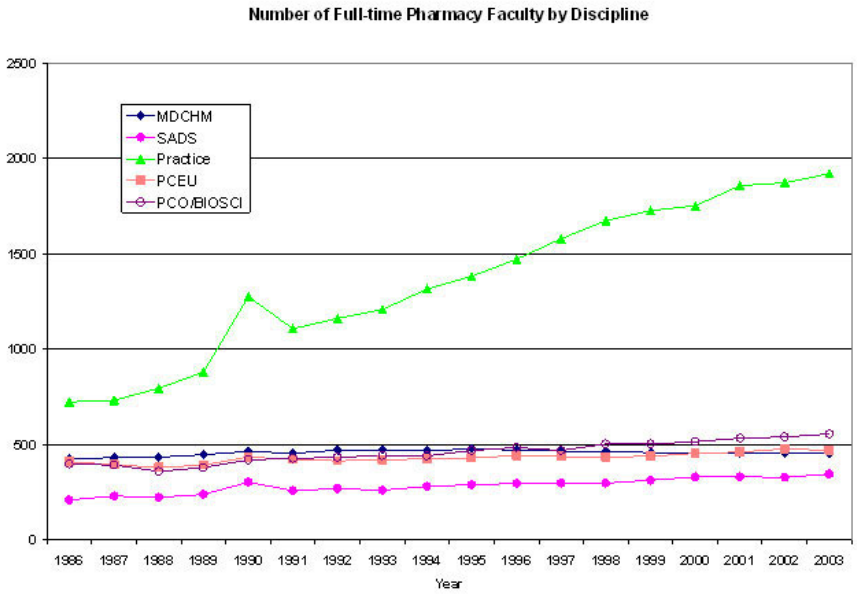

Figure 8. Number of full-time pharmacy faculty by discipline. Figure courtesy of the American Association of Colleges of Pharmacy.

plotting by discipline the trends since 1980 in PhD degrees granted and faculty numbers in colleges of pharmacy. It is clear from these data that the numbers of 'basic sciences' faculty in colleges of pharmacy, particularly those identified as 'pharmaceutics' faculty have been relatively flat; whereas, there has been a dramatic increase in practice faculty. This observation clearly reflects a shift in emphasis in pharmacy schools (Figure 8).

Yet, this relatively static number basic sciences faculty has apparently produced a growing number of PhDs, especially in pharmaceutics, since 1980 (Figure 9).

However, these statistics do not necessarily support that academic pharmacy is rising to the challenge of supplying entry-level scientists with appropriate background in product development and pharmaceutical technology. Clearly, industry's need is acute and persistent. The definition of 'pharmaceutics' research is quite broad and varies substantially from institution to institution. These data more likely indicate that pharmaceutics faculty have shifted to areas more easily funded through peer review sources (eg, pharmacokinetics, transporters, cellular metabolism, and other biosciences) than that they are producing specialists in product development and related technologies. AACP does not break out the subdisciplines nor the sources of support in these surveys.

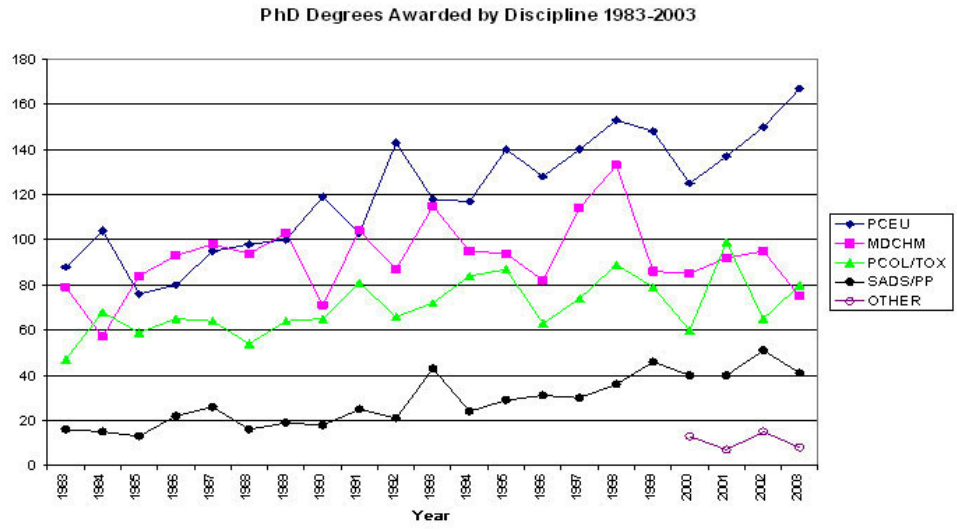

Figure 9. PhD degrees awarded by discipline 1983-2003. Figure courtesy of the American Association of Colleges of Pharmacy.

NEXT STEPS

Future PT Education committees should focus on the following non-limiting list of topics:

1. Exactly what are the current and future personnel needs and the skill sets they should have?

a) What are the current and anticipated future skill-set needs for pharmaceutical scientists specializing in product development and related technologies?

b) The ability to integrate basic sciences with practical application, and the ability to work effectively in an increasingly interdisciplinary environment are frequently cited as important attributes. How do we foster those abilities?

c) How desirable is it to enlist the active participation of industrial scientists in education and research? If desirable, how could we foster the close cooperation between industry and academia needed to make that happen?

2. Where should pharmaceutical scientists specializing in product development and related technologies receive their training?

a) Should AAPS encourage and assist in the establishment of graduate programs in development/technology and/or tracks in academic institutions whether or not they are colleges of pharmacy?

b) Should AAPS develop standards for and qualify such educational programs and tracks?

c) What role is there for educational programs other than doctoral programs, eg, applied Masters program, postgraduate Certification Programs, B.S. in pharmaceutical sciences programs.

d) How successful/promising are joint programs between colleges of pharmacy and engineering? What role should they play?

3. How do we and what role should AAPS play in creating awareness in colleges and universities of our needs and the *incentives* to develop and maintain programs that meet these needs?

a) How can stable funding be provided for programs in product development and technology? What are the sources of support and how can they be leveraged?

b) How can the FDA's Process Analytical Technology (PAT) and Pharmaceutical Quality Systems for the 21st Century initiatives be a 'galvanizer' for funding and appreciation for the importance and role of pharmaceutical technology? It is significant that the PAT Team and Manufacturing Science Working Group report "Innovation and Continuous Improvement in Pharmaceutical Manufacturing" argues strenuously for public and private support for pharmaceutical education:

"The scientific and technical challenges on the critical path towards the "desired state" are significant. The traditional empirical approaches will need to be replaced with a much more fundamental scientific understanding. This will require the talent and know-how of many scientific and technical disciplines. Without sufficient and sustained support our Nation's pharmaceutical education and research system will be unable to meet the needs of the desired state. Significant collaboration and cooperation among industry, academia, and public agencies (eg, National Science Foundation and National Institutes of Health) including FDA will be necessary to find solutions to this challenge."[10]

A corollary to this is whether traditional programs in pharmaceutics or industrial pharmacy training alone are sufficient to meet these challenges and be competitive for public funds. See 2d above.

ACKNOWLEDGMENT

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