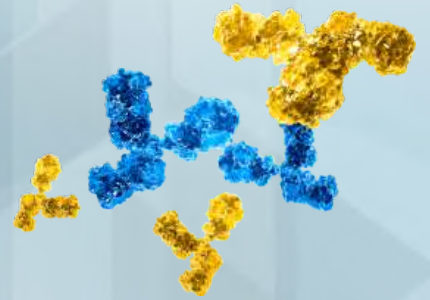


Transforming Biopharmaceutical Manufacturing with AI:

A Case Study on **ADMAlytics**

powered by  **tcgmcube**



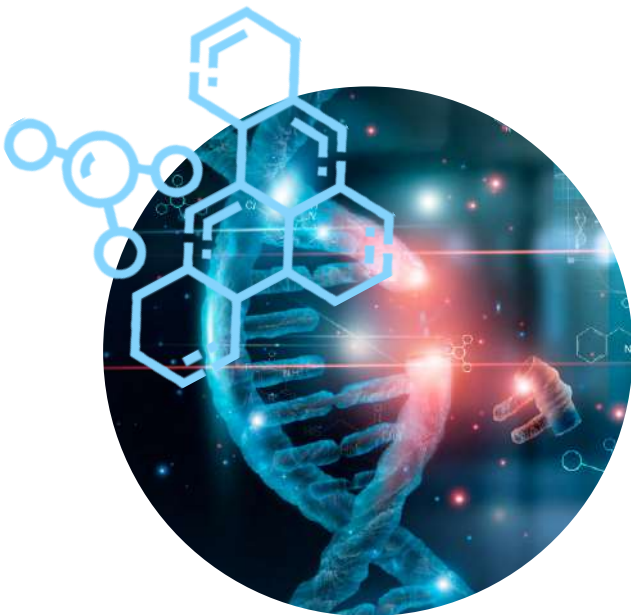
TCG DIGITAL



01

Abstract

This paper discusses the transformative impact of ADMAlytics, an AI-driven platform powered by tcgmcube, on the biopharmaceutical manufacturing processes at ADMA Biologics. It highlights the journey towards operational excellence through innovative implementations of an enterprise data lake with advanced analytics solutions, focusing on plasma pool efficiency and improvements, donor and plasma inventory management, yield prediction, manufacturing KPI monitoring, and application of Generative AI for enterprise search. The superior outcomes underscore significant advancements in production efficiency, data accessibility, and real-time decision-making processes.



02

Background

The necessity for innovation and efficiency in the biopharmaceutical industry is unprecedented, in light of unique challenges in manufacturing processes and regulatory demands. ADMA Biologics, in response, has partnered with TCG Digital to leverage the tcgmcube platform, aiming to revolutionize its manufacturing processes. This collaboration focuses on creating a data-driven decision-making ecosystem, addressing critical operational challenges, automating manual processes, and fostering a culture of continuous improvement and innovation.

