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AI-Driven Raw Material Management in Vaccine Production

Top-10 Global Biopharmaceutical Manufacturer Saves $10 Million at a Single Site with AI

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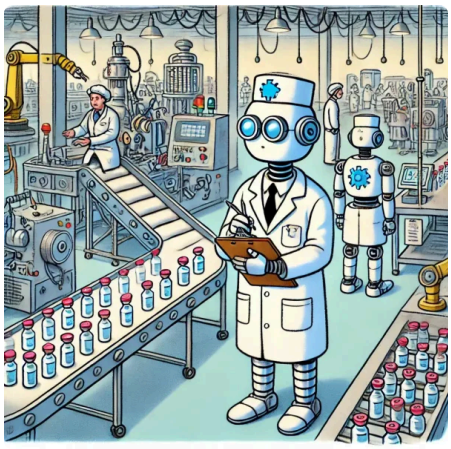

Abstract

This case study explores the collaboration between Katalyze AI and a top-10 global biopharmaceutical company to develop a state-of the-art AI-enabled analytics platform for their vaccine production. Using an AI-enabled platform, the project digitized raw material data, applied predictive analytics, and introduced real-time monitoring to improve process efficiency. The initiative has already increased production yield by 3-5% and is on track to save $10 million annually per site by reducing deviations and root-cause analysis time. This project demonstrated AI's transformative potential in biomanufacturing, providing a scalable solution for enhanced product quality and supply chain reliability.

The Importance of Scalable Vaccine Manufacturing

Vaccine manufacturing plays a critical role in global health by preventing infectious diseases and saving millions of lives. A historic example is the eradication of smallpox, which killed millions annually before the World Health

Organization launched a worldwide vaccination campaign, that culminated in the eradication of smallpox in 1980. However, developing a new vaccine is only the first step; the other challenge lies in scaling up production to meet global demand. Manufacturing vaccines requires precise control over inputs and processes, as it involves complex biochemical procedures that depend on living organisms, such as bacteria, viruses, or cells. This reliance on biological systems makes scaling particularly challenging, as these processes are highly sensitive to even minor changes in environmental conditions, raw material quality, or production parameters. Consequently, small disruptions in necessary raw materials or production processes can lead to significant delays and vaccine shortages. After discovery, efficient scaling becomes the critical bottleneck, determining how quickly life-saving doses reach the population.

The magnitude and seriousness of the COVID-19 pandemic exposed the need for more efficient and resilient vaccine manufacturing processes. The unprecedented surge in demand for the new COVID vaccines, coupled with global supply chain disruptions and limited manufacturing flexibility, exposed weaknesses in the industry's ability to rapidly scale production. A better response by the pharmaceutical industry could have saved many lives. Given the increasing frequency of global health crises and the interconnected nature of supply chains, such situations are likely to arise more often in the future. One solution is to apply AI to existing processes. This case study shows how this has been done through a collaboration between Katalyze and a top-10 global biopharmaceutical company. By implementing advanced AI-powered solutions, these partners aimed to streamline raw material management, improve product yield, and reduce manufacturing costs.

AI as the Next Step in the Evolution of Process Control

Advanced Process Control (APC) refers to a suite of techniques used to optimize industrial processes by continuously adjusting variables to enhance performance. Traditionally, APC focused on parameters such as temperature, pressure, and flow rate, and employed advanced techniques like Model Predictive Control (MPC) to identify key variables that maintain process stability. Despite the power of MPC, it still has limitations in the number of parameters that it can consider and optimize. However, AI allows the incorporation and prediction of an unprecedented number of parameters including raw materials, which were previously difficult to measure

and optimize in real-time. AI augments APC by using machine learning algorithms to model complex relationships, identify potential deviations, and make proactive adjustments—extending control capabilities to the earliest stages of manufacturing.

There are, however, further challenges. In highly regulated industries like pharmaceuticals, manufacturing processes must adhere to Good Manufacturing Practices (GMP) and meet stringent FDA regulations. These frameworks restrict modifications to core production processes, posing challenges for companies seeking to enhance efficiency. Luckily, these constraints apply less to the optimization of raw materials. As a result, raw material management provides a significant opportunity for biopharma companies to improve yield and consistency without compromising regulatory compliance. Focusing on raw material quality offers a pragmatic approach to achieving process improvements, as material inputs often have a direct and profound impact on the final product's performance.

Tackling the Raw Material Challenge

The biomanufacturing industry, and vaccine production in particular, rely heavily on multiple complex inputs, including raw materials such as sugars, amino acids, salts for cell culture, growth factors, and enzymes. These materials must meet stringent quality standards. In this case study, the biopharmaceutical company’s vaccine production site encountered frequent disruptions caused by inconsistent raw material attributes. Variability in materials such as amino acids and nitrogen sources affected the fermentation process, leading to process deviations, batch failures, reduced yields and production downtime. As this biopharmaceutical company struggled to maintain consistency, they approached Katalyze to leverage their expertise in AI and pharma manufacturing to develop a targeted solution.

An initial diagnostic revealed that several factors contributed to these production challenges. Raw material data was dispersed across multiple sources—supplier reports, internal test results, and Certificates of Analysis (CoAs). Much of this data existed in non-digital formats, limiting the manufacturer’s ability to conduct thorough and timely analyses. Unstructured data like this is often referred to as ‘dark data’ and is a perfect match for new AI technologies. Furthermore, raw material quality assessments were heavily reliant on manual processes, which

introduced risks of human error and inefficiency. These challenges culminated in unexpected batch failures, which not only increased production costs but also jeopardized the manufacturer’s ability to meet market demand from its downstream supply chain partners in a timely manner.

