CORRESPONDENCE

PHARMACEUTICAL INTERMEDIATE SUPPLY

To the editor:

I would like to expand on a topic mentioned in Frederick Harrison's article on "Becoming a Pharmaceutical Intermediate Supplier" (March 1986).

An important issue for contract manufacturers of drug compounds or intermediates is their willingness to work with the product manufacturer regarding the presence and level of potential impurities. It is not enough to "clearly meet the manufacturer's raw material specifications." Specifications include test methods which must be validated to detect and measure potential low-level, synthesis-related impurities, side reaction products, and even degradation products (related to the synthetic process).

Most regulatory agencies require data to support detection and measurement of impurities. Many contractors regard the nature of these impurities as proprietary because knowledge of these compounds can give an astute chemist hints to the synthetic process. Hence, the contractor may lose a marketing advantage. Too often, the contractor feels that supplying this information to a regulatory authority via the Drug Master File (DMF) is adequate. This is not true because the manufacturer is responsible for validating Drug Substance specifications before a product can be manufactured. The DMF is reviewed only at the time the New Drug Application (NDA) is submitted for final acceptance. In addition, most prudent product manufacturers seek alternative suppliers, further complicating the issue if more than one synthetic scheme is utilized.

Without a mutual relationship that transcends certain—yet justified—proprietary concerns, the product manufacturer and the intermediate supplier will be unable to agree on a unified set of specifications that are validated and, therefore, meaningful to assure quality and purity.

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IN PRAISE OF INDUSTRIAL SCIENCE

To the editor:

I would like to disagree with a letter by Dr. Malcolm Rhodes (March 1986), in which he states that in 1965 "employers would probably not have permitted their [employees'] participation [in a scientific meeting]."

It may have been true then that the Society for General Microbiology would not have been a convenient forum for presentation of applied or industrial results, but these were frequently presented in meetings of the Society of Chemical Industry in Great Britain or the American Chemical Society in the United States. In the 1950s and 1960s both of these organizations had very active sections dealing with what has since been termed biotechnology. Since genetic engineering either did not exist then or was in its infancy, the presentations dealt with fermentation and biochemical engineering. These are exactly the aspects of biotechnology which Dr. Rhodes goes on to say "have rarely been patented or published" and were therefore "an empirical and largely unscientific business."

The literature of biotechnology is rich in articles describing details of processes for production of antibiotics, citric acid, etc. True, the yields, productivities, and efficiencies cited in the articles are frequently lower than those obtained in practice in the factory plant; but this is true also for technologies that have no connection to biotechnology. The successful industrial producer of chemicals rarely publishes his best results. The reason is simple: one of the most important secrets of any successful manufacturer is the detailed economics of the production process, and the aforementioned parameters are key to it.

I do agree that process improvements are less likely to be published than new compounds simply because the former are often protected as trade secrets owing to the difficulty of obtaining satisfactory patent protection. However, this is just as relevant to non-biological areas as to biological ones.

From my perspective of 30 years' intimate involvement in biotechnology, biochemical engineering, and associated subjects in both academic and industrial environments, I feel that the patent and commercialization issues associated with biotechnology and genetic engineering today are not very different qualitatively from those which have always been associated with the commercialization of new products or processes developed from basic scientific research. What has drastically changed for the better over the last 15–20 years is the involvement of hitherto "pure" university biologists in technology. Twenty years ago, such individuals were proud of the fact that they pursued "pure" knowledge; they were contemptuous of any of their colleagues who dirtied their hands in trade. The relish with which these "virgins" now engage in "sin" when the opportunity presents itself is illuminating to observe!

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SOME ABCs ABOUT THE ABC

To the editor:

The article titled "IBA and ABC Coexist at Arm's Length" (April, p.263) provides ABC with a unique opportunity "to see ourselves as others see us."

There are two additional points about ABC that we apparently have not conveyed well:

1. The Association of Biotechnology Companies is an *international* trade association. ABC currently has members in eight countries, liaison offices in three countries, and is in the process of forming chapters in Canada, Australia, and the Federal Republic of Germany.
2. There are a number of biotechnology companies that belong to *both* ABC and IBA. This is often overlooked since in the case of a number of larger corporations, such as Johnson & Johnson and Sandoz, the parent companies belong to IBA while their biotech units belong to ABC.

In response to Harvey Price's comments [that "it is a disservice to the biotechnology industry to have two trade associations"], we believe there is a distinct need for two groups—IBA representing biotechnology's corporate power structure, with its established staff functions and extended staying power, and ABC representing the newer, more entrepreneurial firms with less staff support and a greater sense of competitive urgency. Where the interests of these two segments of the biotechnology industry converge, the two trade associations, of course, work together.

Warren C. Hyer, Jr.
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