tcgdigital

mcube™ by tcgdigital

Transforming Bioanalytics for Maximum ROI

A Global BiotechCompany's Successful AI-Driven Journey with **TCG Digital**

About an International Biotech Company and its Goals

A leading international biotechnology company, dedicated to developing innovative antibody therapeutics for the treatment of cancer and other serious diseases, sought to streamline its operations and accelerate the delivery of new therapies by digitizing and integrating workflows. This approach aimed to increase efficiency, accuracy, and speed in assay and method validation processes—ultimately supporting its goal of bringing life-saving treatments to patients, faster.

The company's bioanalytics processes, which are critical to its drug development lifecycle, previously consisted of manual workflows involving data transfers between systems. Recognizing the opportunity to transform these processes to save time and avoid errors, the company integrated AI to enhance efficiency, improve accuracy, and accelerate validation. This positioned the company to bring therapies to market more swiftly, reinforcing its commitment to innovation and excellence in drug development.

Creating an **integrated analytics workflow** for the Biotech Company on mcube™

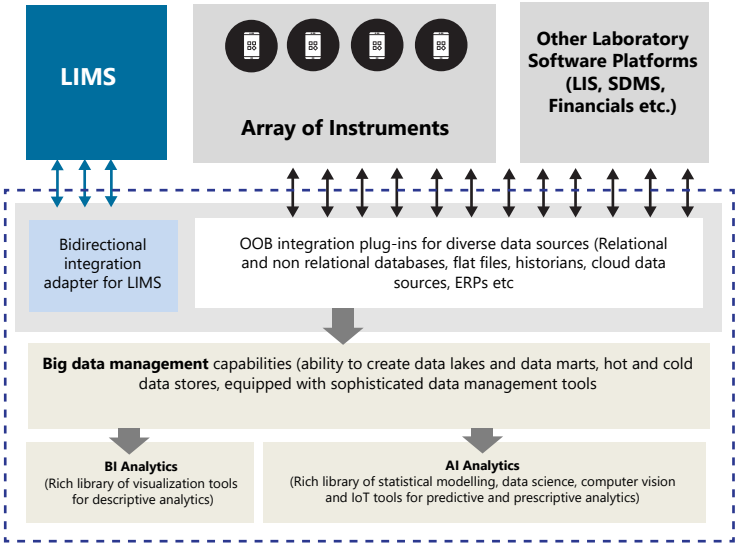
Our integrated assay analytics solutions, built on the mcube™ platform, provide the company with a seamless and efficient workflow for bioanalytics. The mcube™ platform integrates directly with Laboratory Information Management Systems (LIMS), allowing data to be automatically written back to the LIMS after analysis. This integration minimizes the risk of data manipulation and ensures a transparent audit trail, which is critical for maintaining compliance with regulatory standards. The platform supports a wide range of assay analytics, including pharmacokinetic (PK) and anti-drug antibody (ADA) assays, and offers robust features for method validation and reporting.

Scope and Implementation: The collaboration with the company began with the implementation of PK assay analytics, subsequently expanding to include ADA assay and method validation processes. One of the critical aspects of this implementation was ensuring compliance with the new ICH M10 guidelines. Our team of subject matter experts worked closely with the company's bioanalytics scientists to design a customized solution that integrated seamlessly with their existing workflows. By automating data analysis and reporting processes, we have significantly reduced the manual effort required, improved data accuracy, and ensured compliance with FDA and ICH regulations.

Why **mcube™**?

The global biotech company chose mcube™ for its:

- Comprehensive integration capabilities and adherence to regulatory standards. The platform's ability to integrate directly with LIMS systems means that users can conduct their analyses without leaving the LIMS environment, thereby eliminating the risk of data manipulation and maintaining a transparent audit trail.
- Additionally, mcube™'s modular design within the LIMS, along with its APIs and connectors to other LIMS systems, ensures flexibility and scalability.
- Our extensive knowledge of compliance regulations, such as ICH M10 and CFR Part 11, allowed us to design a solution that not only meets but exceeds industry standards, ultimately saving time and resources in the assay workflow.
- This unified platform streamlines the entire assay analysis workflow, saving significant labor hours and reducing costs associated with errors and rework.



PK Assay Analysis

Pharmacokinetic (PK) assays are crucial in drug development as they measure how a drug is absorbed, distributed, metabolized, and excreted in the body. These assays provide essential data to understand a drug's pharmacokinetic profile, guiding dosage.

PK Assay Analytics built on mcube™: The mcube™ platform offers a robust solution for PK assay analytics, integrating seamlessly with existing LIMS.

Key Functionalities:

- Generating best-fit calibration curves using known analyte concentrations, applying various curve-fit- ting models (both linear and non-linear), specifying weights and standards, and building scenarios
- The platform supports selecting and deselecting standards for curve fitting and applying different method specifications.
- The streamlined workflow involves pulling raw assay data from LIMS, performing advanced analytics and processing within mcube™ , and writing the analyzed data back to LIMS, ensuring a continuous and efficient data management cycle.
- This integration eliminates manual steps, reduces errors, and speeds up the analysis process, ultimately driving operational efficiencies and reducing costs.

Results: *The seamless integration of mcube™ with the company's LIMS systems has driven operational efficiencies, reducing manual intervention and associated errors. Easy access to a library of algorithms for PK analysis has expedited timelines and reduced costs, aligning with the company's goal of streamlining operations to bring therapies to market faster.*

ADA Assay Analysis

Anti-drug antibody (ADA) assays are pivotal in immunogenicity testing, measuring the immune response generated against therapeutic proteins. These assays are essential in determining the safety and efficacy of biologic drugs by identifying any adverse immune reactions that could compromise treatment.