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Methodology

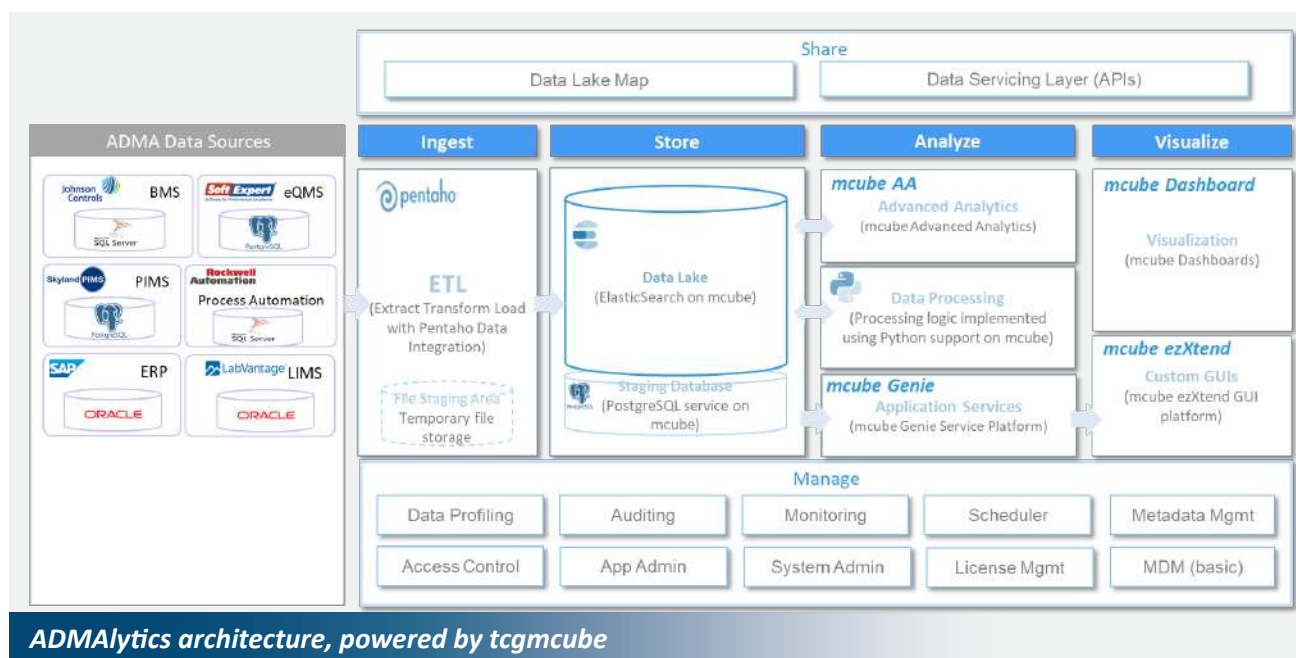
The methodology to build the enterprise data ecosystem involved conducting comprehensive workshops across various departments within ADMA Biologics to identify specific operational challenges and data management needs. These collaborative sessions aimed to pinpoint opportunities for process automation and optimization, laying the groundwork for the development and implementation of the ADMAlytics platform.

Key focus areas included:

- Selecting and optimizing plasma units for plasma pooling to ensure optimal batch yields can be achieved.
- Predicting production batch yield before the manufacturing process, to ensure consistent yields are produced.
- Managing donors and plasma inventory, facilitating the identification and classification of donors that are candidates for special donor programs.
- Monitoring production batch key performance indicators (KPIs) for monitoring and outlier detection.
- Leveraging generative AI to make enterprise search efficient and less time consuming by tracing back to the document from where the response was generated.

04 Architectural Overview

The foundation of ADMALytics' success is in the creation of an enterprise lake house, integrating data from diverse sources to support various business use cases. This strategic move has enabled quick access to data, cost reduction, quality improvement, increased profitability, scalability, elimination of data silos, and positive impact on innovation. To implement the AI program, a few critical components of tcgmcube were proposed as the ADMALytics stack as depicted in the diagram below. The proposed solution is based on four primary functional areas - Ingest, Storage, Analyze / Predict and Visualize. Each of these functional areas are designed as layers of the tcgmcube architecture and implemented based on the best-in-class, time tested open source technologies.



05

Solutions Deployed

■ 5.1 Plasma Pool Optimization:

ADMalytics revolutionizes plasma pooling, a critical step in their manufacturing process, utilizing mixed integer programming. This approach enables the optimization of plasma unit selection based on multiple criteria, including but not limited to age, titer, adherence to CFR, expiry, and volume, to ensure the creation of optimal plasma pools. The solution significantly reduces the manual efforts required for pool creation, enhancing both productivity and accuracy. Furthermore, it allows for real-time adjustments to pooling strategies based on dynamic inventory levels, ensuring that production can adapt swiftly to changes in demand or supply conditions.



Snapshot of the Plasma Pooling solution, built on the tcgmcube platform

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Implementing the plasma pooling process, which historically has been a very manual process, has immediately realized efficiencies for the supply chain functions at ADMA. These efficiencies include the reduction of FTE hours required to construct these pools, assurances that the most efficient mix of plasma is used for each product, and a standardization that could not be achieved through manual pool construction.

