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Fostering Operational Excellence in Biopharmaceutical Manufacturing: Leveraging New Methodologies, Technologies, and Data for Optimal Results

AUGUST 2023



The biopharmaceutical industry is undergoing change at a remarkable pace, keeping up with the momentum observed in the healthcare and technology sectors. What was already complex has become more so, and this trend is expected to continue unfolding even further. Significant breakthroughs have come fast and furiously, resulting in cures for numerous diseases, novel therapies for rare disorders, and improved quality of life for countless patients and their families. The FDA has approved more than 378 novel drugs in the last decade, and the dynamic nature of the industry led to the rapid development of a vaccine for COVID-19 and the immunization of more than 5 billion people worldwide.

This has been fueled by massive investment in biopharma R&D – \$230 billion just in 2021 – and it has paid off in every sense of the term. However, the industry is facing new challenges, including financial pressures, not the least of which is that some of the largest companies will lose market exclusivity for many top-selling products between 2023 and 2028. That change in the market for those drugs represents approximately \$200 billion in lost revenue. The competition to develop new drugs will become more intense for both long-time and new players, and they will need direction.

Facility design must not only ramp up, but it must also adhere to good manufacturing practices (GMP). With the myriad levels of compliance, this can be a challenging task, especially for newer organizations. Furthermore, many organizations come to the realization they do not possess the in-house expertise necessary to provide guidance on aspects such as facility layout, validation, process flows, written procedures, equipment maintenance, risk mitigation, and compliance auditing.

Seeking outside expertise can unlock a multitude of advantages for these organizations.



Introducing lean and agile methodologies

Lean and Agile methodologies significantly enhance customer value, minimize waste, and improve overall quality and efficiency. The application of these principles prioritizes adaptability in project management and can result in optimized resource utilization and faster development cycles. By establishing an Agile framework, organizations are better equipped to organize evolving requirements, foster collaboration among stakeholders, prioritize customer satisfaction and feedback, as well as establish a culture of continuous learning and innovation.

An effective combination of Lean and Agile approaches can yield superior results in project execution and improved outcomes, especially in dynamic and complex environments. For instance, Lean practices can assist Agile teams in identifying and rectifying process inefficiencies, such as unnecessary meetings, excessive documentation, or redundant handovers. Integrating these methodologies necessitates careful planning rooted in a thorough understanding of project scope, objectives, constraints, and alignment with overarching goals and client needs. This seamless integration nurtures an environment of open communication and collaboration among stakeholders, and helps organizations to establish shared terminology, standardized metrics, and consistent benchmarks.

Lean and agile methodologies	Enhance Customer Value	Minimize Waste	Improve Overall Quality & Efficiency
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Advanced analytics to advance efficiencies

Each year, pharmaceutical companies accumulate hundreds of terabytes of data of which 80% is unstructured and from various sources. Amid substantial pressure to expedite drug development and market entry, advanced analytics emerges as a viable solution. By leveraging sophisticated statistical techniques, machine learning, and algorithms, advanced analytics can effectively discern patterns and trends within the data, leading to reduced analysis time. This acceleration translates to faster decision-making, streamlined processes, and ultimately, more favorable outcomes. For instance, advanced analytics can be used to predict the performance of novel drugs prior to clinical trials, providing companies with the means to make informed decisions sooner, potentially resulting in cost savings as resources can be directed to the most promising drug candidates.

Efficient processes are paramount for successful drug development considering the launch of a new drug typically takes 10 years and costs \$2.6 billion. Utilizing cloud-based analytics offers scalability, equipping companies to quickly access and analyze relevant and timely data, resulting in enhanced efficiencies overall. Real-time patient data can improve patient outcomes by enabling personalized medicine and increasing the feasibility of remote monitoring and telemedicine. Substantial cost savings are realized through the elimination of costly IT infrastructure and the associated specialists required to manage it. Automated analysis further conserves resources and reduces expenses. Today, 83% of pharmaceutical companies are leveraging cloud-based data to promote extensive collaboration among stakeholders, facilitating robust sharing with researchers and clinicians within and outside the organization. Additionally, efficient downstream automation can help to simplify decision-making, enabling data-driven decisions for trial design and dosing protocols.

Launching a new drug often takes 10 years and costs \$2.6B

Mitigate human error through automation

Automation and robotics are positioned to play an increasingly significant role in drug development, effectively reducing human error and seamlessly incorporating routine tasks. This transition from manual processes presents a variety of benefits including reduced operational costs, streamlined processes, and increased accuracy. Enhanced worker safety results from automation managing complex and high-risk tasks, while improved process control and the ability to maintain manufacturing entirely in-house, leads to shorter lead times. This acceleration in return of investment enhances competitiveness by reducing manufacturing time and cost per unit. Furthermore, the implementation of automation translates to amplified production output, as these mechanisms operate consistently and autonomously, around the clock, seven days a week. The optimization of equipment and processes minimizes waste, space utilization, and energy consumption, resulting in a reduced environmental footprint. Automation also offers reliable insights into time and cost, thereby improving planning and alleviating the need for outsourcing, often made possible through compact, integrated systems.

