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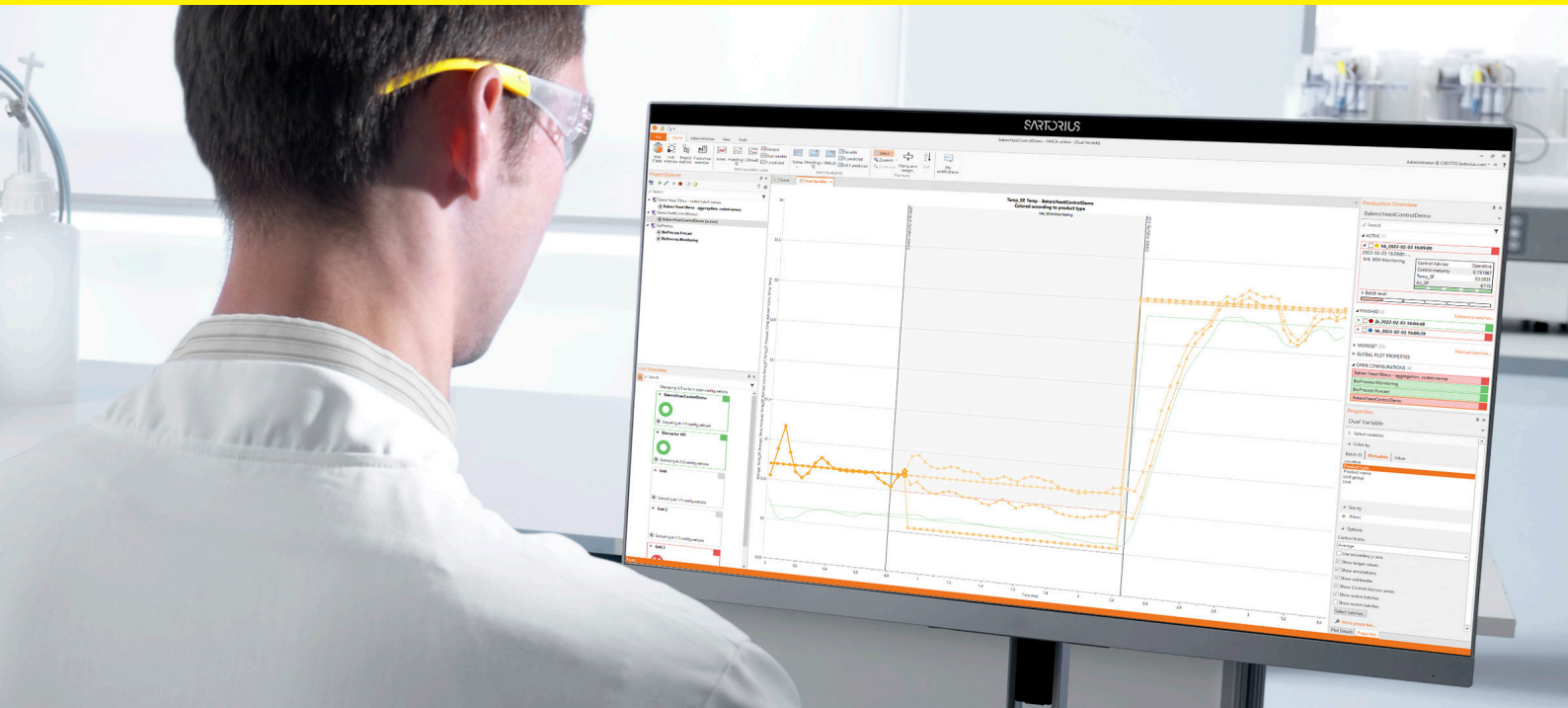
Data Analytics Trends in Biopharma Manufacturing 2022

What Current Trends in Data Analytics Mean for the Future of Biopharma Manufacturing

Data analytics, the discipline of analyzing raw data to understand processes and make informed decisions, is at the heart of industry 4.0, the ongoing transformation in industrial manufacturing and Biopharma 4.0, the framework for adapting digital strategies to the unique contexts of (bio)pharmaceutical manufacturing. What impact does this convergence of IT (information technology) with OT (operational technology) – particularly the real-time interplay of sensors, data, and analytics – have on trends occurring in Biopharma?