Robert Brooks
Director of Data Integrity and IT Operations, ADMA Biologics

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5.2 Transforming the plasma donor onboarding process

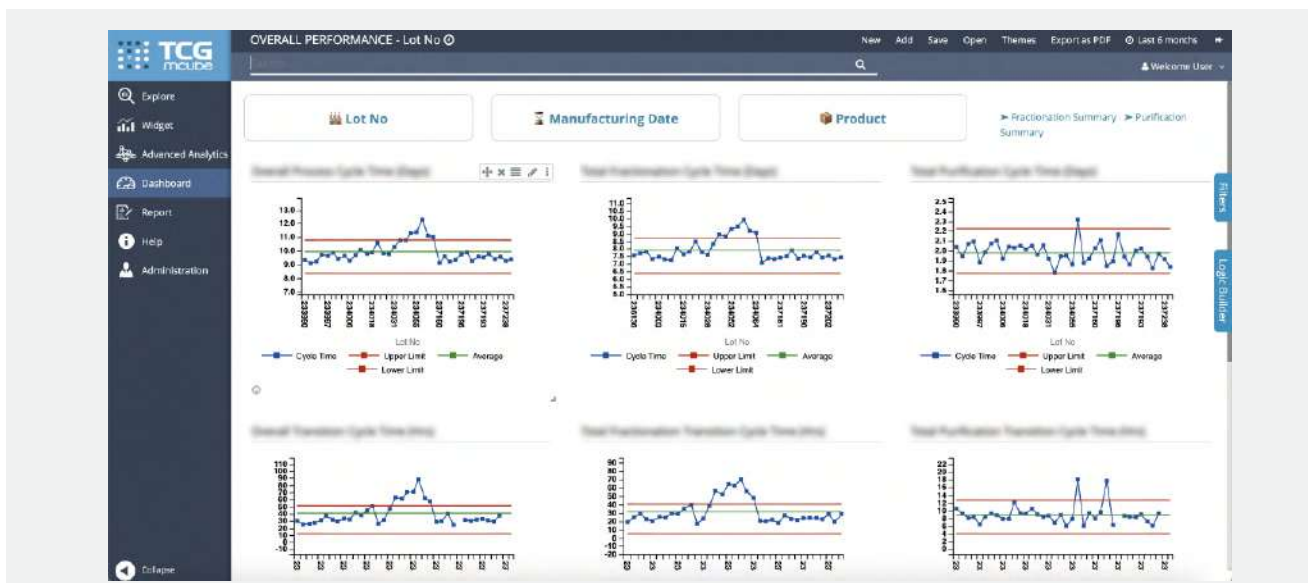
The solution is designed to streamline the process of integrating donors into various donor programs based on titer results. The system is carefully engineered to handle donor identification and selection, automate titer calculations using statistical algorithms, and manage donor drop notifications, all while maintaining an updated data lake to ensure the most plasma inventory is readily available for reporting.

By optimizing the donor onboarding process, ADMALytics is poised to not only improve the efficiency of plasma donation and inventory management but also eliminate the errors that occur during manual processes.

Robert Brooks
Director of Data Integrity and IT Operations, ADMA Biologics

5.3 KPI Monitoring and Outlier Detection

The platform features dynamic KPI dashboards that provide real-time visibility into KPIs across the manufacturing processes. This system employs advanced statistical algorithms for outlier detection, flagging deviations from expected performance ranges. This solution not only streamlines the operational process but also plays a crucial role in maintaining compliance with stringent regulatory standards, ensuring that every batch meets the highest quality criteria.



