

Transforming the performance of batch production

An ever-increasing number of businesses, particularly in the OSD sector are boosting their competitiveness by shifting toward continuous processing techniques. In this context, is it possible for manufacturers and processors that are not yet ready for continuous or cannot move away from batch-based approaches to thrive?

The short answer is yes, thanks to Process Analytical Technologies (PAT).

Martin Gadsby, Director at Optimal Industrial Technologies, looks at how PAT can bring batch-oriented plants to the next level of productivity.

Many process businesses are seeking the multiple benefits offered by continuous flow systems, such as higher product quality, consistency, efficiency and productivity. Yet, batch manufacturing is still widely used and is likely to remain a mainstay for many.

In effect, a continuous approach is not necessarily a panacea that can be applied to any type of plant. For example, the treatment of certain substances and live cultures as well as specific reaction routes can currently only occur in batches.

In these situations, manufacturers and processors are not bound to traditional product quality, efficiency and productivity levels. In fact, they can significantly improve their processes, because key technologies that contribute toward making continuous processing so attractive are now also available for batch systems.

Optimised monitoring strategies

More precisely, the main functional tool allowing plants to run continuous processes is PAT, which minimises the interruptions and process downtime associated with quality control and testing. The technology achieves this by offering a fully integrated system to conduct real-time, at-line, on-line or in-line measurements of critical quality attributes (CQAs) on raw and in-process materials.

The power of PAT is not limited to eliminating the downtime associated with physicochemical analysis. The technology leverages multivariate analysis (MVA) and chemometric models to provide a unique, live and constant insight into how critical process parameters (CPPs) affect end-product quality.

All the data and knowledge generated by PAT, including quality predictions, is collected, sorted and presented in a clear and immediate way to plant operators by robust and easily accessible PAT knowledge management platforms, such as Optimal's synTQ. The interface empowers manufacturers to adjust their manufacturing processes on the fly in accordance with the results obtained as well as set up automated process control mechanisms to meet set quality standards at all times.

For example, many batch production processes still rely on the precise management of process parameters such as temperature, pressure, pH, material morphology etc. to achieve optimum results. This applies whether you are running a bioreactor, forming crystals or running a distillation column, and inevitably each batch will be slightly different. By setting up a PAT system that delivers precise live insights and a control framework based on real time quality, operators in the manufacturing and processing industry can maximise the quality and consistency of their end products. In addition, they

can minimize waste associated with off-spec materials, dramatically reducing costs, while improving energy and resource efficiency.

The ability to build-in quality checks throughout the entire process ensures compliance and maximises traceability. This is one of the main reasons why PAT is strongly promoted by regulatory bodies, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA).

Moving into cyber-physical systems

Advanced PAT knowledge managers, such as Optimal's synTQ, can also help businesses to define and test PAT Methods before processing any material on the physical manufacturing plant. This is the case with the 'Digital Twin' function within synTQ, which offers a cyber-physical system to effectively develop and test a process data flow.

