SPECIAL FEATURE SECTION: BIOCATALYSIS

Editorial

The pharmaceutical industry is facing mounting pressures on a number of fronts: (1) the need to deliver new drugs to market rapidly and efficiently, (2) patent expirations and competition with generic firms, (3) difficulty to maintain its market share and competitive edge, (4) the need to improve its product pipeline—mergers and acquisitions, (5) steady shift of innovation base from big pharma to the biotech sector, (6) tackling complex disease mechanisms and navigating through various regulatory hurdles, and (7) meeting shareholders' expectations. Rapid advances in technology have made a significant impact on drug discovery programmes in industry. Achievements in human genomics, proteomics, and bioinformatics present huge possibilities to unravel new biological targets to understand disease states. Combinatorial chemistry, high-throughput screening, and miniaturized tools allow us to make and evaluate a large number of compounds for biological testing. Consequently, there has been a dramatic increase in potential new drug targets and chemical leads. Biocatalysis has made a significant impact on the drug discovery and development effort in industry. As a large proportion of compounds under development is chiral, this poses huge synthetic challenges where the potential of biocatalysis to catalyze regio- and enantioselective reactions will become crucial. Furthermore, environmental implications in using undesired solvents and reagents commonly used in synthetic chemistry have prompted an increased use of biocatalysis in industry. In the 1980s several big pharma (GlaxoWellcome, SmithKline Beechams, Merck, Roche, Schering-Plough, Pfizer, and Bristol Myers-Squibb) had set up specialized biotransformation groups to complement their internal R&D programmes. The drug discovery path in industry typically takes about 10−15 years to complete. To accelerate and improve its efficiency, pharma has established a more focused operation in all aspects of drug discovery and development. Outsourcing, strategic alliances, and partnership with the academic sector are key components of this process. It is no longer cost effective to do the entire R&D under a single roof. There has been a trend towards increased use of outsourcing various segments of R&D. This increase follows a brief lag (1999−2000) in outside contracting due to consolidations among big pharma. This, however, changed in 2001 due to combined pipelines and overlapping of the product portfolio in the newly merged companies which resulted in a wave of demand for outsourcing. We have therefore seen a scaling down of operations in industry both in biocatalysis and chemocatalysis in favour of outsourcing. The majority of biotransformation groups in the big pharma have sadly all but disappeared. This has resulted in a buoyant niche market for the contract research organizations to use biocatalysis and for the newly emerged technology platforms (combinatorial biocatalysis, directed evolution) to produce building blocks, advanced intermediates, and chiral actives for the pharmaceutical sector. Companies that are likely to succeed are those with multiple cutting-edge technologies that can offer integrated chemical and biological solutions as “one-stop partnering” that mimic the industrial environments. As the power base of innovation and technology steadily shifts from big pharma to the biotech sector, this expertise and momentum will be lost, and pharma will become heavily dependent on its partners to provide its biocatalytic solutions. This will have significant implications on the internal R&D programmes, and this shortsighted view may prove costly for big pharma in the longer-term. This is the first (and hopefully not the last), special issue on biocatalysis for OPRD giving a very comprehensive overview of the recent advances in microbial and enzyme-catalyzed processes. The contributors are the leading practitioners in biocatalysis from a cross section of academia and industry. It is hoped that this special issue would serve as a platform to stimulate further activity in biocatalysis. I gratefully acknowledge the contributions of all participants, especially the hard work of Trevor Laird, Claire Davey, and Sue Parsons from Scientific Update who diligently coordinated this effort.

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