Organic Process Research & Development

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Editorial

One of the areas I try to bring out in my training courses on chemical development and scale-up is that it is the process research chemist—i.e., the chemist who is furthest removed from manufacture—who makes all the key decisions about environmental issues. He or she designs the synthesis, choosing the number of synthetic steps, the degree of convergence, the reagents, stoichiometry, concentration, solvents, and the work up, all of which affect the number, volume, and quality of the effluent streams. It is important, therefore, that process R&D chemists understand the manufacturing environment. Whilst this is relatively easy in small companies, where manufacture takes place a few metres away from the R&D block, in large companies, the process R&D unit may be on a comfortable research site well away from the large scale manufacturing plant.

In chemical and pharmaceutical companies these days, the emphasis (some would say obsession!) is with fast tracking projects and with speed to market. Whilst this is an excellent means of maximizing profit from a patented product, one of the consequences is that the process to make the product may well be far from optimum, since the process R&D chemist will have had little time to investigate alternative routes, or may have got "locked in" to an early route for "so called" regulatory reasons. The result is that, whilst later stage development may allow optimization and validation of the chosen route, the process may well not be the best, both from a cost and from an environmental point of view. There will be a need for intensive further development after the product has reached the market, not just in fine-tuning the chemistry, but in more radical changes, too. I can hear the regulatory guys saying that this imposes too many risks (particularly in the pharma industry), but so long as the impurity profile of the product remains the same, there should be few problems. The advantages of this approach are that cost savings in manufacture would be achieved, *and* that the environmental load should be reduced. New processes, which are patentable, should also extend the product lifetime and allow better competition with generic manufacturers in the future.

I would argue that process development on a product already on the market pays for itself. For example, for a pharmaceutical product involving 10 synthetic steps (assuming 80% yield in each step) manufactured at 100 tonnes per annum and costing $1000/kg to make, an increase in yield of each step by only 1% would save $14 million per annum and reduce the cost to $860/kg. Process development does indeed pay for itself!

Finally, whilst thinking about "green chemistry" issues, the Royal Society of Chemistry has announced the launch of a new journal devoted to this subject. Further details are available from the editors, Professor James Clark and Dr. Duncan McQuarrie at the Centre for Clean Technology, University of York, UK (e-mail greenchem@york.ac.uk). They have been excellent contributors to this journal and I wish them success in their endeavours. I hope that this venture will complement *Organic Process Research & Development* rather than compete with it.

Trevor Laird

Editor

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