The consequences of raw material-related deviations extended beyond production inefficiencies. For a pharmaceutical leader like this manufacturer, the failure to deliver vaccines on schedule also had reputational implications. Moreover, batch failures resulted in significant financial losses, as scrapped batches could cost millions of dollars.

Implementing an AI-Driven Solution

Katalyze developed and deployed an advanced raw material management platform to adderss these issues. The solution involved several key steps.

First, Katalyze digitized raw material records, including Certificates of Analysis (CoAs) from suppliers, lab test results, and material specifications, by leveraging Optical Character Recognition (OCR) technology and a pharmaceutical fine-tuned Large Language Model (LLM). This approach standardized unstructured data from various sources such as PDFs, images, and Microsoft Office documents, enabling the seamless integration of previously siloed information into a centralized system. This transformation ensured the data was analytics-ready and accessible for advanced analysis and decision-making.

The primary challenge with the data was that most was stored in unstructured formats like PDFs, images, and Microsoft Office documents. Even after digitizing these records using OCR and fine-tuned LLMs, standardizing material attributes remained a significant hurdle due to inconsistencies in naming conventions, values, and test methods (e.g., "Fe III" vs. "Ferric Ion (Fe3+)" or "UV Spectrophotometry" vs. "UV-Vis"). Katalyze addressed this by holistically standardizing materials, considering not only attribute names but also their values, test methods, and specifications.

Secondly, Katalyze connected those data points with target process parameters such as optical density and yield. With a unified data infrastructure in place, Katalyze developed and validated traditional machine learning models, including

Random Forests, Decision Trees, and other ML techniques, to predict how specific raw material attributes would impact key process metrics.

The AI models were trained on historical data from production processes. These models provided insights into the relationship between raw material characteristics and process outcomes, enabling the manufacturer to identify which attributes were most important to test, and stopping suboptimal materials before they entered the production process (e.g., when certain raw material attributes fell outside the acceptable range established by the models). Additionally, the solution featured a user-friendly interface that allowed operators to access actionable insights through natural language queries, streamlining decision-making and minimizing response times.

With real-time monitoring capabilities in place, the manufacturer was able to detect deviations early and make immediate adjustments to process parameters. The predictive models also enabled the company to adjust raw material specifications dynamically, ensuring that only high-quality materials were used in production. This approach not only improved production consistency but also reduced the time required for root-cause analysis when deviations occurred.

Results and Impact of the AI-Driven Solution

The implementation of Katalyze's platform yielded significant benefits for the manufacturer. One of the most notable achievements was the improvement in production yield, which increased by an average of 3-5% per batch. This enhancement was directly attributed to better control over raw material attributes and the reduction of material-related deviations. Additionally, the manufacturer experienced a 20% reduction in the time required for root-cause analysis, as the AI-enabled platform provided operators with immediate insights into the causes of deviations by linking process data to raw material data.

From a financial perspective, the project is on track to deliver substantial cost savings. the manufacturer reported direct cost reductions of approximately $4 million per site, primarily through reduced testing and fewer scrapped batches. The improved production efficiency also generated an additional $6 million in capacity gains, as streamlined processes were able to meet market demand more reliably. In total, the initiative demonstrated potential annual savings of $10

million per site, underscoring the transformative impact of AI-driven raw material management.

Beyond the immediate financial benefits, the project also provided qualitative improvements. The increased visibility into raw material performance enabled the manufacturer to engage more effectively with suppliers, fostering better collaboration and alignment on material specifications. This transparency also benefited upstream partners, as suppliers gained insights into how their materials impacted downstream production outcomes. As a result, the project contributed to a more resilient and efficient supply chain, with reduced risks of material-related disruptions.

Scaling the Solution and Future Opportunities

Following the success of the pilot project at a site in Toronto , the manufacturer and Katalyze are exploring opportunities to expand the solution to additional production sites. The scalability of the platform makes it well-suited for broader adoption, and discussions are underway to integrate supplier data into the system for predictive procurement. This integration would allow the manufacturer to identify alternative suppliers proactively and mitigate risks associated with material shortages or quality issues.

Katalyze is also planning to extend its platform to adjacent industries, such as food and beverage manufacturing, where raw material quality plays a similarly critical role. The company aims to leverage the lessons learned from its collaboration with the manufacturer to drive innovation in other sectors, enhancing manufacturing processes through data-driven insights.

Conclusion: A Call to Action for the Pharmaceutical Industry

This collaboration demonstrates the transformative potential of AI-driven solutions in the pharmaceutical industry. By addressing the challenges of raw material variability and optimizing production processes, the project delivered both operational and financial benefits, setting a new standard for vaccine manufacturing.

This case study highlights the importance of leveraging advanced analytics to unlock the full potential of biomanufacturing operations. With AI-powered tools,

companies can improve yield, reduce costs, and enhance supply chain resilience, ultimately ensuring a more reliable supply of life-saving vaccines.

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About the Author

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Reza is serial entrepreneur and current CEO of Katalyze AI. With a background in engineering, AI and consulting, he is passionate about leveraging the potential of AI for high impact manufacturing industries such as biopharma.

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Reza Farahani is a business and artificial intelligence professional whose work focuses on translating advanced analytics and machine learning into measurable organizational value. His interests span data-driven decision-making, predictive modeling, and the responsible deployment of AI systems in operational and managerial contexts. He has contributed to applied projects that integrate statistical learning, data engineering, and stakeholder-centric design to support strategy, performance improvement, and process optimization. Farahani is also engaged with the professional community through his LinkedIn profile, where he shares experience and perspectives on emerging AI methods and their business implications. He can be reached at m.farahani.r@gmail.com, and additional professional background is available at https://www.linkedin.com/in/reza-farahani-/.

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