Advancing Pharmaceutical Manufacturing Without Modifying Production Lines

With minimal investment, pharmaceutical manufacturers can streamline off-line testing in analytical laboratories while enhancing data integrity and regulatory compliance strategies. To achieve this, automated solutions that do not require process re-validation can be implemented, shortening downtime and boosting manufacturing efficiency.

Martin Gadsby, Director at Optimal Industrial Technologies, explores the key benefits of automation in analytical laboratories and how these can be realised.

Martin Gadsby
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Martin graduated from the University of Bath in the late 1970's, and after working through a few positions in industry, he became the new European R&D Process and Process Automation Group Leader for Kraft Foods. After a few years at Kraft, Martin decided to set up a process automation business with a colleague, Dave Richards, and Optimal was born.

Optimal Industrial Automation was formed over 33 years ago, with Martin now being the main owner and CEO. Optimal Industrial Technologies was formed more recently as the products division and is the market leader in the field of Process Analytical Technology (PAT) with its PAT Knowledge Management product – synTQ. Martin is intimately involved with progressing the evolution of synTQ and advising the Optimal development team on what he believes to be the optimum development direction. Over the last few years, he has taken on the overall responsibility not only for the company, but also for the sales and marketing of synTQ whilst remaining very active in ensuring that the development of synTQ continues unabated. On the personal front, Martin is a bit of a 'petrol head' and enjoys flying aerobatics and racing cars.

The implementation of new technologies in pharmaceutical manufacturing plants is particularly challenging, as it is a regulatory requirement for businesses to re-validate any process modifications to prove that they will not impact end product quality.

Regulatory bodies worldwide, such the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) are also raising the bar on data integrity and transparency as well as product quality. New or updated guidance is being issued on the necessary pharmaceutical data to ensure compliance.

As increasing volumes of data are being used for quality assurance, regulators recognise that innovative new software technologies for manufacturing operations and data management are essential to improving quality. This is why they are also making concrete efforts to drive adoption. In particular, businesses interested in improving their operations with limited investments can still take advantage of a number of key technologies that do not involve any process modification and, in turn, process re-validation.

Automated laboratory solutions offer precisely this. Oral solid dosage (OSD) solutions rely on robots or self-driven machines that can collect solid samples from production lines and bring them to off-line testing facilities, where analyses are performed, and the results stored. Liquid sampling can also be achieved by using specialised sampling systems that transport the sample to the analytical laboratory. Enhanced automation can free up lab technicians from the repetitive tasks associated with quality control while also considerably increasing the time they have available for value-added activities. It is estimated that a traditional mid-sized company that produces a variety of small-market OSD forms without utilising PAT or Lean manufacturing spends approximately half of its cycle times on necessary quality controls.[1]

Enhancing Data Integrity without Re-Validation

In addition to speeding up testing and manufacturing activities, automated laboratory solutions can help

pharmaceutical producers set up a reliable, fully computerized data management system. For example, Optimal's total quality management software, synTQ, provides a data repository tool that is compliant with current regulations on electronic signatures and records (ERES). These include the U.S. Food and Drug Administration (FDA)'s 21 CFR part 11.