Pressures in biopharma encourage caution. Safety and efficacy are sacred. Manufacturing units work by the doctrine "if it isn't broken, don't fix it". Failed batches and products can mean the death of a company, or the death of a promising therapeutic approach. Yet, adapting to new technologies and embracing the move toward digitalization holds the answer to solving issues of product quality, process control and compliance.



Biopharma Manufacturing is Changing

Biopharma manufacturing continues to evolve, both from the need to embrace digital transformation and improve processes, as well as from regulatory pressure. Market scenarios have emerged that reflect these changes. We can see two main forces at work:

1. The success of classes of biomolecules that allow platform processes and continuous improvements based on data.

2. Smaller product niches due to more players and more customized treatments. Producers must look at ways to reduce production costs without the benefit of economies of scale.

Together, these forces enable and encourage the use of data to improve processes — to avoid batch failures, to increase yields, and, ultimately, to improve process economy.

Automation is Inevitable

Automation relies on good control, and good control requires effective data analytics. The data collected at every stage from development to production to manufacturing must be evaluated to keep the process and quality under control. Data from development describes the production process and data from ongoing manufacturing steers how improvements can be achieved –fulfilling the promise of Quality by Design (QbD). A well-designed (and well-documented) process has more room for adaption (and correction) during operations. Even a cautious process developer or production head will find this attractive. Data analytics is the key to good automation and opens possibilities with Internet of Things (IoT), Artificial Intelligence (AI), machine learning, and other digital tools awaiting exploitation.

How is data analytics impacting some of the most important trends in Biopharma?

Let's look at the role data analytics plays in supporting these top trends in the biopharma industry.

1. Platform processes
2. Biosimilars
3. Advanced Therapies
4. Process intensification
5. CDMOs
6. Personalized medicines
7. Artificial intelligence

1. Platform Processes

Some of the most successful drugs currently being produced rely on platforms based on data collection and analysis during both development and manufacturing. For example, any of today's largest blockbuster drugs are well-established monoclonal antibodies (mAb)s – laboratory-produced molecules engineered to serve as substitute antibodies. mRNA therapeutics can join mAbs as a category of therapy that benefits from manufacturing platforms based on data analytics.

Market reports speculate that Pfizer-BioNTech and Moderna sales of mRNA vaccines could reach $50-$90 billion this year (2022)[1]

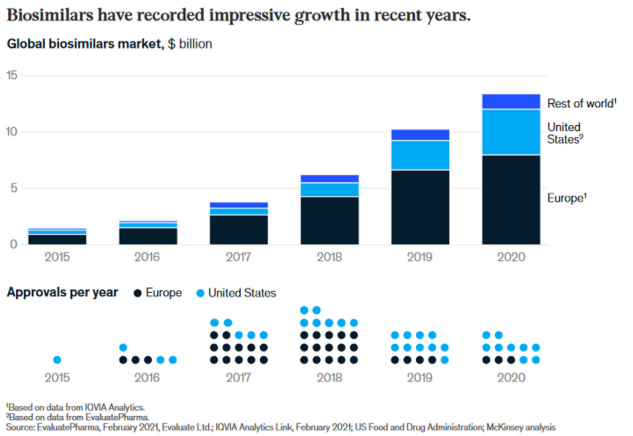
Whereas a completely novel biomolecule demands a process with many unique characteristics, classes of molecules, like mAbs and mRNA, can be manufactured using the same unit operations in platform processes.

Whether it's embracing the principles of Quality by Design (QbD), incorporating Process Analytical Technology (PAT) or optimizing your supply chain, data analytics plays a significant role in fostering digital transformation in the biopharma, healthcare and life science industries. Top Biopharma Trends Supported by Data Analytics.

With mAbs that have been around for decades, companies have widely adopted Design of Experiments (DOE) and data analytics in line with QbD principles[2] for drug development. mRNA will surely follow the same path.

