

# The Power of the Digital Thread in Life Sciences

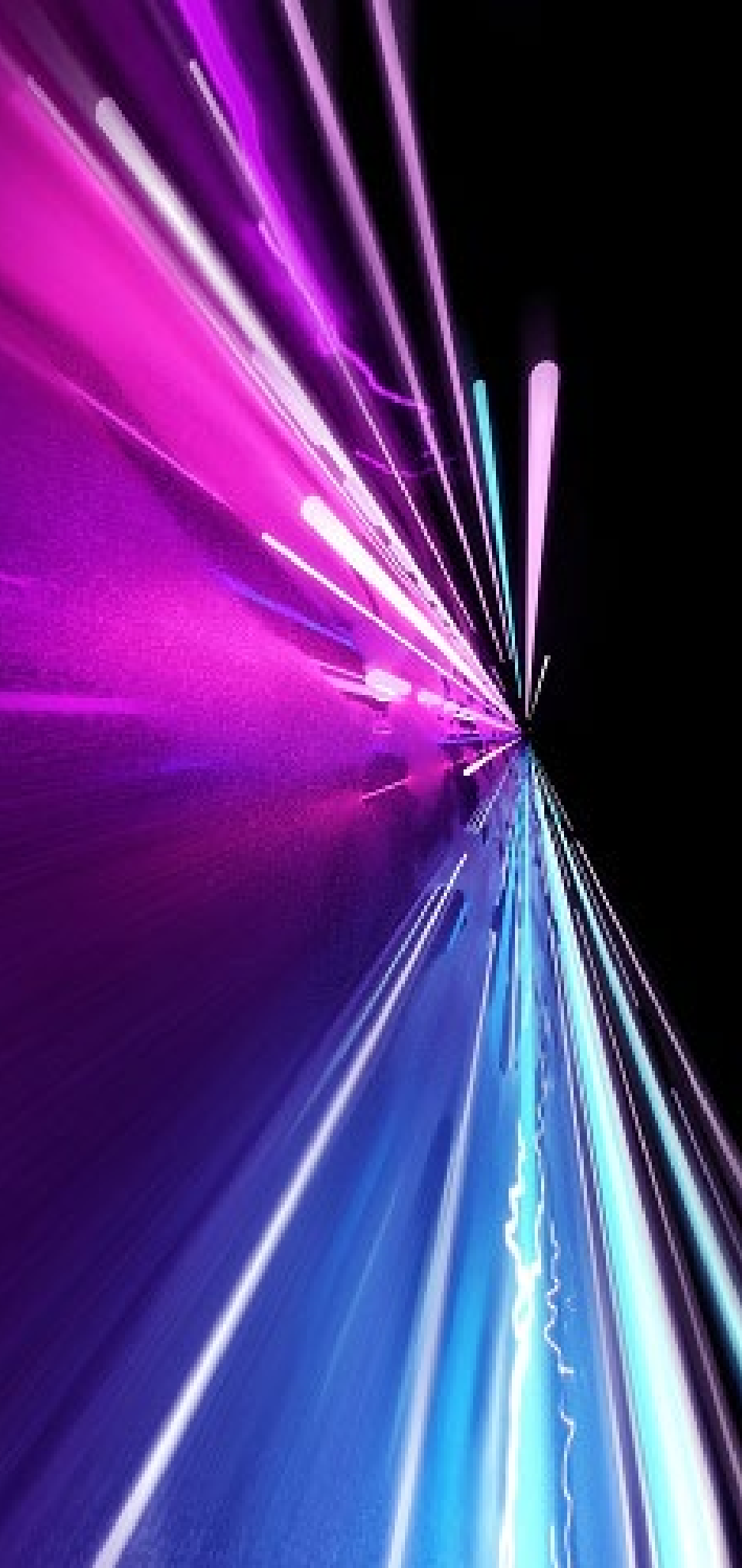
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To be in life sciences today is to be in a constant state of flux driven by advances in science which also bring increases in complexity. Breakthrough treatments are having a huge impact on patients and creating tremendous opportunities for pharmaceutical companies, but they require intricate manufacturing, supply chain and quality control processes that can be challenging to support.

As Barry Heavey, Managing Director at Accenture points out, “over a decade ago, the world’s bestselling drug was made up of 33 carbon atoms and today’s bestseller includes over 6,000 carbon atoms. Five years ago, cell and gene therapy was still an academic area of research and now several personalized treatments have come to market for patients with previously untreatable forms of cancer. And in early 2020, there were no mRNA-based treatments and now billions of doses have been administered to slow the COVID-19 pandemic.”

It might seem like these new developments create more business issues than they solve, at least in the short-term. But that’s a challenge being solved by the **digital thread**, a digital solution that accelerates the scale in the supply of complex treatments from the clinical trial through the commercial

production and launch and through the entire lifecycle of the product.

By building upon established tools like a company’s enterprise resource planning (ERP) software and various scientific and manufacturing data management systems, the digital thread enables better collaboration for faster decisions and lower risk of non-compliance or under-performance in supply.

While the digital thread is a digital solution, its real power lies in how it enables the rest of an organization’s operating model systems.

