ZAETHER

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Digital-Driven Biopharma:

6 Proven Strategies to Accelerate Innovation and Success

The drug discovery, development, and commercialization process is undergoing a digital revolution that has sharply cut the time and cost required to identify new drug candidates, conduct clinical trials, and bring more targeted, effective treatments to patients in need.

For example, using Artificial Intelligence (AI) learning models enabled researchers to **identify an immuno-oncology molecule in just eight months** – far faster than the typical four to five years.

Digital technology is also revolutionizing clinical trials. According to the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS), digitally enabled decentralized clinical trials (DCT) "**could make clinical trials more efficient, effective, and equitable**" by expanding accessibility and leveraging real-time data collection.

The challenge is how best to implement these enabling technologies to maximize their impact and ensure a future in which the development of new drugs is faster, more efficient, and more precise – saving more lives.

In this eBook, we share six proven strategies to enable your organization to reap the benefits of the digital biopharma revolution confidently.

1 Leverage Digital Data Early and Often

In the biopharma industry, data is not just a byproduct of research and development; it is the foundation upon which successful commercialization is built. From early-stage Discovery to full-scale Manufacturing, collecting, analyzing, and acting on data is critical to making informed decisions that help ensure a product's success.

The earlier a Digital and Data Strategy is implemented, the greater the competitive advantage. In Discovery, digital data enables quick analysis to weed out unpromising candidates and strengthen the pipeline. In Development, digital data informs decision-making and product refinement to guide investments. In Clinical Trials, digital data feeds the FDA submission/documentation process. In Manufacturing, digital data enables Review by Exception and what's trending for process improvement insights.

The challenge is that the volume of data generated is staggering – and much of it is unstructured, making it extremely difficult to extract meaningful insights. There are many companies still working in non-digital formats because the plethora of technology choices and associated costs are simply too daunting. Also, deploying a Digital Strategy in selected areas can lead to data silos across different departments, risking poor collaboration and delays in decision-making.

To overcome these challenges, ZAETHER works with each client to develop a Digital and Data Strategy tailored to their specific needs, goals, and baselines. Strategic Planning includes data prioritization and advanced data management strategies to ensure data is **FAIR** – **F**indable, **A**ccessible, **I**nteroperable, and **R**eusable. Having FAIR data opens the door to fully leveraging that valuable information.

For example, a Top 10 pharmaceutical giant reduced its data processing times by 40% by moving from proprietary data warehouses to an integrated data platform, enabling faster decision-making and more efficient operations.

To build on the Digital and Data Strategy, ZAETHER can deliver a full Data Infrastructure Roadmap of prioritized deployments designed to capture the most critical data at each phase of Drug Development. This Roadmap lays the foundation for AI/ML modeling that will unlock further Discovery and Speed to Market opportunities.

2 Plan Early to Accelerate Commercialization

The transition from Clinical Trials to Commercial Manufacturing is one of the most critical stages in the Drug Development process. Often, the goal is to have Batches ready for Quality Approval and shipment immediately upon Regulatory approval. Additionally, the reams of data captured during the Development and Clinical phases must be accurately captured and cataloged to inform Commercial scale-up – a hugely labor-intensive undertaking.

A well-developed Digital Roadmap takes this into account early on and enables leaders to plan and budget for this enormous effort. Depending on various factors, there may be planned deployments of Data Historians, Manufacturing Execution Systems (MES), LIMS, and the Quality Management systems required to support Commercial Manufacturing. In many cases, a Product Lifecycle Management (PLM) deployment is included to enable collation of data for Regulatory Submission and the Digital Tech Transfer from Clinical to Commercial.

ZAETHER works with clients to ensure a full understanding of Commercial goals. Knowing which data are most needed helps the team to develop a robust plan for infrastructure and tools that best support the product release timeline.

An early focus on data priorities is also key to establishing a solid foundation for AI readiness. The ZAETHER AI Readiness Assessment also considers existing and planned data infrastructure, process/data mapping and accessibility, talent capabilities, corporate cultural aspects of innovation and technology adoption, and other factors.