2. Biosimilars

The biosimilars market is set to continue its double-digit growth, doubling in size to more than $30 billion by 2025, and over $60 billion by the end of the decade. [3]

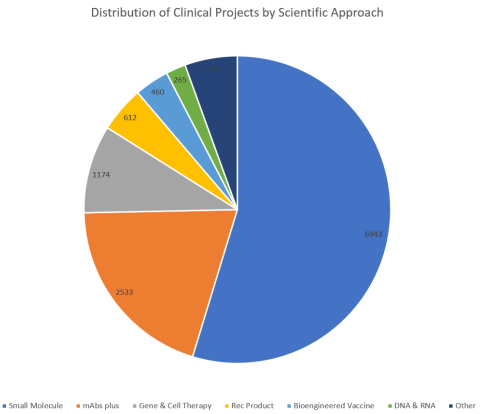


In biopharma, the complexity of the molecules being produced, and the systems and technologies needed to produce them, is huge, but tools and equipment within the workflow can be inter-connected digitally, from end-to-end, reducing human errors and adapting to changing conditions automatically. Biosimilar producers are forced to re-think manufacturing processes and adopt the latest and best methods, including automation. Feedback control requires good data and real-time monitoring and analysis. We can also expect more sophisticated analysis of the interplay of different parameters in-order to improve process yields and process economy. For example, by applying MVDA (multivariate data analysis) new insights can help control, adapt, and improve production processes.

Governments and health insurance systems see biosimilars a way to reduce healthcare costs and make otherwise expensive but effective treatments more widely available. Biosimilars should be cheaper to develop, but since they are copies of a small number of original molecules, each manufacturer will be producing smaller amounts - meaning that they lose out on economies of scale. Production costs can, nevertheless, be lower if manufacturers grasp opportunities to make production methods more efficient and batch failures fewer.

3. Advanced Therapies

Advanced therapies are a class of therapeutics that are based on genes, tissues, or cells. They offer groundbreaking new opportunities for the treatment of diseases. [4]



Of projects in clinical development, almost 10% belong to the category of advanced therapies (gene and cell therapy), according to the PhRMA (2021). [4]

The average time for a new drug development project increased from 7-9 years in the 1990s to 10-15 years in the 2000s and 2010s.[6,7]

Risk assessment and mitigation are areas of special focus whenever novel products are being developed. From the manufacturing perspective, the design space and process control are important to ensure reliability and robustness. Data analytics helps to describe unit operation performance, to define the operating space, and to avoid potential failures.
A few failures could sabotage a whole field's commercial potential, making developers and manufacturers extremely cautious regarding radically new production technologies.

By 2025, the FDA anticipates that it will have approved 10–20 more cell and gene therapy products. And in the next decade, the gene therapy market is expected to grow at a 30 percent compound annual growth rate. [5]

The future is bright, with biopharmaceutical companies looking to expand beyond rare diseases to oncology and other chronic conditions.
We still await the first blockbuster in gene therapy - when it happens, the floodgates might open. In the meantime, developers and manufacturers will advance with care, using data to understand processes, diagnose problems, predict risks of failures and, ultimately, control conditions that deliver the most reliable and economic performance. Companies that are prepared with digital processes and data analysis technologies will be poised to take leadership positions.

4. Process Intensification

Process intensification encompasses all approaches that increase productivity, reduce waste, and get products to market faster. Flexibility might also need addressing, in terms of the ability to adjust production amounts or to be able to switch rapidly to production of another product. Achieving more for less is the constant challenge. Data is key to being able to measure performance and understand the factors that influence it. Without access to good data and methods to analyze it, it is unlikely that a manufacturer will understand what factors have the greatest impact on performance and how to get the most out of a unit operation or process.