The digital thread brings the full power of digitally-native thinking, simplified and optimized legacy systems, and the best of what new technology has to offer such as internet of things, machine learning, and cloud computing to work for today’s life sciences companies. Challenges that were once complete roadblocks to innovation are now manageable because the digital thread allows companies to accelerate the scale-up of clinical and commercial supply.

Digital thread opens the door to faster process development, accelerated tech transfers, shorter manufacturing cycles, lowered risk of shortages and higher rates of predictability in life sciences. Here are five practical advancements:



# 1. ADVANCED ANALYTICS AND BIOLOGIC MANUFACTURING



Industries based on physics and chemistry such as aerospace and oil and gas are seeing regular progress in manufacturing processes that can be modelled with advanced analytics. But even though manufacturing processes based on biology can be more complex, with a far greater number of variables to model, advances in our understanding of the biology and increased computation power, is opening up the possibility of modelling these processes as they are scaled up from small scale clinical batches to large scale commercial production.

The digital thread creates the ability to apply advanced analytics and share the insights generated from clinical production to commercial production, to ensure continued progress in speed, consistency and efficiency in production for New Science-based medicines. Over time, life sciences will be able to combine real-time data and historical data to transition from reactive to proactive management of the production process, ultimately speeding up manufacturing operations.



## 2. TECH TRANSFER



Highly specialized teams in the life sciences industry focus on the various stages of supply, from small-scale clinical to large-scale commercial. Handoff of knowledge between these groups has traditionally been paper-based, which introduces delays, risks, shortages, and unpredictability to manufacturing cycles. A fully digital transfer of knowledge enables the acceleration of ongoing collaboration with the most advanced and innovative new technologies.

*“The digital thread gives companies the ability to immediately, and in some cases, automatically transfer learnings about manufacturing challenges back into the molecule design process. Our customers are now applying both of these advances by leveraging cloud-based technologies like IOT, data mesh, machine learning, and knowledge graphs.”*

– Chris Kopinski, Business Development Manager at AWS.



### 3. CLOUD COMPUTING



Companies that have been the most successful with the digital thread are the ones that leverage the best of cloud computing in the work they do. In moving to the cloud, these companies have been able to migrate important applications such as ELN, LIMS, MES and quality management systems, to scale environments automatically and free up their IT resources.

In the big picture, this allows those companies to accelerate clinical development, speed up filings or approvals, share insights between different teams and optimize and create more efficient manufacturing operations and execute flawless tech transfer between teams.

*“This additional capacity allows teams to create an environment of innovation. Companies can leverage data generated in the process of bringing those new therapies to market and scale the manufacturing process globally while also ensuring the necessary security, compliance, and resiliency measures are in place. And in doing so, companies are able to evolve their business policies in order to help break down silos between functions and truly create an end-to-end data strategy.”*

– Chris Kopinski, Business Development Manager at AWS.

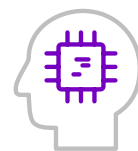
## 4. CELL AND GENE THERAPY



In cell and gene therapy, the raw materials, the manufacturing process and the final product are all based on unique patient characteristics and in some cases specific patient samples. These products are at the cutting edge in terms of complexity in manufacturing and are an increasing area of focus for many clients because their efficacy data in areas such as oncology is so compelling. But in order to achieve the best possible clinical outcomes, real-time information is needed across the value chain from providers, lab technicians, plant manufacturing, and patients.

*“Manufacturing and supply chain visibility are more important and more challenging than ever for life-saving medicines that rely on cell and gene therapy,” said Kopinski. “Everyone involved in the process needs real-time data. And now, the same technologies that enable Amazon to show you when a package can be delivered to your home can also help to show you and all those stakeholders when the drug product is likely to arrive, and to then make real time changes to your plan manufacturing or infusion at the hospital or care center.”*

– Chris Kopinski, Business Development Manager at AWS.



## 5. MACHINE LEARNING

Machine learning was one of the important technologies that expedited the industry's ability to discover and develop new vaccines and therapies in a small fraction of the time it normally takes, such as the COVID-19 vaccine. The digital thread allows companies to collect enormous amounts of manufacturing and lab data over many years of producing a product and then seamlessly run it through advanced analytics and machine learning to surface insights on how the manufacturing process can be optimized.

But the real benefit is not just harnessing data over time. The combination of the digital thread and machine learning enables an organization to get data about the molecule and the similar molecules out of those many data silos that are spread across research, clinical, and manufacturing divisions. Over time, life sciences companies can use the digital thread and machine learning to identify the key parameters that predict how easy it will be to manufacture a given molecule before the company has even begun clinical manufacturing.





# SAFETY, SPEED, AND PATIENT SUCCESS WITH THE DIGITAL THREAD

The speedy development and manufacturing scale-up of the COVID-19 vaccine and various oncology treatments is not taking place in a vacuum. These examples represent technology that is now readily available for many different uses in many different kinds of sciences, including drug development. The real question is whether pharma companies are prepared: prepared to disrupt the industry, to become pioneers, and to scale up the intricate manufacturing, supply chain, and quality control processes that must be in place to support the products that can come to market faster than ever thanks to the digital thread.





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