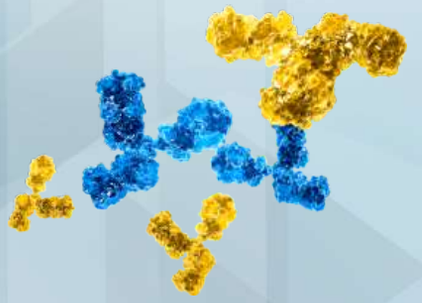
Optimizing Biopharmaceutical Manufacturing with AI:

A Case Study on **ADMAlytics™**

powered by mcube™ by tcgdigital



ADMA BIOLOGICS

tcgdigital

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 engaged 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.

03
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 manufacturing to ensure optimal batch yields.
- Optimizing ADMA proprietary hyperimmune donors and inventory management programs, facilitating the identification and classification of donors that are candidates for specialty programs.
- Monitoring real-time production batch key performance indicators (KPIs) for monitoring and outlier detection.
- Leveraging generative AI to enhance document reconciliation to allow for enterprise search efficiencies for previously created reports and data, while maintaining traceability to document sources.

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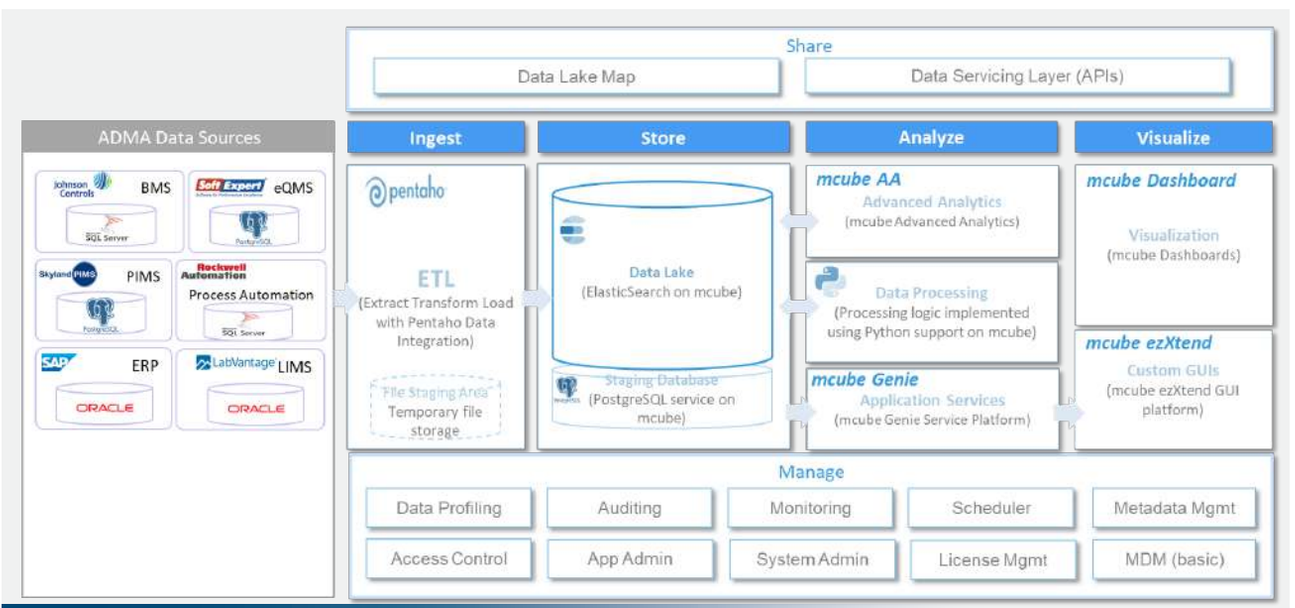
Architectural Overview

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.



ADMAlytics™ architecture, powered by tcgmcube™

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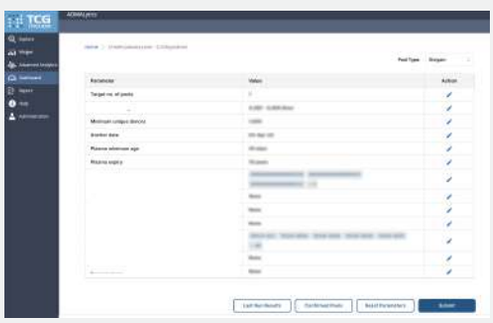
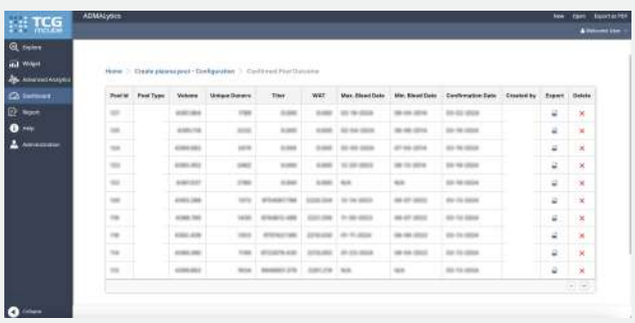
Solutions Deployed

