WHITEPAPER

Life Sciences

Smart innovation, smart devices, smart processes

expleo.com

expleo

Editorial

by Romain Saiget, Head of Healthcare & Life Sciences

The COVID-19 pandemic, and the unprecedented, and rapid development of vaccines and treatments has highlighted the vital role of innovation and the need to fast-track the development of products and solutions in Life Sciences.

Digitalising processes, adopting ground-breaking technologies, new processes, and unleashing collaboration can change the paradigm of care. It refocuses it on the delivery of personalised medical care suited to each patient's needs, whilst significantly enhancing productivity and reducing costs for all the stakeholders.

However, in a risk-averse industry, some significant challenges remain. They include the need to protect patients' privacy, to secure connected medical devices and healthcare IT systems, and improve the speed and efficiency of quality & validation.

As Life Sciences evolves on the edge of digital disruption, Expleo, a global engineering, technology and consulting service provider, is uniquely positioned to assist all the sector's key players - large pharmaceutical groups, research labs & institutes, biotechs and their ecosystems, hospitals and healthcare providers. We provide a large range of solutions to foster innovation and improve processes to deliver "Life Sciences 2.0".

This vision is behind our recently announced acquisition of Assystem Care, the life sciences and chemical division of Assystem.

With 30 years of experience in health and life sciences, Assystem Care works with some of the world's largest healthcare, biopharmaceutical, medical device and prognosis companies.

We are very excited to welcome our new 400 colleagues from Assystem Care. Having delivered services and solutions to some of the most high profile clients in healthcare today, the company has built very strong expertise in compliance, quality, and validation services. Coupled with Expleo's skills in digital transformation, this will significantly enhance our offering to provide end-to-end engineering, quality, and performance management throughout the entire product lifecycle.

In this whitepaper, we will explore the transformation at play currenty in Life Sciences, the disruptive trends reshaping the industry, and find out why the three pillars of the sector's transformation are smart innovation, smart devices and smart processes.

CONTRIBUTORS

Xavier DE BUSTOS, Life Science Director
xavier.debustos@expleogroup.com

Matthew HEDGES, Sr Consultant
matthew.hedges@expleogroup.com

Shane FITZPATRICK, QARA Practice lead
shane.fitzpatrick@expleogroup.com

Romain SAIGET, Head of Healthcare and Life Sciences
romain.saiget@expleogroup.com

On the edge of digital disruption

Digitalising Research & Development (R&D) is a strategic priority in Life Sciences.

The sector has somewhat lagged others in this endeavour: only 20 % of biopharma companies are digitally maturing, a survey by Deloitte and MIT revealed[1].

However, using a variety of emerging and disruptive technology such as data analytics, cognitive intelligence, blockchain, cloud, AR/VR, could considerably speed up innovation by enhancing productivity and significantly reduce costs during the development phase of new products and services in the industry.

R&D expenditures have hampered innovation over the past decades. McKinsey conducted an analysis of the ratio of revenue to R&D spend[2]. It revealed that productivity reached its nadir between 2008 and 2011 – with return on investment (ROI) falling to 0.5 in 2008 after a decade-long decline, due to high, and therefore expensive, failure rates.

The adoption of new digitals tools can shift the paradigm of research in healthcare by making it cheaper to experiment, and by enhancing productivity, with quicker delivery of initial results and insights.

1) Gerald C. Kane et al., Coming of age digitally: learning, leadership, and legacy, MIT Sloan Management Review and Deloitte Insights, June 5, 2018
2) McKinsey, The R&D productivity challenge, 2017

A new set of revolutionary digital tools for R&D

"Life Sciences R&D is very conservative, requiring long and expensive development stages. Often researchers fall short of the full innovation iteration process due to lack of resources, but also because through lack time or due to the ethical considerations. At the end of the full process, the product or solution is expensive for the patient," notes Romain Saiget, Head of Healthcare & Life Sciences.

Generics, for instance, have changed the healthcare market, with lower prices. However, they have not greatly disrupted or reinvented the R&D process, offering no new value proposition for the early part of the cycle.

Digital technologies are a game changer. Introduced at all levels – product development, clinical trials, manufacturing – they can speed up R&D, help develop cheaper solutions and create a blueprint for the creation of any device or treatment.

R&D transformation does, eventually, get greater benefits faster to the patients.

Digital twins: a revolution in Life Sciences

Digital twins, or the digital representation of a physical object, process or service by gathering the data and information which exists about them, are a significant development. They are positively disruptive force in medical research: from the early planning stages to the design phase, virtual models provide an immersive and comprehensive understanding of a product and its lifecycle. Computational models can test them, allowing for incremental innovation at an increased pace.

"In healthcare, this means devices can be virtualised for model-based system engineering, test automation, RPA etc. for all categories of feasible tests," said Xavier De Bustos, Life Sciences Director at Expleo.

