Digitalising compliance – a performance driver for the health and life sciences players

The growth outlook for the health and life sciences sector is strong and sustainable. Demand for products and services that are safe, effective, innovative and accessible is constantly rising on a global scale. But at the same time, it is a sector characterised by ever tighter regulatory constraints, creating an increasingly complex environment for players who are seeking to develop their business or hold on to their leadership position.

Vincent GENET
CEO / Assystem Care

Biotechnology engineer, Vincent Genet has more than 18 years of experience in innovation and growth strategy consulting in the Healthcare & Life Sciences sector.

It's no longer enough to be an innovator. You now have to be the first to break into the market. It's no longer enough to keep on top of regulatory changes, technological developments, or digital disruption. You now have to be able to anticipate trends in order to gain competitive advantage and meet market expectations. Against this backdrop, one of the key challenges for industrial players in the health and life sciences sector is to ensure that their production equipment is compliant – right from when it is brought into service and throughout its life cycle – while combining compliance with cost control.

> **"Compliance is the cornerstone of performance for industrial players in the health sector."**

Compliance – A universal challenge

The first major therapeutic advances were made by drawing on the potential of chemical active ingredients that target pathologies suffered by large populations of patients. Then, the emergence of biological approaches opened up new horizons for personalised medicine, addressing more targeted populations. And the recent breakthroughs in gene and cell therapies have created new prospects for individualised medicine.

While the full potential of chemical, biological and genetic approaches has still not been fully leveraged, the advent of digital therapies is broadening the possibilities for therapeutic innovation even further.

"Nowadays we don't just treat the common denominator of large target populations. We are working on making treatments and medical devices much more personalised - even individual. But whatever the approach, compliance is the cornerstone of performance for industrial players in the health sector."

Optimised production equipment to reduce time to market

Compliance is particularly relevant when it comes to biological approaches – a domain in which it is impossible to guarantee 100% reproducibility of an active ingredient from one product to another. *"To guarantee the compliance of a finished product such as a vaccine for example, the compliance of that product's manufacturing process has to be guaranteed. This also applies to gene and cell-based approaches, where the risk-benefit ratio is particularly critical."*

The increase in bio-production capacities in Europe in response to rising global demand is helping to create safe access to innovative products for as many people as possible. Competitiveness in this sector is not just based on an industrial player's innovation capacity but also on how quickly it can make its innovation available for sale (time to market). This means that moving fast to have a production system that is compliant – i.e. that meets the requirements of the regulatory and oversight authorities – is a way of accelerating time to market and scoring a competitive advantage.

A holistic and systemic approach to **compliance**

Compliance entails the qualification of the equipment and systems used in the production process, and the validation of the processes involved in manufacturing a product. It forms the essential component of the quality system and guarantees that production operations are carried out in accordance with the requirements of Good Manufacturing Practices. Another essential component of compliance is ensuring the traceability of products, i.e. making sure that

full information is always available throughout a product's life cycle.

Today's increasingly strict regulatory requirements don't just concern medicine and biomedicine, but cover all products and services, as illustrated by the new regulatory frameworks applicable to medical devices, cosmetic active ingredients and nutritional supplements. *"At Assystem Care, we fully leverage digital technology – and therefore data – to continuously improve our clients' overall compliance performance."*

> **"We often find that manufacturers are not forward-looking enough when it comes to drawing up compliance status reports."**

Manufacturers are subject to the regulatory frameworks imposed by national and international authorities and agencies (notably the EMA, FDA and NMPA) and have to adapt their practices to their local end markets. Before a manufacturing facility is brought into service (both new-builds and facilities that have undergone repair or maintenance), the authorities inspect the equipment and the underlying quality system. This can sometimes reveal a gap between what is expected by the regulators and the way in which manufacturers actually carry out and document their operating processes.

"In view of this, we take a systemic approach to our clients' compliance needs. First, by helping them assess the current compliance status of their equipment. For us, this stage is more of a diagnostic phase rather than an audit, as the audit process falls more within the domain of the authorities. When we perform these diagnostic analyses, we often find that manufacturers are not forward-looking enough when it comes to drawing up such compliance status reports. And this can result in differences between what the regulators require and a manufacturer's on-site processes."