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

> *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***

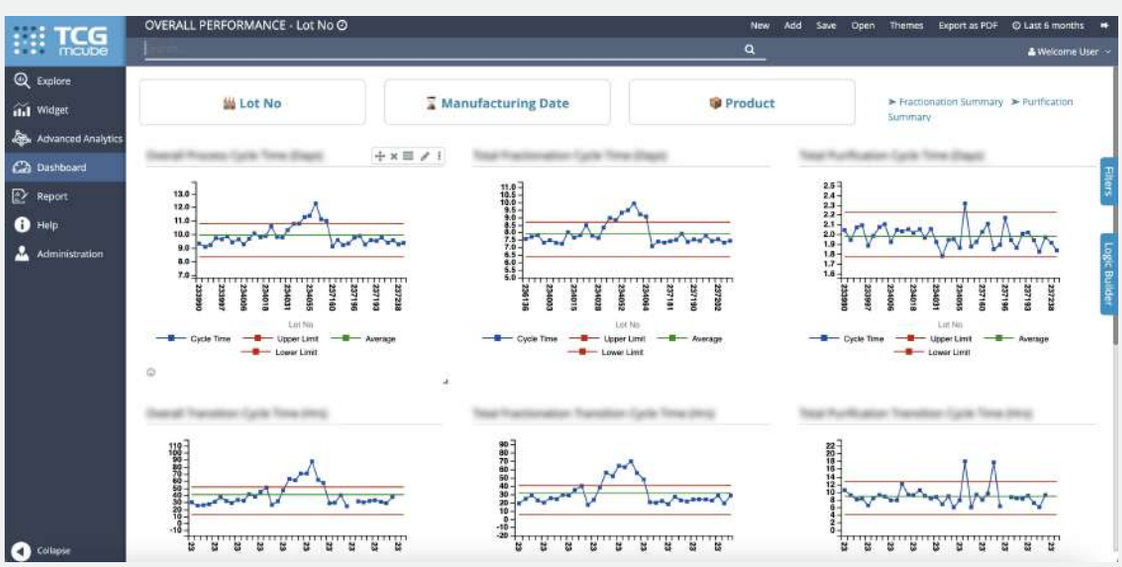
5.2 Transforming the plasma donor onboarding process

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 ensuring precision and accuracy through a validated process.*
>
> ***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.

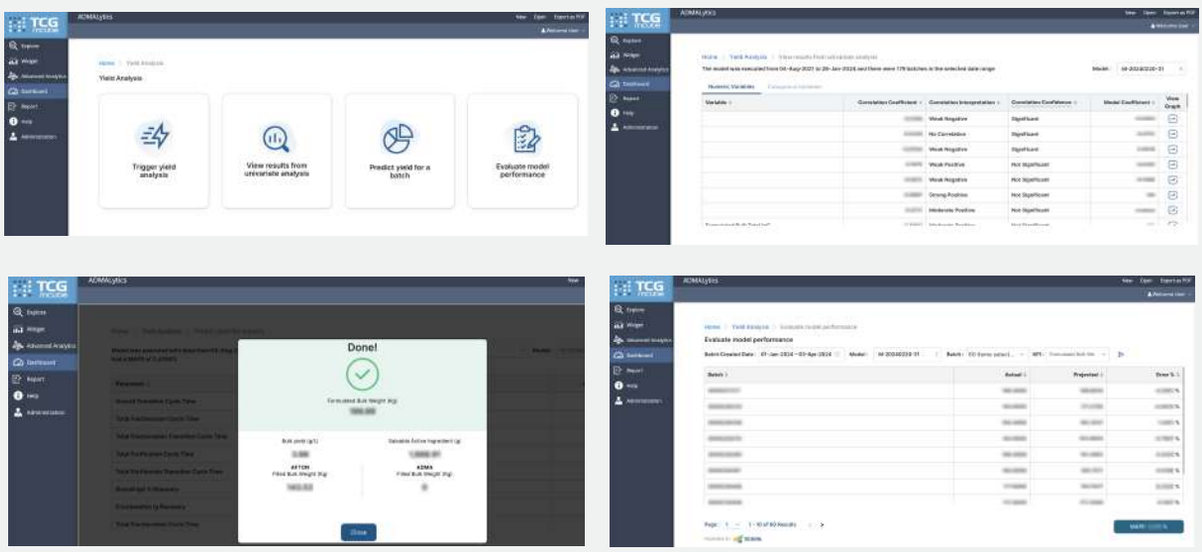


Snapshot of the KPI Dashboard solution, built on the tcgmcube™ platform (for illustrative purposes only)

> *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 accurately, leveraging historical data and real-time process parameters. This predictive capability enables adjustments for future production batches, thus optimizing yields and reducing waste. By leveraging advanced machine learning models to forecast yields, ADMA can better plan for raw material procurement, schedule production runs and manage logistics, leading to improved operational efficiency and cost savings. This approach allows for informed decision-making and optimization strategies, driving improved batch margins.