"The development of the COVID-19 vaccine is another example, with a reduced time to market. Digitalising care is both a public health and a business issue, vital for society and pharmaceutical groups," he added.

Just in case, just in time... and patient-centric

The healthcare industry is ripe for the general implementation of new processes and strategies to address wide or specific issues.

"While in the past, healthcare companies would come to us with a particular project or requirement, they are now asking us to help them solve a problem," explains Romain Saget. "*To help them, we use new approaches such as design thinking, the lean start up model where you learn to 'fail fast.' Another is the theory of inventive problem solving or TRIZ – the 'free, perfect and now' concept, an organised and systematic approach to problem solving using innovative technology that can lead to the best outcomes."*

Technology supports this more agile mindset. Digital twins and other innovations of the new industrial revolution will facilitate the mass deployment of a 'just in case, just in time' approach in healthcare.

Examples of future, digitally enhanced patient processes include the development, validation and manufacturing of tailor-made medical devices since each human body is unique. For instance, hospitals currently have stocks of protheses of all sizes to fit each. Using digital twins and 3D printing, hospitals could create prostheses perfectly adapted to the patient's anatomy. They will also be able to produce them quickly, on site, on demand and at low cost.

This will empower hospitals or other healthcare organisations to become their own orthopaedic manufacturers or start prototyping more using 3D printers. Going forward, it may be possible, for instance, to use 3D printed material to create skin grafts or full organs, specifically made for each patient, after solving the challenge of biocompatibility. Printing on site could also address potential supply chain issues or help with primary packaging development.

During clinical trials, virtual tools such as digital twins can optimise testing and reduce the need for trials on animals, as the industry strives to become more ethical.

In parallel, the use of Data Analytics & Machine Learning (ML) can deliver real AI-driven innovation for pharmaceutical & MedTech companies.

> **"AI can speed up research, laying the ground for cost-controlled fast innovation, and accelerate the go to market time. All these new technologies can shift the paradigm of medicine to 'patient-centricity' – one patient, one device, one treatment. They allow the industry to offer tailor made – at scale."**
>
> **Xavier De Bustos,** Life Science Director, Expleo

Medical care and medicines could also be further personalised. Cancer patients for example, would benefit from treatments based on their DNA.

"Expleo is currently helping a client create a cytometer to support the implementation of Advanced Therapy Medicinal Products (ATMP) for children suffering from cancer, bringing all its IT & Engineering expertise. We enable this evolution," notes Romain Saiget.

Other disruptive technologies include cobotics, for computer aided diagnostics or computer-aided surgery (CAS), where data-gathering and the extra knowledge provided on various factors such as the patient's breathing and bone movement can help perfectly adapt the procedure to the patient's circumstances and biology. Technology can help better plan, guide and execute surgical interventions.

In a manufacturing context, disruptive technologies like digital twins, automation or AI, fit in with the development of the Factory of the Future, with End-to-End digital continuity for products, processes, supply chain management. There are benefits for all the stakeholders, from regulators to the pharmaceutical groups themselves – with less need for prototyping, optimised clinical trials, more virtual testing for manufacturers.

Digital transformation, the convergence of technology and new engineering methods is creating unprecedented disruption.

"IT/OT (Operational Technology) convergence is the ultimate industrial challenge in Life Sciences. Expleo is a very relevant solution provider. As a consulting company, we have a very good understanding of business issues, technical challenges and IT solutions," states Xavier De Bustos.

"We can implement these innovations in a controlled industrial environment, handle the full process, and manage these new production tools. To support this transformation, the industry needs new IT architecture. Expleo can provide adaptable and flexible solutions for our clients."

What Expleo offers

INNOVATION MANAGEMENT & SOLUTIONS	TRANSFORMATION CONSULTANCY	DIGITAL TRANSFORMATION	PRODUCT & PROCESS ENGINEERING	MANUFACTURING & SUPPLY CHAIN
Design Thinking & Lean Startup	Business Agility	Hyper-automation	Digital Twin & Digital Thread	Re-engineering & Prototyping
Innovation Lab	Business Analysis & Transformation	IoT & Edge computing		
Go-to-market strategies	Strategic Consultancy & CX			

Augmented solutions tailored to individual patient's requirements

How can we improve health communication and better care for the patient using augmented solutions? Answer: increase the use of digital technologies and smart connected devices equipped with sensors that can collect data, store it and analyse it to provide further insights.

Connected to a network or to each other, new types of systems and devices can allow remote patient monitoring and diagnosis, providing an accurate and instant snapshot of the patient's health.

Internet of Things (IoT) solutions, with high-tech electronics and embedded software, are increasingly integrated into the healthcare environment. It is a fast growing market: the Internet of Medical Things (IoMT) will likely increase from US$30.79 billion in 2021 to US$187.60 billion by 2028, which represents an annual growth rate of nearly 30%[3].