When such gaps are identified, the authorities issue comments or injunction letters to the manufacturer concerned requiring it to put in place a remediation plan.

The fact that Chief Compliance Officer positions are increasingly being created in manufacturers' corporate governance structures shows that there is an awareness of the need to address compliance in a holistic and systemic way.

> **"The CQV steps generate a very large amount of data."**

Digital – Generating opportunities to achieve performance gains

Digital technology is revolutionising how industrial challenges can be addressed and projects performed. In synergy with the Assystem Group's "Engineering Powered by Digital" initiative, Assystem Care has launched a programme called "Compliance Powered by Digital", which is structured around three key principles: using data science to move from document-based to data-based governance; developing bespoke digital solutions so that users can achieve efficiency gains; and developing a systems engineering approach based on modelling in order to more effectively manage requirements throughout the product life cycle.

When a new site (i.e. a building or manufacturing facility) is created, it is necessary to ensure that it complies with

the applicable regulatory framework. This is done through a multi-stage process carried out by engineers specialised in CQV (Commissioning Qualification Validation). *"These different stages generate a high volume of data, documents and man hours. And that's why we offer our clients data science expertise in order to enable them to switch from a document- to a data-based approach. We also seek to accelerate all the different processes, all the while ensuring that they remain safe and secure and keeping the same level of quality. The aim is for the manufacturing facility to be able to produce batches of drugs as quickly as possible so as to get them to market faster than the competition."* It is important to leverage the advantages of digital in order to increase agility, both during the facility's commissioning phase and throughout its entire life cycle.

From **Text Mining to digital twins**, digital solutions

Text Mining solutions can be employed to automatically retrieve information in documents, natural language processing (NLP) can be used to interpret the meaning of text, and artificial intelligence algorithms can be applied to develop smart search engines. On the ground, there is now widespread use of tablets rather than printed paper test sheets for recording qualification tests. All of this represents a shift away from paper, which leads to efficiency gains as photos can be directly integrated into documents and computerised data is easier to read than hand-written information. It also improves traceability, as information is input in real time, and data integrity principles are respected. All of which can result in substantial time savings.

> **"However, we mustn't see digitalisation as an objective in itself, but rather as a means to an end, namely enhancing engineering performance."**

In addition, thanks to 3D modelling of industrial infrastructure and the use of digital twins, some tests can now be carried out virtually, therefore accelerating facilities' CQV phases. Through such modelling, different scenarios can be viewed virtually, or work can be carried out on a predictive basis (such as preparation for shut-downs/technical stoppages or maintenance planning, predictive maintenance, simulation of activity streams for complex operations or multi-party projects).

The use of "bespoke" digital solutions can also enhance industrial performance when it comes to managing multi-party projects, supervising work and equipment, and providing oversight, control and maintenance support. Digital solutions enable procedures to be implemented more holistically and uniformly, which means that they help improve compliance, facilitate the oversight and performance analysis of projects, accelerate processes, and simplify and harmonise the implementation of procedures. *"As these different methods and approaches allow work to be better organised and planned, the impact of shut-downs on a manufacturing facility can be minimised, shut-down times can be optimised, and the safety, security and compliance of production equipment can be improved."*

Towards the digitalisation of complex **diagnostic tools**

It is not just production equipment that has to be compliant – processes and organisation structures do too. Assessing the compliance of these processes and structures, or making changes following compliance audit observations, requires complex diagnostic tools that can extract data related to the applicable compliance requirements and can carry out comparisons with similar cases. Here again, digital solutions are key as they make it easier to analyse the regulations and regulatory changes, using artificial intelligence combined with a digital systems engineering approach.

"Assystem Care's proprietary methodological approach can be used to perform diagnostic analyses of the compliance, or even the maturity, of production equipment, and can deal with remediation issues in order to optimise production re-starts", bearing in mind that manufacturers have to always be able to prove to the regulatory authorities the integrity of all of the data and operations used to create their final product, whether the process is digitalised or not.

Digital solutions are, without question, an excellent way of achieving performance gains in the health and life sciences sector. *"However, we mustn't see digitalisation as an objective in itself, but rather as a means to an end, namely enhancing engineering performance"*. ■