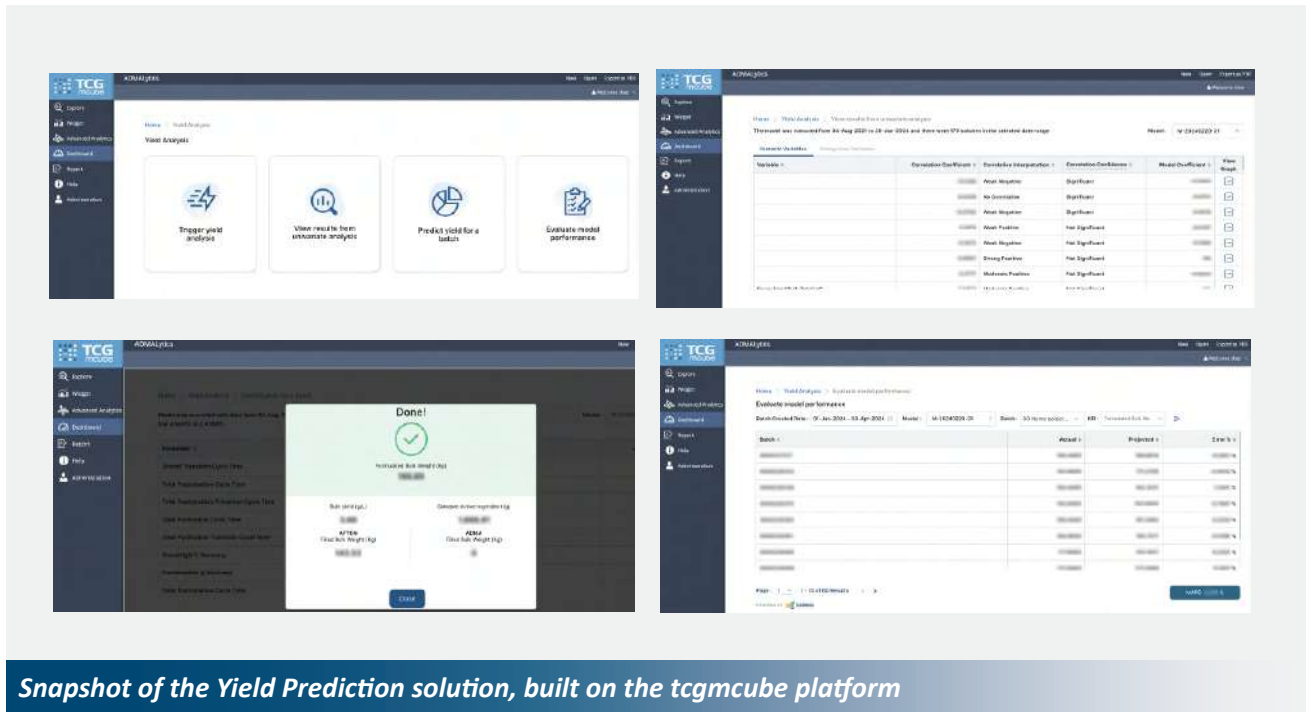
Snapshot of the KPI Dashboard solution, built on the tcgmcube platform

Implementing the business intelligence features built into ADMALytics has allowed decision makers at ADMA to have access, in one dashboard, to a wide range of KPIs to the manufacturing process, that previously was housed across different applications. Additionally, this data pipeline has reduced the manual effort previously required to create reports and charts used to identify trends in manufacturing.

Robert Brooks
Director of Data Integrity and IT Operations, ADMA Biologics

5.4 Batch Yield Prediction

ADMAlytics integrates advanced machine learning (ML) models to predict production batch yields with high accuracy, leveraging historical data and real-time process parameters. This predictive capability enables proactive adjustments in the manufacturing processes, thus optimizing yields and reducing waste. By accurately forecasting yields, ADMA can better plan for raw material procurement, schedule production runs and manage logistics, leading to improved operational efficiency and cost savings. This preemptive approach allows for informed decision-making and optimization strategies, driving improved batch profitability.



Snapshot of the Yield Prediction solution, built on the tcgmcube platform

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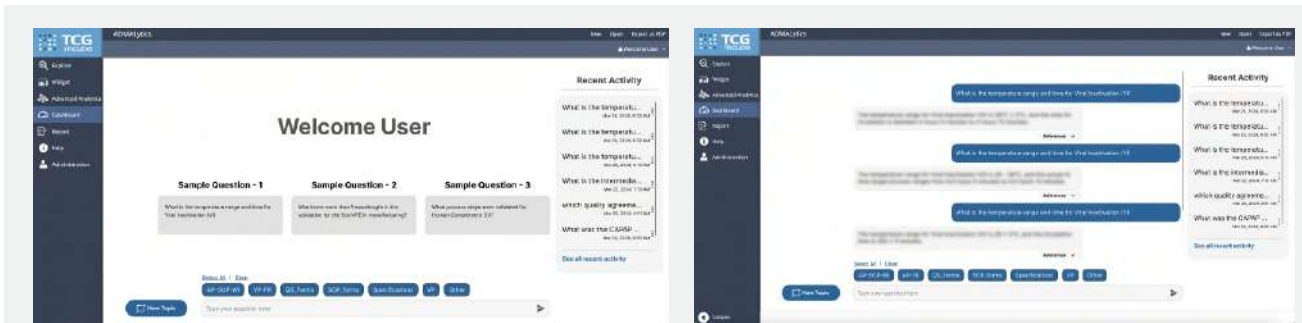
The batch yield prediction was the logical expansion of the plasma pooling tool, allowing ADMA to predict the yield of each pool proposed based upon the makeup of donors. This forecasting model provides ADMA the opportunity to plan for yields and downstream impacts to production, proactively.