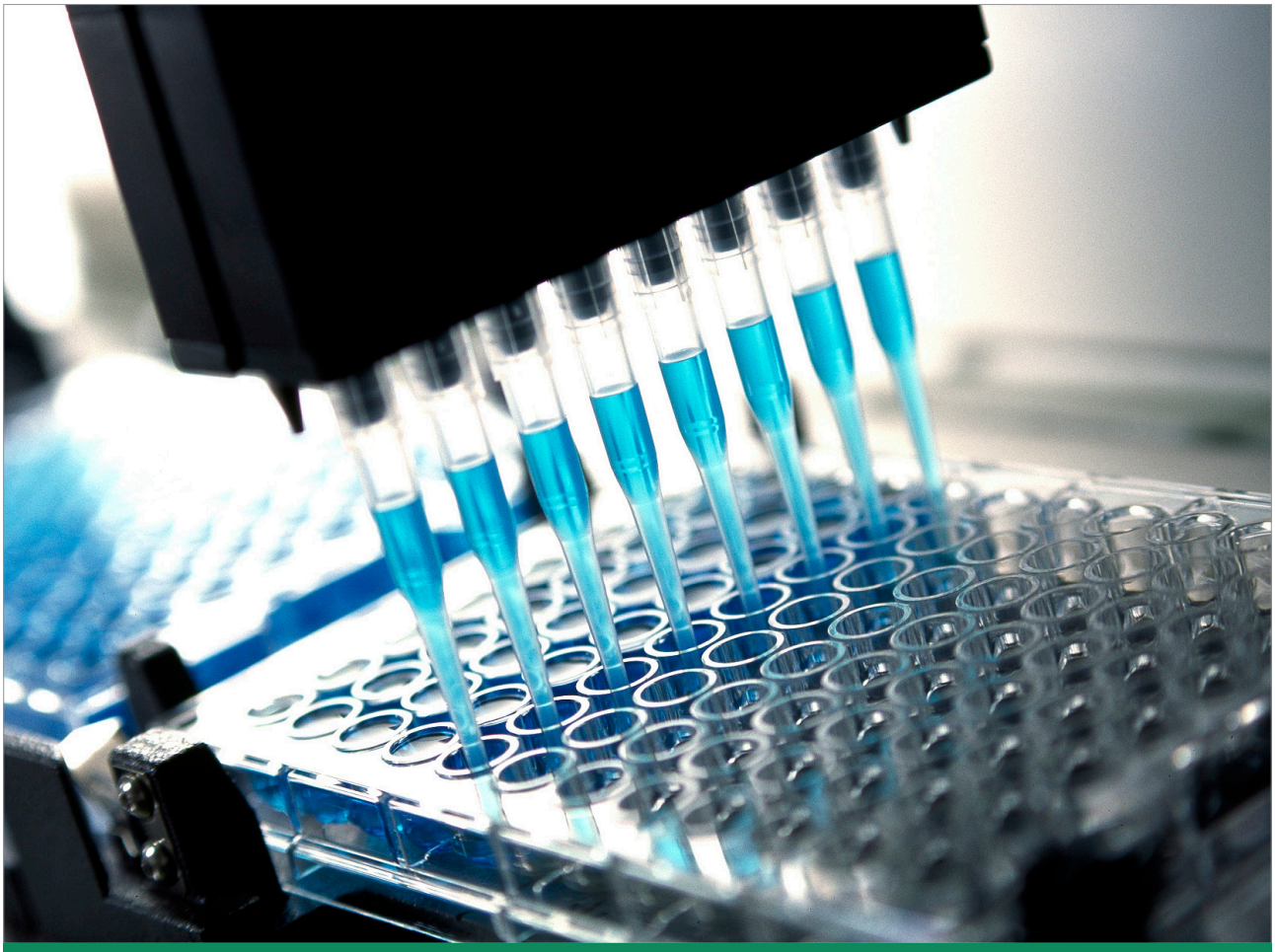
This data management platform can support data transparency as well as integrity practices for quality auditing and regulatory compliance. More precisely, businesses can ensure that their datasets adhere to the ALCOA+ principles throughout their entire lifecycle, as raw data are transformed into information and, in turn, into product knowledge and intelligence. This means that all records are attributable, legible, contemporaneous, original and accurate - hence the acronym ALCOA - as well as consistent, available, enduring and complete.

Ultimately, by using an automated management solution for advanced data integrity, it is possible for pharmaceutical manufacturers to help prevent substandard or falsified medicaments from entering the market. This is crucial, as the current shortages and unprecedented consumer demand for pharmaceutical products are providing a breeding ground for the traffic of fraudulent medical and pharmaceutical products.

