SPECIAL FEATURE SECTION: PROCESS ANALYTICAL TECHNOLOGY

Editorial

PAT: The New Hype?

For our chemist colleagues from the petrochemical, polymer, and food industries who have been using in situ analytical tools for decades, the question might be: why so much fuss about this right now? Why this new hype in the pharmaceutical industry, for which even a new name: PAT − process analytical technology − was invented?

The answer to "why now?" lies in the exponential increase in computing power over the past 15 years. This made it possible not just to collect and store but also to analyze large amounts of data in a much shorter time. The use of information-rich techniques (FT-MIR, NIR, FBRM) became practical for real-time analysis—both in the lab and on reactor scale. For those of us in the pharmaceutical or fine chemicals industry, typically running a huge variety of batch processes in multipurpose equipment, this was just what we were waiting for. The opportunity was recognized by both the corporate world (users as well as equipment manufacturers) and the regulatory bodies. Pharma managers have never before been so easily convinced of the benefits of making investments in new technologies as now for PAT—the links to "magic expressions" like time-to-market and compliance are so obvious. The FDA issued its guidelines in September 2004, which will further boost the spreading of PAT in the pharmaceutical and associated industries.

"OK, but what's in it for me?" asks the organic chemist working in process R&D. As most of us did, I used to make jokes about reactions having been perfect until the point we received analytical results. However, for a few years now we have been learning to use a new language in common with our analysts. We are shown reaction progress curves where we have seen only indiscriminate shoulders on spectra before. We are learning about multivariate analysis and spectral manipulations. We can determine kinetic parameters and elucidate mechanisms more easily and faster. We will know more about our processes than ever before. Using PAT, we will be able to sort out scale-up issues and have much better control of our pilot- and full-scale processes. Ultimately, PAT will make our products, and our plants manufacturing them, safer. PAT is here for the long run—it is here to stay.

Beyond controlling reactions and crystallizations, PAT is currently being introduced in almost all process steps of the pharmaceutical industry from identification of raw materials through chemical and pharmaceutical manufacturing to packaging. This special feature section does not attempt to cover all these aspects—it is meant to be a delicious appetizer rather than a dull full menu. I thank all of the authors for the time they spent in contributing these articles.

Please welcome this special feature and enjoy reading it!

András Horváth

Chemical Development, Johnson & Johnson Pharmaceutical Research & Development, Turnhoutseweg 30, B-2340 Beerse, Belgium
E-mail: ahorvath@prdbe.jnj.com

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