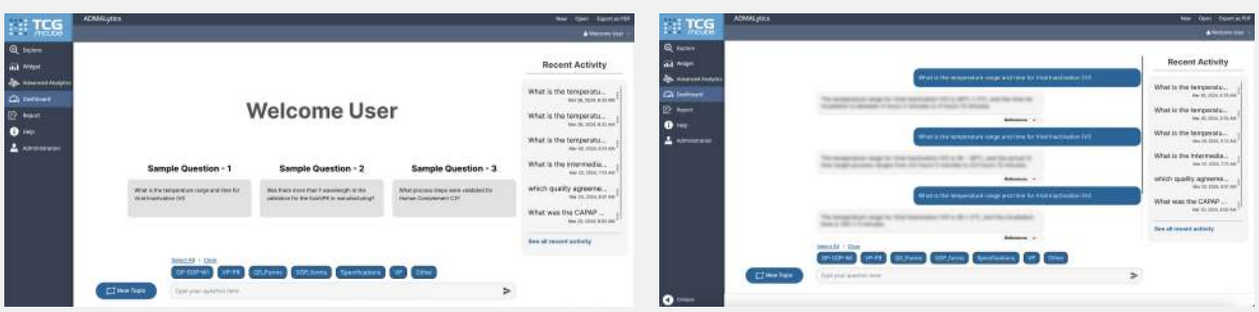


Snapshot of the Yield Prediction solution, built on the tcgmcube™ platform

> *Enhancing visibility over the 7-12 month plasma product manufacturing process is key for the continued growth of our product portfolio. Being able to have Generative AI predictors provides ADMA the opportunity to plan for forward looking commercial enhancements, proactively.*
>
> ***Adam Grossman President and CEO, ADMA Biologics***

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

> *The generative AI chatbot replaces our manual method of searching in documents for information using traditional 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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Conclusion

> *ADMA's collaboration with TCG Digital underscores a commitment to leveraging cutting-edge technology to address complex operational challenges. ADMA Biologics' adoption of TCG Digital's tcgmcube™ AI platform marks an important milestone in biopharmaceutical manufacturing by setting new standards for efficiency, productivity and innovation. 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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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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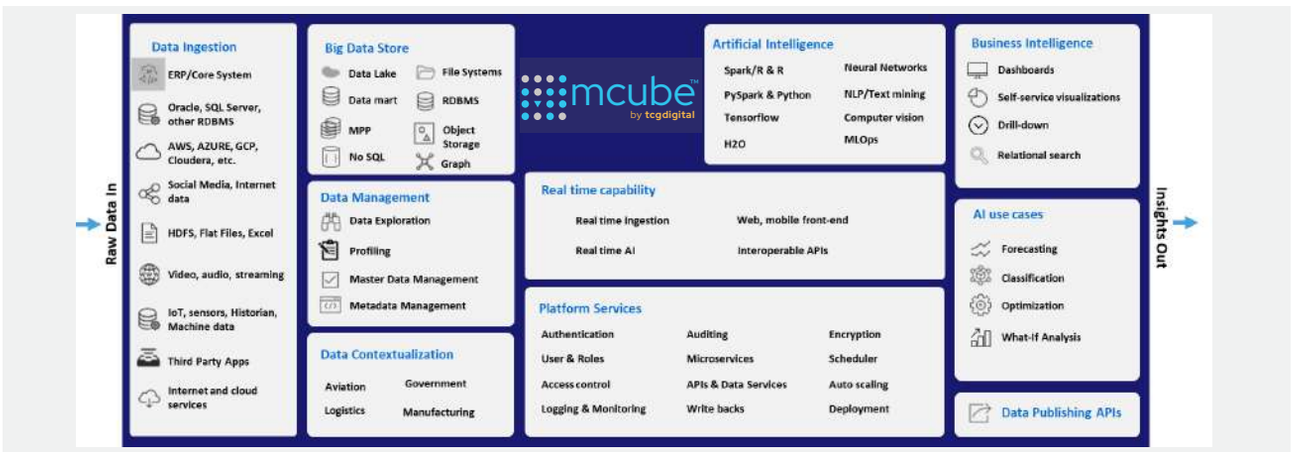
About TCG Digital

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

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