In the end, the goal for biologic drug manufacturers is always to bring more high-quality therapeutic products to more patients, faster, and at lower cost. Manufacturers need to be prepared to increase product scale massively and/or accelerate time to market. This is particularly true for infectious diseases when emerging pathogens arise. There is no clearer example of this than the COVID-19 pandemic. While devastating, it has showcased both the incredible power of biologics (namely vaccines and antibody therapeutics) and the need to mobilize in a matter of weeks to save countless lives.
DOE can be used to shorten time to market by creating experimental efficiency and greater confidence in the processes.

An effective DOE can greatly reduce the number of experiments needed to define your design space and ensure robust and stable products. In some cases, it could cut the number of experiments needed by half.

The Pharmaceutical CDMO Market was valued at USD 184 billion in 2021. It is expected to reach USD 290 billion by 2027, registering a CAGR of 7.3% during the forecast period. [8]

5. CDMOs

As pharma companies become more focused on their core competences as well as looking for better ways to reach new geographical markets, CDMOs have become increasingly relevant and integrated into company strategies. Clearly, to be successful, a CDMO must itself stay abreast of the latest technologies to offer a competitive service. CDMOs are the early adopters when it comes to most of the techniques that are mentioned related to Pharma 4.0. Skills in data analytics help them be efficient in their own production scenarios and a modern approach to tracking and exploiting data is expected by their clients. Several drivers lie behind the increasing popularity of CDMO services. These include:

- To avoid difficulties and costs of staying abreast of state-of-the-art manufacturing technologies
- To focus on other areas of competence than manufacturing during biopharmaceutical development
- To meet growing market demand both at home and abroad (geographical expansion)

Specialization in key competence areas and widespread collaborations to access these competences are likely to be important success factors in future biopharma. In development and manufacturing, this is where Pharma 4.0 is likely to happen.

6. Personalized Medicines | Targeted Therapies

The onset of tailor-made therapies, based on an individual's phenotype and/or genotype has been long-awaited. Personalized medicines should be seen as an evolution, rather than a revolution, and many challenges remain before its successful application across healthcare systems.

The bottom line here is that sensor technology, real-time data analytics and feedback control are keys to economically viable production, if the age of personalized medicines is to be a reality.
Biopharmaceuticals are increasingly targeting smaller patient populations, which introduces challenges. Production volumes will be smaller than for traditional blockbusters. Also, market predictions could be very hard to make. Manufacturing methods need to be not only economically viable, despite the smaller scales, but also very flexible to meet unexpected shifts in demand. These characteristics should encourage single-use approaches that are more agile than those in traditional facilities. Smart factory concepts – where unit operations run in an autonomous manner, self-optimize, and learn in real-time would certainly help. Continuous processes should be favored since they also allow adaptation to change in demand.

AI will trend as the most disruptive technology in the pharmaceutical sector in 2022. [10]

7. Artificial Intelligence

The use of artificial intelligence (AI) in the pharma and biopharma industry has gone from science fiction to science fact. Increasingly, pharma and biopharma companies are adopting more efficient, automated processes that incorporate data-driven decisions and use predictive analytics tools. The next evolution of this approach to advanced data analytics incorporates artificial intelligence and machine learning.
AI can be used in many ways to make production more efficient with faster output and less waste. For example, a process that typically relies on human intervention to input or manage process data can be done using CNC (computer numerical control). The AI machine learning algorithms not only ensure tasks are performed very precisely, but also analyze the process to find areas where it can be streamlined. This results in less material waste, faster production, and more consistently meeting the product's Critical Quality Attributes (CQAs).

Conclusions

Disruptions are often said to be the harbingers of technological transformations and paradigm shifts. The biopharma industry has taken the brunt of the impact of the COVID-19 pandemic and has responded by delivering vaccines in record time using novel biomolecular approaches and production methods. The response has been massive, global, and, it must be said, largely successful.
Modern biopharma is in a different state compared to pre-COVID times and has shown its ability to develop and adapt quickly. The basis for speed, agility and improved productivity is good data and the best exploitation of that data. Although biopharma is not pioneering regarding digital transformation tools, like IOT, AI, edge computing, digital twins, cybersecurity, etc., it is embracing data analytics in the light of the trends listed in this article, as the foundation of its digital future.

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