A comprehensive Digital Roadmap is beneficial at any stage of an organization's evolution, even those already on the road to implementing Generative AI. By considering all aspects of successful data management, the most realistic timelines can be developed and executed, thereby ensuring a successful Tech Transfer and a highly efficient product launch.

Early planning can have major positive repercussions. For example, one of the leading manufacturers of COVID-19 vaccines began production planning years before its approval. This enabled the company to scale up Manufacturing and meet global demand.

This proactive approach not only contributed to a 30% reduction in time to market and significant cost savings but also prepared the company to face the extreme challenges posed by the pandemic.

3 Ensure IT/OT Integration for Seamless Operations

To optimize biopharma manufacturing operations, it is essential to integrate Information Technology (IT) and Operational Technology (OT). However, that is often easier said than done. Many companies struggle with this integration due to legacy systems, data silos, and the complexities of aligning IT and OT systems and associated organizations.

The problem is that IT and OT systems have traditionally operated in silos, with IT focusing on data management and OT handling the physical processes of Manufacturing. This separation can lead to inefficiencies, data inconsistencies, and increased risk of error. While this model does provide benefits in terms of network segmentation and security, a more modern approach, such as Unified Name Space (UNS) or Data Hub, delivers greater business agility and lower cost. For companies in transition to this flatter data architecture, the holistic ZAETHER approach recommends the development of cybersecurity mediations, such as OT Incident Response Plans for cyberattacks, loss of data connectivity, loss of cloud connectivity, etc.

In today's digital age, where real-time data and automation are critical, the lack of integration between IT and OT can significantly hinder a company's ability to operate efficiently and meet regulatory requirements.

The best way to integrate IT and OT systems – and ensure seamless data flow between digital and physical processes – is to enlist the services of a systems integrator with proven biopharma industry experience, tools expertise, and process knowledge.

The investment can be well worth it. By integrating its IT and OT systems, a Top 10 European pharmaceutical giant achieved a 20% increase in production efficiency and a 15% decrease in operational costs.

This integration enabled real-time monitoring and control of manufacturing operations, improving efficiency and product quality.

4 Conduct a FEED Analysis for Risk Mitigation and Cost Optimization

A thorough Front-End Engineering Design (FEED) analysis is essential for mitigating risks and optimizing costs in biopharma manufacturing. This analysis is the foundation for successful project execution, ensuring that all technical, logistical, and regulatory aspects are thoroughly considered and planned for.

Why is a FEED analysis so critical? Because of the complexity of biopharma manufacturing, coupled with stringent regulatory requirements and the need for precise control over environmental conditions. Without it, companies risk encountering delays, cost overruns, and quality issues that can jeopardize the entire project.

Companies can identify potential risks early with a detailed FEED analysis and develop mitigation strategies. Recently, a multi-million-dollar U.S. biopharma implemented a thorough FEED analysis for a new manufacturing facility.

This resulted in a 15% reduction in project costs and a faster time to market for its latest product.

By identifying and addressing potential bottlenecks before construction began, this proactive approach ensured smooth and efficient project execution.

5 Select Technology Carefully for Long-Term Success

The rapid pace of technological advancement in the biopharma industry presents opportunities and challenges. While new technologies offer the potential to enhance efficiency and accelerate time to market, the technology selection process must be approached with a complete list of criteria to ensure long-term success.