"When devices become connected, and therefore intelligent, they offer an infinite number of possibilities," says Romain Saget. *"They can help patients better self-administer their medicine for instance, help their health practioner monitor the health of their patients and provide crucial insights so health service providers and national health systems optimise investments in some areas or their policy."*

A new paradigm for healthcare

Wearables and biosensors are not new: they have been used for years now for heart rate, temperature or breathing monitoring. Going forward, there will be an increasing range of applications for smart devices in medicine – from connected inhalers to automated insulin delivery (AID) systems, connected syringe pumps for targeted drug delivery – and even ingestible sensors.

3) Fortune Business Insights, Medical Internet of Things Market Size, 2021-28

A promising area for devices is micro-invasive surgery: the more intelligence is collected on the human body, the least it needs to be probed, cut, enquired. Augmented solutions such as integrated sensors on catheters can allow heart surgeons to better understand a patients' venous system, thus increasing the chances of a successful outcome. Smart devices can also assist with patient positioning. Software assistance can help a surgeon better locate surgical screws or plates during back surgery by tracking the patient's breathing and back movement in real time.

In the future, micro smart devices could be implanted inside the human body. Since 2016, Expleo has been involved in a ground-breaking project with the Clinatec Endowment Fund – the development of a brain-machine interface that allows quadriplegic patients to regain mobility by mentally controlling an exoskeleton, known as the BCI project ("Brain Computer Interface").

Clinatec has created a neuroprosthesis implantable on the surface of the patient's motor cortex, which collects and transmits brain signals in real time to control the four limbs of an exoskeleton. During the clinical trial, a young quadriplegic patient was implanted with the device. His movement intentions could be captured and decoded, and he was able to regain lower and upper limbs mobility thanks to an exoskeleton.

The micro-illumination technique developed at CEA-Clinatec alongside BCI project will allow practitioners to better understand how the brain works. They can also help better track the evolution of degenerative diseases such as Parkinson's or Alzheimer's, which are currently major public health issues and will become even more problematic as the world's population lives longer.

"Expleo has developed a world class capability for critical embedded systems. Our engineers created one of the key sensors of the NASA InSight mission, as well as brain implants to help a quadriplegic patient control an exoskeleton. The required reliability of electronics on Mars or in a patient's brain is similar – the systems must be 100 % trustworthy."

Romain Saiget, Head of Healthcare & Life Sciences, Expleo

Some regulatory, testing and ethical concerns need to be addressed

There are some challenges, however. When a device contains intelligence, it is essential to prove that it is effective and that risks, whatever the usage, are controlled.

To ensure the safe and effective development of smart medical devices, the European Union is also putting devices under greater scrutinty, with the European Medical Device Regulation (MDR).

Protecting patient data, ensuring that devices will not harm the users and that cyber security is optimal are vital elements to make IoMT take off and to enjoy its numerous benefits – enhanced & personalised healthcare, reduced costs, greater innovation to name a few.

Another crucial ingredient in the mix is thorough and smarter testing. The development of a connected healthcare device involves designing, followed by physical testing. Only once the device has been proven safe and validated, can it be commercialised. When a device needs to upgraded, the whole cycle of testing & validation starts again.

To speed up this stage, testing automation tools are a pre-requisite. *"Combining a health diagnostic tool with a server that records patient data allows automated regular maintenance that can pick up potential issues with the device, the software or the system. It then becomes easier to run test updates very fast and ensure test coverage at every stage of the whole cycle,"* Shane Fitzpatrick, QARA Practice lead, stated.

What Expleo offers

DIGITAL TRANSFORMATION	PRODUCT & PROCESS ENGINEERING	QUALITY & TESTING
Big Data, analytics, AI & advanced algorithms	Systems engineering	Product and Process Validation
Cybersecurity	Product Design & Engineering	
	Embedded Systems	
	FPGA & Electronic Systems	
	RAMS	

III. SMART PROCESSES

Regulatory paradigm

The regulatory landscape in Life Sciences is increasingly complex and fragmented, as a wave of disruptive changes in technology is changing the industry beyond recognition, coupled with the need for ever-greater patient data protection.

However, one thing is certain: regulatory bodies worldwide are increasing their scrutiny of Life Sciences businesses and introducing progressively stringent regulations. This is despite the fact that regulatory and legislative pressures can be significant barriers to growth and innovation.

Ensuring compliance with stricter regulations and protecting patient's safety and privacy – while speeding up innovation, is a significant challenge for the Life Sciences industry. The industrial processes involved in pharmaceutical and biotechs compliance remain too complex, requiring a huge amount of paperwork. Change needs to happen – and fast.