ADA Assay Analytics built on mcube™: The mcube™ platform offers a comprehensive solution for ADA assay analytics, seamlessly integrating with the company's LIMS.

Key functionalities include:

- Supporting the complete workflow configuration for screening, confirmatory, titer, and neutralization tiers.
- The platform applies sample acceptance criteria to generate sample status (Pass/Fail), applies cut points from method validation on passed samples to generate results (Positive/Negative), computes final results based on sample status and immunogenicity, computes titer values, and applies plate acceptance criteria to generate plate status (Pass/Fail).
- Reviewers have options to accept or reject the overall analysis for a tier.
- The computed analysis, including sample and plate statuses, titer values, and immunogenicity results, is written back to LIMS, ensuring a streamlined and efficient workflow.
- This integration reduces manual effort, minimizes errors, and accelerates the analysis process, ultimately enhancing compliance with regulatory standards and operational efficiency.

Results: *Implementing mcube™'s ADA assay analytics solution has resulted in improved manpower efficiency, reduced rework costs, and enhanced compliance.*

Method Validation

For the company, we implemented a comprehensive method validation solution on the mcube™ platform to streamline and enhance their bioanalytics processes. This initiative was crucial to ensure the accuracy, precision, and reliability of their assay results, which are fundamental for regulatory compliance and drug development. By integrating method validation directly with the company's LIMS, we aimed to reduce manual effort, minimize errors, and expedite the validation process.

Key Differentiators: The mcube™ method validation solution stands out due to its extensive configurability and integration capabilities.

- It supports both qualitative and quantitative assays, offering a wide range of experiment types such as accuracy, precision, dilution linearity, dilution integrity, selectivity, sensitivity, specificity, robustness, and stability.
- Additionally, the platform allows for configuring cut point computations for ADA assays, including screening, confirmatory, titer, and neutralization.
- Its role-based access control ensures data security and compliance, while the easy configuration of reports facilitates seamless data interpretation and decision-making.

Results and Impact: *The implementation of mcube™'s method validation solution has significantly enhanced operational efficiency. By automating the validation process and integrating it with LIMS, achieved increased efficiency, reduced rework, and improved compliance with regulatory standards. The seamless integration and user-friendly features of mcube™ have positioned to better meet stringent regulatory requirements while accelerating their drug development pipeline.*

ICH M10 Compliant Reporting Solution

Being compliant with ICH M10 guidelines is critical for pharmaceutical companies to ensure the accuracy, reliability, and consistency of bioanalytical data. Non-compliance can result in significant financial penalties, delays in drug approval, and potential market losses. Companies that fail to meet these stringent guidelines risk fines that can run into millions of dollars, along with the reputational damage that can further impact their market position.

Ensuring compliance with regulatory standards like ICH M10 is crucial to avoid hefty fines and operational disruptions. The mcube™ solution significantly mitigates these risks (mentioned below) by providing automated, compliant processes.

Features of ICH M10 Reporting on mcube™:

The mcube™ platform enabled the company to achieve robust ICH M10 compliance through a comprehensive reporting solution. It enabled the creation of 16 detailed reports, including 12 derived from calibration curves, ensuring thorough and accurate data analysis.

- The solution provides easy access to reports from a centralized landing page, offering user-specified parameter-driven dynamic reports, and over 20 out-of-box report types.
- Additionally, the ability to configure new reports through an intuitive interface and the inclusion of both tabular and graphical report formats greatly enhanced usability and compliance

Designing the Reporting Architecture: The reporting architecture was meticulously designed based on ICH M10 guidelines and the company's Standard Operating Procedures (SOPs). This ensured that all critical elements were mapped accurately, facilitating compliance and operational efficiency.

By leveraging mcube™'s capabilities, we enabled seam-less integration with LIMS, automated report generation, and ensured role-based access control for secure and compliant data handling.

Results: The result led to improved efficiency, reduced rework, and enhanced compliance.

By implementing these features, mcube™ helped the company streamline their reporting processes, ensuring they remain compliant with regulatory standards and enhance their overall operational efficiency.

Conclusion

By implementing mcube™, the international biotech company not only streamlined its bioanalytical workflows but also realized substantial financial benefits through increased efficiency, reduced errors, and enhanced compliance.

Get in touch with us at **contact@tcgdigital.com** for a robust digital strategy and powerful demonstration of this easily deployable platform.

About TCG Digital

TCG Digital is the digital & AI arm of The Chatterjee Group (TCG), a multi-billion dollar conglomerate with a diverse portfolio in Aviation, Pharmaceuticals, Biotech, Petrochemicals, and Real Estate across the US, EU, and South Asia. Our umbrella includes companies such as LabVantage, Lummus Technology, and TCG LifeSciences. At TCG Digital, we are driven by our mantra of delivering "Velocity to Value", helping enterprises transform faster and smarter. Our AI Analytics platform mcube™ is at the heart of these transformations. We enable organizations unlock the full potential of their data, and by seamlessly integrating AI/ML capabilities into their business processes, we empower businesses to accelerate their digital transformation journey, enhancing agility and driving impactful results.

For more information please visit our website at **www.tcgdigital.com**

tcgdigital