Organic Process Research & Development

Organic Process Research & Development **2001**, *5*, 1

Editorial

A friend of mine alerted me to an investigation report concerning a fire and explosion, which took place at the Morton Speciality Chemical Company in New Jersey in April, 1998. The report has been published in full by the U.S. Chemical Safety and Hazard Investigation Board on their website (http://chemsafety.gov/reports/2000/morton/morton_01.htm) and makes fascinating reading for all of those involved in development and operation of manufacturing processes. I will cover this report in full in next month's Highlights, trying to pick out important lessons for us all, but it is depressing to read that, despite the amount of published information on nitrocompound manufacture using batch and semibatch processes over the last 30 years, the same mistakes are being repeated—what I will call corporate memory loss.

I feel sorry for the process operators in these organisations. The process operator is often handling highly dangerous processes without adequate information on potential runaways, yet it is he (or maybe even she?) that is likely to be injured if the process becomes uncontrollable. The management of change is important, not only for GMP and process validation, but also for process safety. In many investigations of runaway reactions, it is relatively minor changes to the raw materials quality, dosing rate, conditions, equipment, etc. which have contributed to the process "misbehaving". We all need to be vigilant in this area when designing processes. With the "fast-tracking" of chemical process R&D, there may not be enough time to design synthetic routes and processes which are inherently safe, and the result is that those performing scale up have to ensure, by suitable monitoring and control, that runaways do not occur. However, inherent safety (i.e., safe by design) should be our ultimate goal in development and manufacture of all products. Process R&D managers *must* ensure that they have adequate resources to enable this goal to be met, either in the initial process R&D or maybe, once it is clear that the product will reach the market, by "second-generation" process development (with all of the regulatory issues that this might entail!). In an earlier editorial a couple of years ago I intimated that process R&D departments seemed under-resourced—I have seen nothing in the last two years to change my view. The molecules have become more complex, the time scales for kilogram production shorter, and the quality requirements, quite stringent—my fear is that there is little time to worry about *inherent* safety, only about the safety of each individual part of the process. I welcome views on this topic.

To assist with dissemination of process safety information, I welcome any accounts of incidents, near misses, and potential runaways, which have occurred in the last year. I would incorporate this information in forthcoming Highlights sections.

The last issue of OPR&D in 2000 was the largest at 180 pages containing 30 papers. In 2000 OPR&D comprised 618 pages compared to 497 in 1999 and 437 in 1998. The continued expansion of the journal has been in part, due to the two special editions on oligonueleotides and polymorphism/crystallisation but also to expansion of the Highlights section and the introduction of Patent Highlights in 2000. Both of these sections have been very popular with readers. My thanks must go to my co-contributor to Highlights, Stephen Hermitage of Glaxo and to Keith Turner, who writes the patent summaries based on my rather arbitrary selection of the vast array of process patents. My thanks must also go to our many reviewers, to all of the authors, and to the Associate Editors who contributed to the success of the journal in 2000.

Trevor Laird

Editor

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10.1021/op000129t CCC: $20.00
Published on Web 12/30/2000