"Faced with an increased load of regulations, documents validation in the Life Sciences sector has become an exercise in file stacking," remarks Shane Fitzpatrick.

An industry drowning in documents

The mission of Quality Assurance (QA) is to determine whether a product or service meets specified requirements, to control risk.

However, this systematic process has shifted over the years towards providing a large volume of documentation and completing numerous, rigourous, and sometimes unnecessary, checks.

"As a result, QA teams are overworked and all too often SME's initiatives are blocked even if they are potentially very impactful. Everything is tested, no matter the risk level & criticality, due to the sensitive nature of the industry. A smarter approach is required," Shane Fitzpatrick stresses.

"We need to become more agile and open, and free up innovation. Many players stop themselves from trialing and testing new technologies or processes for fear of failing validation and certification – and that means wasted opportunities."

A more holistic approach to risk management is required

Some health authorities like the Foods and Drugs Administration (FDA) in the USA are currently revising their requirements to promote the development of the industry. They aims to shift the paradigm of the regulation and validation process to 'risk control' to put it at the heart of quality assurance.

"This is a welcome first step towards a new, testing-based approach which shows it is more important than just piling up documentation. The FDA has introduced the notion of a more concise validation pack. We need the regulators and the industry to work more collaboratively, enabled by developing technologies, to support positive and innovative outcomes for patients," argues Fitzpatrick.

"Tomorrow, we will adopt a different approach where we focus on identifying risk," Romain Saiget agrees. *"The Life Sciences sector needs to conduct overall risk analysis to see how their entire organisation manages it, to reduce the shortcomings linked to quality assurance; to accelerate the launch of new treatments for patients. By being smarter in this area, one of our clients, a US pharmaceutical group, reduced its validation efforts by 40 %."*

Numerous benefits for the stakeholders

For patients, device manufacturers, medical experts and regulatory authorities, there is a plethora of advantages linked to a smarter approach to the validation process. They include less documentation to produce and a significantly increase in the entire process's efficiency (validation, testing, QA etc.). It can also help deliver new products or updates quicker to the market and alleviate the workload linked to reviews – rather than use the common 'check then fix' approach. This means there will be more time to identify and work on rootcauses. As a result, audits will be quicker, and oriented towards actual problem solving.

Furthermore, digital technologies can allow the testing process to be virtualised, reducing the need for real-life trials and therefore costs. It will allowing greater agility by shortening the upward curve of the V cycle.

Digital transformation is a huge opportunity for the Life Sciences sector to unleash all its innovation, talent, experience to it can share benefits with the rest of the world and provide a more human, personalised, more efficient and cheaper health care for all.

What Expleo offers

DIGITAL TRANSFORMATION	QUALITY & TESTING
Hyperautomation	Product and Process Validation
Big Data, analytics, AI & advanced algorithms	Quality Management System
	Regulatory Affairs Validation Plan
	Product and Process Validation

How we can help

Expleo is a global engineering, technology and consulting service provider with strong expertise in Life Sciences that partners with leading organisations in the sector to guide them through their business transformation, helping them achieve operational excellence and future-proof their businesses.

Expleo benefits from more than 40 years of experience developing complex products, optimising manufacturing processes, and ensuring the quality of information systems. Leveraging its deep sector knowledge and wide-ranging expertise in fields including AI engineering, digitalisation, hyper-automation, cybersecurity and data science, the group's mission is to fast-track innovation through each step of the life cycle.

Our 15,000 highly-skilled experts across the globe deliver value in 30 countries.

For more information about how we can help transform your Life Sciences business and get in touch, visit expleo.com

info@expleogroup.com

expleo.com/global/en/contact/

XAVIER DE BUSTOS

Director Life Sciences
ERD Director

25 years+ supporting LS companies innovate, thrive and stay ahead of competition

CATHAL MURPHY

Client Director –
Life Sciences, Healthcare & Manufacturing

12 years+ supporting clients across the Life Sciences, Healthcare and Manufacturing Sectors to mitigate risk with business and IT change programs.

DR MATT HEDGES

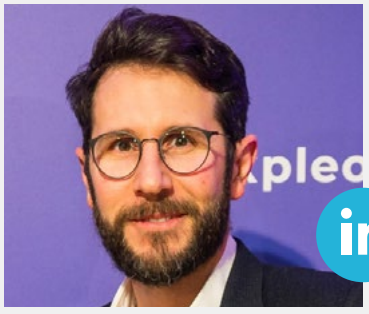
R&D practice lead

15 years plus of experience in medical devices, designing novel minimally invasive technologies

SHANE FITZPATRICK

QARA practice lead

10 years+ ensuring LS companies stay compliant and follow all regulatory requirements



ROMAIN SAIGET

Business Development Director
Head of Healthcare & Life Sciences Portfolio

20 years+ enhancing performance in highly competitive industries

[expleo]

Think bold, act reliable