

Review: “Process Analytical Technology – Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries”

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1. A worthy companion

This 2010 Wiley textbook (2nd ed.) is rightly called “The PAT Bible” across many scientific disciplines and applied technology industry sectors, e.g., analysis, vibrational spectroscopy, NIR, RAMAN, chemometrics, process engineering, and sampling. A review of the first edition (launched in 2005) stated: “This book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology” (Current Engineering Practice).

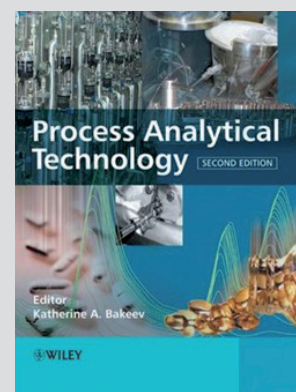
As the editor of SST, I recommend this book enthusiastically, with no reservations what-so-ever! If you are reading (in) this issue of SST, it is probably because its focus on PAT is of significant interest to you. As soon as you have finished reading the articles curated here, it is time to go on the internet to order this book! Why? Answering this question is the world’s easiest job, as the blurb(s) for ‘the PAT Bible’ are extensive, very informative and scientifically impeccable – see below.

But first, allow one anecdote. Fifteen minutes after the publication of the first (2005) edition, Editor Bakeev received a very stern phone call from an irate younger version of the present SST editor: “Congratulations on a major achievement – but you have omitted the most fundamental critical success factor for PAT to be scientifically successful: representative sampling of the process segment to be analysed by one of the many, impeccably described analytical modalities in this wonderful compendium!” [I have toned down considerably this rendition of my then remarks for the sake of politeness].

THE BOOK

Process Analytical Technology: Spectroscopic tools and implementation strategies for the chemical and pharmaceutical industries.

Editor, Katherine A. Bakeev. Wiley Publishing.
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All hail and praise to Ms. Bakeev, who readily agreed, with no equivocation or excuse! So, it was decided I should write up a chapter on the missing topic: Hey Presto! This is why one finds a new chapter 3 in the 2nd ed. entitled: “Process Sampling: Theory of Sampling (TOS) – the missing link in Process Analytical Technologies (PAT)”.

2. Reviews of the book (both editions):

1st Edition: The use of real or near real time measurement of chemical production process parameters as the basis for achieving control or optimisation of a manufacturing process has wide application in the petrochemical, food and chemical industries. Process analytical chemistry (PAC), or process analytical technology (PAT) as it has recently been called, is now being deployed in the pharmaceutical industry, where it is seen as a technology that can help companies to improve their conformity with manufacturing compliance regulations. The objective of this book is to provide a starting point for implementing process analytical chemistry tools in process monitoring applications or as part of a total quality management system.

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Written from the perspective of the spectroscopist required to implant PAT tools in a process environment, attention is focused on measurements that are made in process at-line or off-line, providing data on product during manufacture.

2nd Edition: Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this 2nd ed edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added. Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectroscopy: Technology and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging.

LIST-OF-CHAPTERS (2ND EDITION):

1. Overview of Process Analysis and PAT
2. Implementation of Process Analytical Technologies
3. Process Sampling: Theory of Sampling (TOS) – the missing link in Process Analytical Technologies
4. UV-visible Spectroscopy for On-Line Analysis
5. Near-infrared Spectroscopy for process Analytical Technology: Theory, Technology and Implementation
6. Infrared Spectroscopy for Process Analytical Applications
7. Raman Spectroscopy
8. Near-infrared Chemical Imaging for Product and Process Understanding
9. Acoustic Chemometric Monitoring of Industrial Production Processes
10. Process NMR Spectroscopy: Technology and On-line Applications
11. Fluorescent Sensing and Process Analytical Applications
12. Chemometrics in Process Analytical Technologies (PAT)
13. On-line PAT Applications of Spectroscopy in the Pharmaceutical Industry
14. NIR Spectroscopy in Pharmaceutical Analysis: Off-line and At-line PAT Applications
15. Near-infrared Spectroscopy (NIR) as a PAT tool in the Chemical Industry: Added Value and implementation Challenges
16. Future Trends for PAT for Increased Process Understanding and Growing Applications In Biomanufacturing

This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focusing on PAT.

As professor, I have used ‘the blue book’ as curriculum for master level chemical – and process engineering students for two decades. It covers practically all aspects to consider when – or rather before – considering starting up an industrial PAT project (chaps. 2,15,16). The 2nd edition (aka ‘the blue book’) and the present SST issue are complementary in many ways:

While the blue book carries two comprehensive textbook chapters, one on sampling (chap. 3) and one on chemometrics (chap.12), its dominating value lies in presenting essentially all principal analytical modalities that can be used for PAT purposes (chaps. 4–11), with a clear focus on two industry sectors, pharma (chaps. 13,14) and chemistry (chap.15). This is of immense usefulness for everybody getting started with PAT.

The present SST issue has been ‘composed’ so as to complement ‘the blue book’ to the fullest degree possible with a curated survey of further developments since 2010, with highlights of newer meta-theoretical and practical issues, ushering in a fresh 2025 understanding of PAT. It turns out that the concept of the process sampling interface shows up as a new, key success factor of reckoning.

Be all this as it may: Get hold of ‘the blue book’, ‘the PAT Bible’!