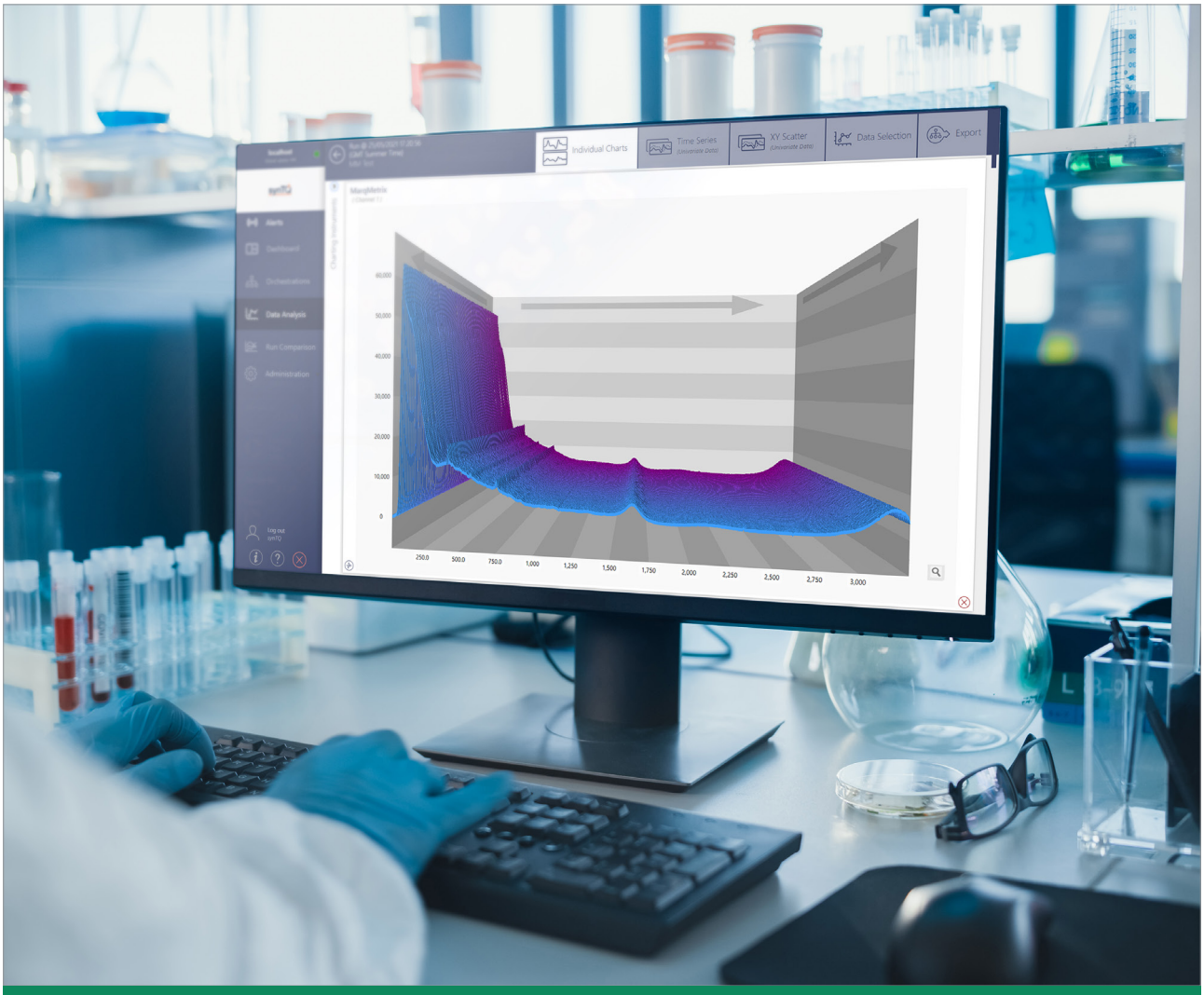
For instance, INTERPOL's Operation Pangea XIV, which concluded in June 2021, resulted in 113,020 web links for unauthorised pharmacies being closed down or removed, the highest number since the first Operation Pangea in 2008. During the operation, authorities also seized over three million fake medicines and devices worth more than USD 13 million in the UK alone.[2]

Flexibility to Support Future Operations

A well-designed automated laboratory system that utilises an advanced data management solution is also a step forward in futureproofing existing manufacturing facilities. It can support the expansion



The implementation of automated laboratories can streamline off-line testing and does not require process re-validation.



By implementing a well-designed automated laboratory system with advanced total quality management software, such as synTQ, businesses can improve product quality, regulatory compliance and manufacturing efficiency.

of a company's analytical capabilities as well as the future implementation of complete Process Analytical Technology (PAT) frameworks while facilitating process re-validation. Similarly, it can simplify the adoption of additional digital technologies, such as Cloud and Edge computing.

For example, synTQ offers Cloud data pump capabilities. All the data collected from different analytical instruments can be stored and analysed in a centralised platform. This can produce a unique data-driven insight that can help businesses define key activities to optimise their operations.

Automated laboratory solutions can be adopted both to reduce quality control times and lay the foundations of digital transformation strategies. By implementing a well-designed system with advanced total quality management software, businesses can benefit from a flexible setup to improve product quality, regulatory compliance and manufacturing efficiency.

References

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