

The Nation Needs a Comprehensive Pharmaceutical Engineering Education and Research System

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The pharmaceutical science education system must be transformed to ensure that we continue to meet our public health objectives and to maintain a competitive industry.

A recent re-examination by the US Food and Drug Administration of the current pharmaceutical quality decision-making system raised fundamental questions about its efficiency and its continuing effectiveness to address the increasing complexity of pharmaceutical systems. FDA's analysis improves our understanding of some factors that make this a reactive decision-making system. Those factors include the low success rate for identifying the root cause of deviations and out-of-specification observations as well as the predominant focus on end-product testing—often based on an inadequate statistical consideration of inherent variability and static process conditions—which, some argue, evolved to facilitate regulatory document expectations for “process validation.” FDA also has recognized that a reactive decision-making system is not conducive to innovation or continuous improvement. In a reactive environment, it is difficult to remove built-in inefficiency; the public bears the burden of this inefficiency because its cumulative costs reduce our ability to serve our customers well (1).

In current public debate, the pharmaceutical industrial community is generally viewed as reactive. For example, pharmaceuticals often are regarded as a healthcare cost or burden; counterarguments highlighting the cost-saving contributions of pharmaceuticals generally are drowned out. Adding to the challenge are growing concerns about drug safety, drug shortages caused by manufacturing difficulties, highly publicized manufacturing problems with significant economic impact on companies and their investors, counterfeit drugs, and unethical compliance practices by a few “bad apples.” This challenge is significant and long-term. Ideally, the environment in which the pharmaceutical industrial community operates should facilitate its ability to meet, and preferably exceed, the needs (therapeutic, affordability, and informational) and expectations of patients and society.

The objective of this column is to share a point of view that the symptoms observed in the current pharmaceutical system are, in part, a reflection of the current state of the pharmaceutical science ed-

ucation system. It is fragmented and diffuse (e.g., few focused university programs, diverse in-house on-the-job training, and casual for-profit educational programs). The academic pharmaceutical science programs have limited resources and are burdened by a practice environment that restricts their ability to generate knowledge with broad applicability. Much of the focus today, especially in pharmaceutical industrial operations and associated regulatory functions, seems to be based on a “documentation and checkbox” approach, in which deviations are a source of significant inefficiency and contribute to cross-disciplinary and cross-organizational circular arguments of art *versus* science. A reactive decision-making system, in turn, works in a cumulative manner to undermine the credibility of the pharmaceutical industrial community. The current pharmaceutical science educational system is in dire need of transformation to ensure that we continue to meet our public health and security objectives efficiently and to maintain a highly competitive environment for the US pharmaceutical industry.

Transforming the focus from industrial pharmacy to pharmaceutical engineering would create a more rigorous quantitative approach, to provide a means to create a new professional identity and a structure for considering opportunities for professional licensing and a culture of continuous education. Several points of view on a need for a pharmaceutical engineering approach have been expressed previously, often by individuals who received their basic training in disciplines *other* than pharmacy (2–4). This paper provides the point of view of an individual who received basic training *in* the discipline of pharmacy.

The proposed transformational change should be guided by the lessons learned from the evolutionary path of several engineering disciplines, particularly mechanical and chemical engineering (see

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Figure 1), and the process by which the National Science Foundation's (NSF) policies were shaped to foster the growth of several engineering disciplines. FDA's analysis can provide a good starting point for developing the public health and economic objectives; the factors contributing to the current reactive regulatory decision-making system can provide a platform for discussing how to structure a national education and research agenda.

It is recognized that efforts to improve pharmaceutical science and engineering education have existed for several years, and new programs have been initiated recently (2–7). A significant concern remains, however, that these efforts are scattered and may not be sufficient or sustainable without the long-term commitment of a stable funding mechanism and an improved system for recognizing the talent and contributions of scientists and engineers working in this field. Such mechanisms will be essential to continue attracting high-caliber scientists, engineers, and students to this field of study. The pharmaceutical community must consider developing a national agenda for debate and planning activities leading to the development of a comprehensive pharmaceutical engineering education and research system.

To engage a broad range of stakeholders in these discussions at the national or international level, we first must overcome the disciplinary and organizational divide within our community and avoid the "blame game" that arises in the regulated, multidisciplinary, applied scientific environment in which decision-making responsibility is divided to facilitate "compliance." A multidisciplinary collaborative framework and positive vocabulary will be essential. A new NSF funding program, the Science of Design (SoD), may be useful in this regard (8). Although the current SoD program is directed at the scientific study of the design of software-intensive systems, it is intended to address challenges familiar to the pharmaceutical community: In software systems, as in pharmaceutical systems, complex interdependencies pose a challenge for creating, maintaining, comprehending, and controlling these systems. The SoD program seeks to rectify this situation by building a foundation for the systematic creation of software-intensive systems. This foundation is proposed to

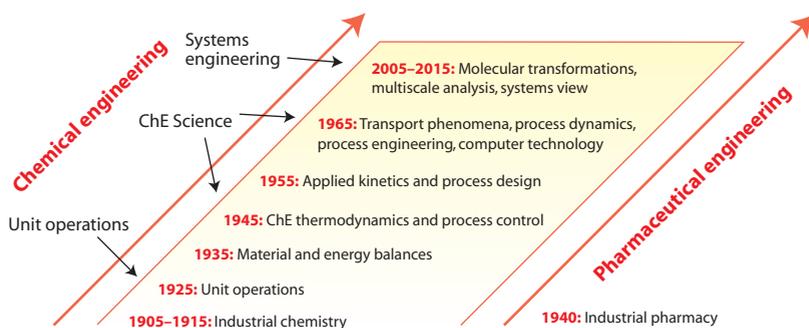


Figure 1: The evolutionary path of chemical engineering suggests a dynamic process moving toward molecular transformations, multiscale analysis, and a systems approach for addressing the needs at all scales and supplying tools to deal with dynamics, complexity, uncertainty, and external factors (10).

consist of a body of theoretical and empirical knowledge about design, computational methods and tools for design, and a new curriculum for the next generation of designers.

To summarize this point of view, it seems appropriate to draw a parallel between challenges facing pharmaceutical and software systems using a thought-provoking analysis of software engineering education (9). The following selected statements highlight some of the broad issues in software engineering; to illustrate their relevance, certain terms (*e.g.*, *industrial pharmacy*), relevant to this discussion have been added or inserted (in brackets) in place of the original terms (9):

- Despite years of hard work and dedicated champions, [industrial pharmacy] still struggles to become the discipline its founders envisioned. Its educational, industrial [and regulatory] constituents have not only failed to converge on a set of foundational principles, but the already large gap between [pharmaceutical education] and industry [and regulatory practice] continues to grow.
- Curricula are diffuse, [pharmaceutical] systems continue to have ever large error counts, and the financial risks of taking on [pharmaceutical] projects are growing.
- [The chemical and mechanical] engineering disciplines have done the job right, and [genetic] engineering is at least trying to do the job right. They have managed vast complexity and achieved a high level of public trust. [Industrial pharmacy] could take lessons from either discipline—and this

is not simply an academician's [or a regulator's] lament; the cost of [pharmaceuticals] is enormous and the risk to public safety daunting.

- "And like the heroes of the French Revolution, we look to a future that will bring us everything or nothing, depending on the public trust" (9).

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