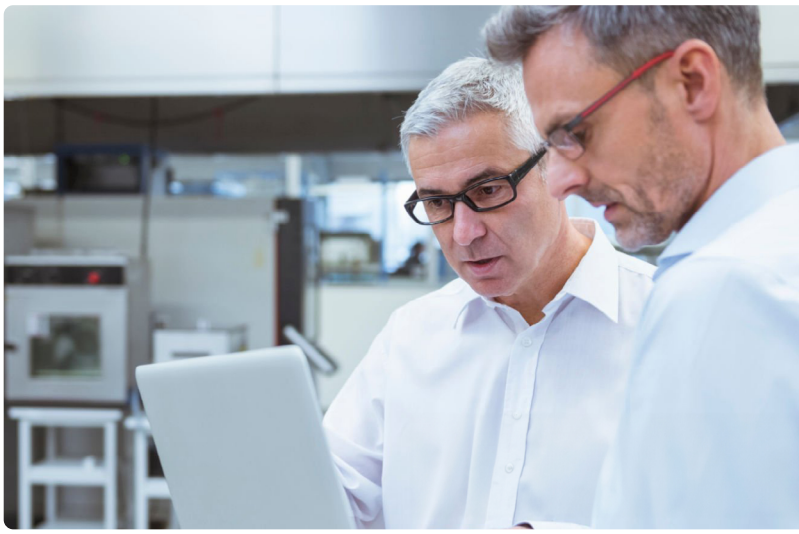
The challenge is that the biopharma technology landscape is vast and constantly evolving, making it difficult for companies to determine which solutions align with their long-term business objectives. Companies must balance the desire for cutting-edge technology with the practical considerations of scalability, integration, and cost-effectiveness.

ZAETHER employs a proven process to support informed technology decisions. After an initial review of business goals and criteria, the ZAETHER team uses their extensive industry experience to develop a short list of appropriate potential solutions. The team then partners with the client to evaluate a matrix of factors, including compatibility with existing systems, ease of integration, and total cost of ownership. This ensures that the deployment will be fit for purpose and aligned with the client's goals.

Proof of that can be seen at a Top 10 UK-based pharmaceutical company. The company elected to have a detailed analysis performed to determine the ramifications of adopting a state-of-the-art Manufacturing Execution System (MES) before making the final MES selection.

Doing so enabled the company to increase production throughput by 20% and reduce operational costs by 15%.

This investment in technology enhanced the company's manufacturing capabilities and supported its long-term growth strategy.



6 Partner for Success in a Complex Ecosystem

In the biopharma industry, success often depends on building and maintaining strong partnerships with vendors, regulators, and other stakeholders. Effective collaboration is essential for navigating the complex biopharma ecosystem.

Fostering relationships is a key focus for the ZAETHER team, which includes many former biopharma colleagues. We maintain a strong interest in industry trends and partner with a variety of proven technology vendors.

The solution ecosystem can play a vital role in supporting the development of digital strategies, helping to reveal what, if any, intersections and dependencies there will be and any risks they may introduce. Without robust collaboration, there will inevitably be missed requirements, poor solution adoption, and, ultimately, limited ROI.

Effective collaboration ensures:

Reduced risk of missed requirements

Increased innovation

Alignment on the system use case

Greater awareness of solution benefits across the enterprise

Quantified adoption and ROI

Intracompany collaboration is also essential. Consider taking these key actions to build a truly collaborative team:

- **Make it a diverse and well-rounded group. In addition to technologists, engage industry and enterprise expertise, communications, and Change Management specialists.**
- **Share and review vendor documentation and training materials rigorously.**
- **Establish feedback cadences.**
- **Evaluate adoption trends across the organization; Is the total enterprise truly ready, willing, and able?**
- **Really listen to the resistors – their feedback may improve the product.**

The positive impact of strong partnerships cannot be overstated. For example, by establishing a close strategic relationship with a leading technology vendor, a major Swiss-based pharmaceutical company was able to accelerate the implementation of a new digital platform and reduce time to market by 30%. This collaboration enabled the company to enhance its competitive position and meet growing product demand.

Taking the Next Steps

As these six strategies demonstrate, the journey from drug development to commercialization is complex and challenging, but success is well within reach. With its deep expertise in digital enablement and biopharma processes, ZAETHER is uniquely positioned to help you navigate these challenges and achieve your commercialization goals.

By leveraging advanced data management, integrated IT/OT systems, and strategic technology selection, ZAETHER helps biopharma companies optimize their operations, reduce time to market, and ensure long-term success. Whether you are in the early stages of production planning or looking to enhance your IT/OT integration, let ZAETHER help you bring life-saving therapies to market faster and more efficiently. Contact us today to get the conversation started.

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