Digitalisation in biopharma starts with PAT

30 June 2023

With Industry 4.0 quickly becoming an established reality, (bio)pharmaceutical R&D, manufacturing and quality control facilities are implementing novel sensors and analysers that generate complex data. During each digital journey, it is equally significant for companies to set up a suitable framework to derive meaningful insights from data. A state-of-the-art Process Analytical Technology (PAT) knowledge management platform can form a strong backbone and support the digitalisation of (bio)pharmaceutical companies.

Alan Messenger, Sales Director at Optimal Industrial Automation, and Manuel Kuhs, Business Development Manager for Europe at Optimal Industrial Technologies, look at the importance of PAT software for Pharma 4.0-oriented data management.

It is impossible to negate the leading role of data in driving the competitiveness of manufacturers and opening the door to the future of highly optimised production. In line with this, it is no surprise that complex in- and on-line analysers, such as Raman and near-infrared (NIR) spectrometers, are populating the facilities of even the most conservative and cautious (bio)pharmaceutical companies. Such technologies enable the real-time measurement of many Critical Quality Attributes (CQAs) that were previously only accessible offline and with a significant time delay.

By supporting the proliferation of data sources, companies can develop an in-depth understanding of their processes and what defines their performance as well as how to optimise productivity, efficiency and quality. It is therefore possible to obtain value-adding knowledge, proactively make decisions and act on this intelligence. If suitable, it is also possible to automate tasks and operations, creating integrated, intelligent systems.

With disparate analysers generating large volumes of data in real time, and the necessity of maintaining multiple chemometric models to convert this raw data into CQAs, it is crucial for companies to have a plan on what to do with them. Typically, this involves optimising the collected data and models to achieve the quality-centric control of Critical Process Parameters (CPPs). As processing, fusion and analysis are key to unlocking the opportunities of Industry 4.0 and the digitalisation transformation, industry players in the (bio)pharmaceutical industry should set up a solid framework to effectively handle data and control processes based on quality goals.

Crossing paths

A useful tool for supporting this is a PAT knowledge management system, which has long been used to support quality control and quality assurance activities. While PAT finds its origin in Quality by Design (QbD) principles, well before the rise of the fourth industrial revolution, it is well aligned with data-centric Industry 4.0 principles. The similarities are easy to identify, when considering that the focus of PAT is on designing, analysing and controlling manufacturing processes through the timely measurement of CQAs to effectively control CPPs for optimum results.

Since its establishment and first implementations, PAT has required a data management infrastructure, namely a PAT knowledge manager, to acquire, store, process and analyse data from key sources. In addition, this has been helping (bio)pharmaceutical manufacturers visualise the actionable insights generated for monitoring, intervention and auditing purposes.

With the latest advances in sensing and detection systems as well as digital technology, future-oriented PAT knowledge management systems have evolved, adopting many of the opportunities and applications offered by Industry 4.0. A notable example is represented in the increasingly accurate determination of how CPPs can influence CQAs through sophisticated predictive models, which may be able to leverage artificial intelligence (AI) and similar technologies.

Additional elements include Cloud connectivity and the ability to interact with a broader range of devices and instrumentation to implement highly mechanised processes, such as automated, quality-centric feedback and feedforward control.

A state-of-the-art PAT knowledge management platform can therefore do more than support quality control and quality assurance strategies. It forms a hub that runs data-driven operations and delivers high visibility. As a result, it sets the foundation for flexible, responsive and highly efficient processes. Ultimately, it can enable the digitalisation of (bio)pharmaceutical facilities, from Smart R&D laboratories all the way to commercial-scale manufacturing plants and clusters of factories.

These features are turning well-designed PAT knowledge management solutions into essential elements of industrial automation projects, just like controllers, robots, MES, ERP and HMIs. Clearly illustrating this trend is synTQ, a market-leading, award-winning software that is helping players across the entire (bio)pharmaceutical value chain benefit from a scalable environment for Big Data analytics for innovative Industrial Internet of Things (IIoT) applications. Adopted by over 60% of global pharmaceutical majors, synTQ is strengthening their competitiveness and continuous improvement by increasing transparency, efficiency, responsiveness in labs and shop floors.

Image captions:

Image 1: A state-of-the-art Process Analytical Technology (PAT) knowledge management platform can form a strong backbone to support the digitalisation of (bio)pharmaceutical companies.

The image(s) distributed with this press release are for Editorial use only and are subject to copyright. The image(s) may only be used to accompany the press release mentioned here, no other use is permitted.

About Optimal Industrial Technologies Ltd

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.

Press contact:
Optimal Industrial Technologies
Martin Gadsby
Vice President
Tel.: +44 (0) 1454 333 222
mgadsby@optimal-ltd.co.uk

PR agency:
DMA Europa
Chiara Civardi
Progress House, Great Western Avenue, Worcester,
WR5 1AQ, UK
Tel.: +44 (0) 1905 917477
chiara.civardi@dmaeuropa.com
news.dmaeuropa.com