Moreover, robotics play a valuable and pivotal role in aseptic environments. In addition to mitigating contamination risks, automated systems adhere unwaveringly and reproducibly to defined standard procedures, reinforcing compliance with Good Manufacturing Practices (GMP).

Quality and compliance

Navigating the ever-evolving landscape of the pharmaceutical industry demands adherence to more stringent regulatory standards compared to most other sectors. This amplifies the significance of quality and compliance as integral components of achieving success. Notably, recent shifts in regulations underline the importance of developing phase-appropriate quality systems to uphold compliance.

Engaging an external partner well-versed in the complexities of developing phase-appropriate quality systems can offer substantial support to organizations aiming to adhere to applicable regulations for their products and intended uses. Moreover, experienced partners can assist their clients in establishing initiatives and teams dedicated to compliance and risk management. These teams assume the responsibility of identifying potential challenges and risks, staying up to date on regulatory changes, and proactively preventing warnings or citations.

When developing compliance and risk management programs, seasoned partners can aid companies in streamlining internal workflows, effectively outlining ownership and responsibilities, and fostering effective communication among stakeholders. Additionally, they can aid in the selection and implementation of quality management system (QMS) software, further facilitating the monitoring of compliance initiatives and adherence.

Partner for success

The biopharmaceutical industry must swiftly adapt to the continuously shifting demands and expectations of patients, investors, and regulatory agencies. While technology continues to assume a more significant role in drug development, the human aspect in the development, launch, and marketing of new products remains critical and must also evolve.

Expert guidance rooted in real-world experience is essential for successfully navigating these complex changes, and it is unlikely that companies will always possess such specialized expertise in-house. In order to keep up with the evolution of innovative manufacturing methods, the increasing pace of technological advancements and automation, as well as the unwavering emphasis of GMP compliance, it's imperative that companies are willing to partner for success if they want to cultivate teams that are adaptable and dynamic.

Established pharma companies, potentially hindered by extensive and redundant systems, as well as emerging startups, fueled by enthusiasm but lacking essential expertise, can greatly benefit from engaging with a strategic and functional partner. The extensive experience of seasoned industry experts enables

organizations to remain big picture oriented while tackling immediate needs and concurrently developing a long-term strategy. In the current landscape, harnessing every accessible resource is crucial.

A partner who brings strategic and operational expertise with a holistic perspective on success could prove to be the most powerful asset. Ultimately, a fully operational facility, achieving swift compliance and optimum efficiency, derives its true value from the benefits it provides to all stakeholders, especially patients.



Real-world example

A leading global Life Sciences supplier needed to quickly increase production capacity for animal-origin free enzymes, which required the construction and validation of two US-based manufacturing facilities. A project of this size typically requires three months of planning at a minimum. However, the client's timeline required that planning happen in a fraction of the time – just three weeks.

Construction followed a similarly accelerated schedule. Sequoia coordinated the design and construction of the new GMP biomanufacturing facilities, a combined total of 250,000 square feet, in less than a year. The facilities included multiple modular clean rooms, dual suite QC laboratories, warehouses, and final package areas that, altogether, supported three unique product lines.

This massive undertaking included more than design, build, infrastructure, and compliance. Sequoia also facilitated the complex international technology transfer between Europe and the new US bioprocessing sites, including translating and updating documentation to meet North American standards. The initiative was overseen by a team of Sequoia subject matter experts who also conducted proactive risk assessments, developed a quality management system, created standard operating procedures, and led commissioning, qualification, and validation (CQV) activities.



“Working with Sequoia’s experienced, dedicated team who showed care for us as clients was a refreshing aspect of the project. They quickly responded to our needs, understood our concerns, and addressed them directly. Their process-oriented approach to problem-solving proved invaluable to the project’s success.”

– Director of Technical Operations



Conclusion

Sequoia Consulting Group partners with organizations on a profound level to establish a solid foundation that drives growth. We recognize the vital importance for pharmaceutical companies, regardless of their size or market presence, to challenge the status quo. Our teams of seasoned professionals continuously expand their expertise in various aspects of facility design, innovative manufacturing practices, and operational support. Additionally, we acknowledge the need for clients to have complete confidence that our services encompass critical aspects of what it takes to bring a product from concept to the patient, reliably, on time, and within budget.

About Sequoia Consulting Group

For over a decade, Sequoia Consulting Group has supported life science companies by delivering functional, strategic, and lasting solutions that shape their journey to success. Our mission is to remove the barriers that hinder the path from innovation to delivering essential advancements for patients. We achieve this by providing solutions that ensure the safe and efficient delivery of life-saving diagnostics, therapeutics, and medical devices. With a portfolio of 200+ Life Science clients and 5000+ projects, Sequoia is a reliable partner for the challenges and opportunities that the ever-evolving life science landscape presents.

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