Abstract

PAT in different industries: challenges and opportunities for near infrared spectroscopy

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Introduction

PAT is process-based while QbD (Quality by Design) is product oriented. PATs are tools that make QbD possible. Across processing industries, one can use a systems engineering approach and decompose any process into raw materials (RM), processing steps and end-product. Processing can be done in multiple consecutive unit operation steps. At all three components there are properties (chemical, physical or biological) influenced by process parameters. We demonstrate how NIR has intrinsic capability as a PAT tool to link process to product and be a QbD enabler across multiple processing industries.

Materials and Methods

Monitoring within PAT should be done on whole samples as they represent the raw material/process/end-product. Process spectroscopy is an effective way to obtain multiple parameters from a single spectrum. A less commonly used approach is NIR spectroscopy as a process fingerprinting technique; advantage is taken of its intrinsic ability to capture chemical and physical information, avoiding the need for calibration development and making the most of the availability of on-line in-situ measurements for batch supervision. These fingerprinting capabilities are so powerful that the process trajectories drawn from those fingerprints resemble very closely those produced by other measurements. Examples of both applications of NIR will be described for three situations namely biofuels, petrochemical refining, and biopharmaceuticals manufacturing.

Results and Discussion

PAT involves considering all monitored variables. As in-process monitoring techniques are normally multiparametric, their use should be advocated in process development and manufacturing. Multiparametric process spectroscopy techniques enable several parameters to be measured simultaneously, highlighting the correlation of different parameters on a whole sample. That increases the capabilities for process fault detection and diagnosis, real-time and capturing scale effects, and will help to pinpoint and solve scale-up problems. Chemometrics, multivariate analysis techniques and systems engineering (altogether called PAT), will play a decisive role in bio/pharmaceutical manufacturing in years to come at sample, batch and process levels. An overall picture emerges of the entire multistage process based on an accurate picture of its unit operations. By using the PAT tools deployed in sample and batch levels, correlations between different points in the manufacturing process can be established. Use of PAT in this feed-forward mode is important in anticipating and resolving problems that will have a negative impact on the process downstream. This strategy has been applied throughout processing industries for: i) accessing and controlling the variability of complex RMs, developing RM supervisory systems and formulating RM blends for targeted specifications; ii) handling variability during process by monitoring quality attributes through in-process, at-line or on-line process supervision and controlling critical issues to quality parameters iii) end-product multiparametric QC using good modelling practices for calibration development.

Conclusion

The potential of PAT in manufacturing areas is far from properly exploited due to the insufficient use of intrinsically multiparametric monitoring tools (e.g. NIR), little use of available process information, and not taking a process/plant wide perspective for the proposed PAT strategy. PAT tools based on spectroscopy are so versatile and their advantages so diverse, it makes little sense to invest in chemical laboratories to analyse feed-stocks and the end-products of manufacturing plants. With current ASTM standards addressing NIRS use for quantitative and qualitative analysis, the road is opened to the use of these monitoring techniques as PAT tools across processing industries.

Reference paper as:
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