Adam Grossman President and CEO, ADMA Biologics

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5.5 Generative AI for Enterprise Search

Employing generative AI technology, ADMAlytics transforms the enterprise search experience internally within ADMA Biologics. This solution leverages natural language processing (NLP) and ML to understand the context of search queries, delivering precise and relevant search results. By significantly reducing the time spent on information discovery, employees can focus on higher-value activities, fostering a more efficient and innovative organizational culture. Additionally, this technology facilitates improved knowledge sharing and collaboration, as it enables users to quickly find and reference critical information across the organization's vast data repositories.



Snapshot of the Generative AI chatbot solution, built on the tcgmcube platform

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While still in its early phases of adaptation, the generative AI chatbot replaces our traditional method of searching for documents with eQMS search bars and allows an interactive and natural language driven approach to finding information. We are excited to see how this shapes how our knowledge repository is leveraged and the speed at which information can be found using this new tool.

Robert Brooks
Director of Data Integrity and IT Operations, ADMA Biologics

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06 Conclusion

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ADMA Biologics' adoption of TCG Digital's tcgmcube AI platform marks a significant milestone in biopharmaceutical manufacturing by setting new standards for efficiency, productivity and innovation. ADMA's collaboration with TCG Digital underscores a commitment to leveraging cutting-edge technology to address complex operational challenges. This initiative has successfully addressed key challenges, including the integration of disparate data sources, breaking down organizational silos and scaling the data architecture for future growth. The value delivered by ADMAlytics exemplifies the potential of AI and advanced analytics in driving the next wave of innovation in biopharmaceutical manufacturing

Debdas Sen
CEO, TCG Digital

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References

<https://ir.admabiologics.com/news-releases/news-release-details/adma-biologics-successfully-implements-innovative-ai-program>

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Authors

Robert Brooks

Director of Data Integrity and IT Operations, ADMA Biologics

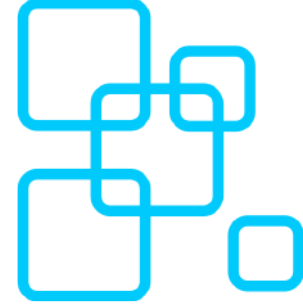
Soumyopriyo Saha

Senior Director, Lifescience - AI and Analytics, TCG Digital



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About ADMA Biologics



ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently manufactures and markets three United States Food and Drug Administration (FDA)-approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides blood plasma for the manufacture of its products. ADMA’s mission is to manufacture, market and develop specialty biologics, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency, or who may be immune compromised for other medical reasons. ADMA holds numerous U.S. and foreign patents related to and encompassing various aspects of its products and product candidates. For more information, please visit www.admabiologics.com.



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About TCG Digital



TCG Digital enables organizations to go digital by leveraging transformative technologies, advanced analytics, and operational expertise to accelerate value realization for our clients. They are the flagship technology consulting and solutions company of “The Chatterjee Group”, a multi-billion-dollar portfolio of corporations. This relationship empowers them with access to global talent, subject matter expertise, and an impressive array of over “1,000 digital minds”.

TCG Digital’s clients range from major global Pharmaceutical brands and large government entities to small and mid-sized companies with a recognizable roster of enterprise logos. They differentiate through deep systems and sectoral knowledge, acute agility, impeccable quality and ready to use products. For more information please visit www.tcgdigital.com

About tcgmcube

tcgmcube is highly scalable to serve growing volume and speed of data. It is cloud agnostic, which makes it deployable on any public platforms or on premises. It is highly extensible to address newer requirements which may arise in the future. This platform is distributed and can be scaled up horizontally by adding more components in clusters as required.



Capabilities of tcgmcube (A full stack distributed data management, BI & AI platform)

The primary features of tcgmcube are listed below:

- Scalable Data Lake technologies
- Designed for Polyglot Cloud
- Comprehensive Data Integration
- Robust AI/ML engine and libraries
- Low code AI workflow development
- Complete IoT integration
- Natural Language Processing
- Data Contextualization
- Data Quality Management
- Deep Learning including Computer Vision

Contact Information

ADMA Biologics Florida Campus

 5800 Park of Commerce Blvd
NW Boca Raton, FL 33487

 561-989-5800

 561-989-5801

TCG DIGITAL SOLUTIONS LLC

 265 Davidson Ave, Suite 220
Somerset, New Jersey 08873

 732-515-7376

 contact@tcgdigital.com