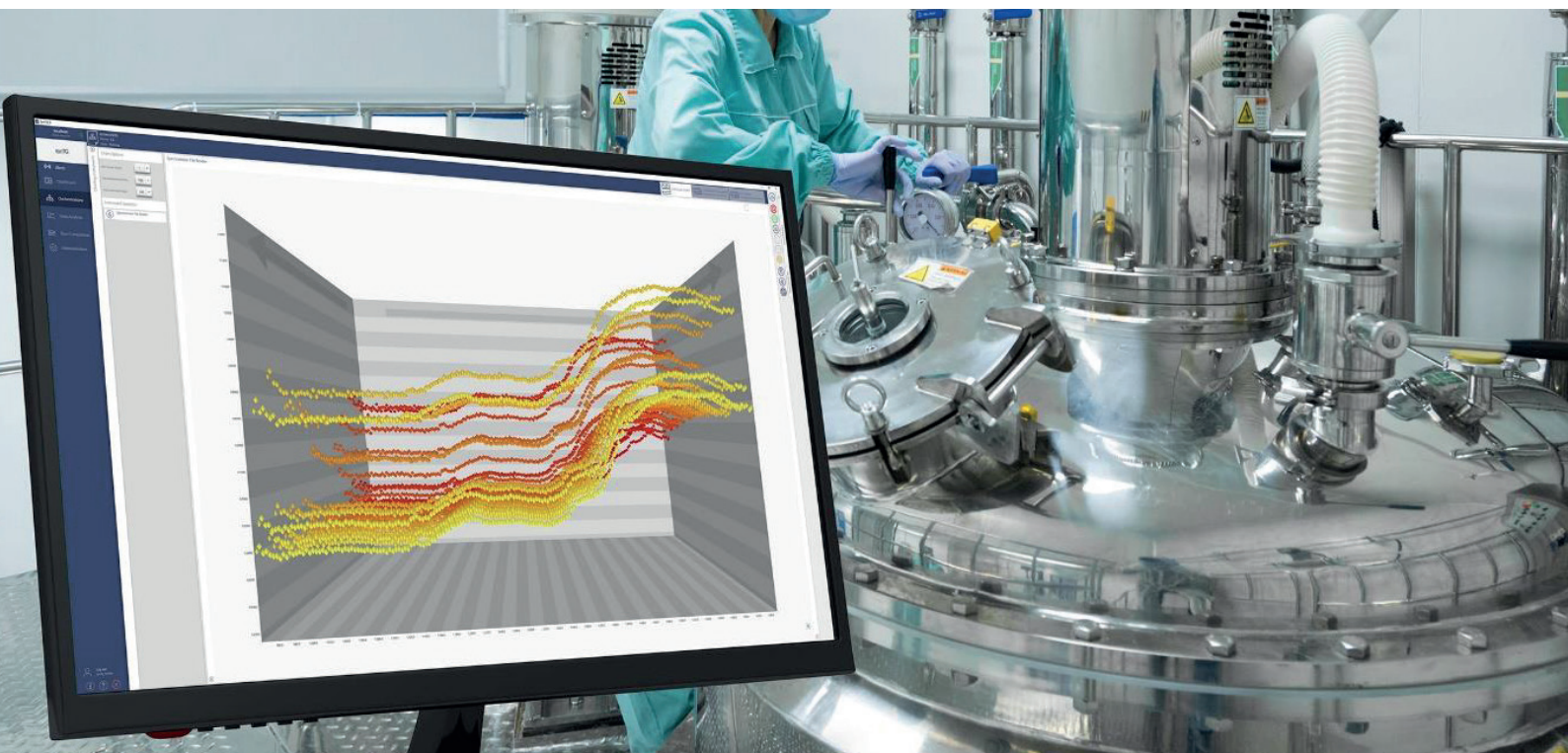
In practice, this tool enables users to run partial or complete PAT Methods (or Orchestrations, as they are called in synTQ), virtually, with-

out requiring any real-time data. As the PAT knowledge management software has access to historic instrument data and prediction models together with additional data, in the first place it allows the testing and refinement of the PAT Methods off-line, and later on it can be used to generate more knowledge and improve the quality predictions. Thus, the digital twin can be used to refine or optimise the process whilst reducing material and energy consumptions as well as waste generation.

Finding the ideal solution for tangible benefits

The picture presented clearly shows how enhanced productivity, efficiency and product quality are easily accessible to PAT users. For example, large molecule manufacturers have reported how the adoption of PAT has tripled their batch productivity of an upstream biotech process. While the process was not upgraded to continuous, the PAT framework sets the foundation for future adoption.

Ultimately, all the substantial benefits offered by



PAT helps batch-oriented manufacturers to enhance productivity, efficiency and product quality.

comprehensive PAT set-ups give batch-driven manufacturing and processing plants the opportunity to thrive in an increasingly competitive market. All it takes is the will to embrace this innovative technology and the support of a reliable PAT and knowledge management specialist.

By relying on skilled and experienced PAT specialists, such as Optimal, businesses in the manufacturing and processing sector can benefit from crucial support in planning, implementing and using appropriate PAT strategies in order to fully reap the benefits of this technology. Even more, they can count on leading software, such as synTQ, which is currently in use by over half of the world's top pharmaceutical companies.

About Optimal Industrial Technologies

Within the Optimal group, we have more than 30 years' experience in the automation and optimisation of control and data management systems for the food, chemical, pharmaceutical, biotech, life science and other process industries.

The demands being placed on manufacturers in relation to getting products to market sooner, minimising development and production costs together with increasing product quality and business sustainability are ever increasing. Our primary aim is to deliver measurable improvements in all these target areas.

In addition to practical automation and system integration expertise, Optimal Industrial Technologies has also developed the world-leading PAT Knowledge Management software platform – synTQ® – which is used by over 60% of the world's leading pharmaceutical and biotech companies, and is now being adopted by other process industries. synTQ has been a proven enabler of QbD via PAT by significantly increasing productivity and quality, while reducing waste, time to manufacture and time to market for batch and continuous processes.

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