Biotechnology Education

Commentary: Bioprocessing and the Essentials of Biochemistry

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While the media might portray the essence of the Biotechnology industry as a direct route from DNA to an effective biopharmaceutical, we understand that it is somewhat more complex. What distinguishes the life sciences industry from traditional pharmaceutical development is that in Biotechnology, it often requires a living system to produce a therapeutically effective product. Examining what initiated the modern bioscience industry (commercial production of insulin and erythropoietin for example) makes it clear that the industry was founded through producing previously known and well-characterized biomolecules efficiently enough to become commercially viable and reproducibly enough to meet the rigorous requirements of regulatory agencies such as the US Food and Drug Administration. The complexity of manipulating living systems for industrial purposes might have had roots as early as the production of bread, beer, and wine, but today’s life sciences industry requires vastly more precision and sophistication. The complexity of higher order protein structure and often problematic stability make for challenging issues of production and quality control. Not to take anything from the fermentation skill of a vintner of fine wine, but there is no tolerance for a difference in “vintages” for our biopharmaceuticals—they must be exactly the same every time for every patient.

The commercial production of recombinant hormones, peptides, growth factors, monoclonal antibodies, and vaccines has been increasing at a rapid pace, providing benefit for sufferers of numerous diseases. As a result, within the industry there has been much discussion of the impending shortage of production facilities. The physical facilities required to produce biomolecules involve long lead times and enormous capital to design, build, and validate. Less is heard regarding an equally difficult, expensive, and time consuming challenge: having enough sufficiently educated people who not only appreciate the engineering challenges required to make a GMP (Good Manufacturing Practices) facility, but who also understand the basic principles of biochemistry, cell biology, and structural biology. It makes little sense to invest in expensive facilities that will produce biopharmaceuticals if there will not be enough sufficiently trained people to operate and manage them. More importantly, however, if we cannot produce the molecules that will cure and prevent disease, we deny the benefits of our science to society.

If our students are to participate in the production of new biomolecules, it is imperative that we review our Biochemistry and Molecular Biology curricula to assure the proper balance of recombinant DNA technologies with structural biology and physical methods, especially in regards to protein structure and function. There is already far too much material to teach in most of our courses so it will take an active discussion among academic disciplines to work out strategies for teaching the basics effectively. However, there must be time within our curricula to include a complete survey of protein purification technologies, physical methods of structural analysis, and kinetic methods for quantitative analysis of enzymatic activities.

My informal and unscientific survey of course material reveals a decreasing proportion of Biochemistry and Molecular Biology courses devoted to the “old fashioned” principles of protein chemistry. However, it is essential that our students understand the basic principles of protein purification and the criteria used to establish the meaning of “pure.” They must have at least an appreciation of the power and limits of the technologies employed to determine protein structure, purity, and function. This will include spectroscopic and physical methods that are the underlying technologies used in the industry, from Raman spectroscopy to differential scanning calorimetry. While it will not be easy to fit these into curricula already jammed with important molecular concepts that are expanding every day, it must be actively discussed, and then appreciated as foundational material.

It might not be important to know how a particular protein is purified; only that it functions as predicted as a treatment. That is true enough if all you want to do is be a user of the product. The real opportunity to effect change and to benefit from it optimally comes to those who develop, understand, and control the technology. The people who have this power will be those who understand how to produce the wonderful products yet to come. They should be our students.