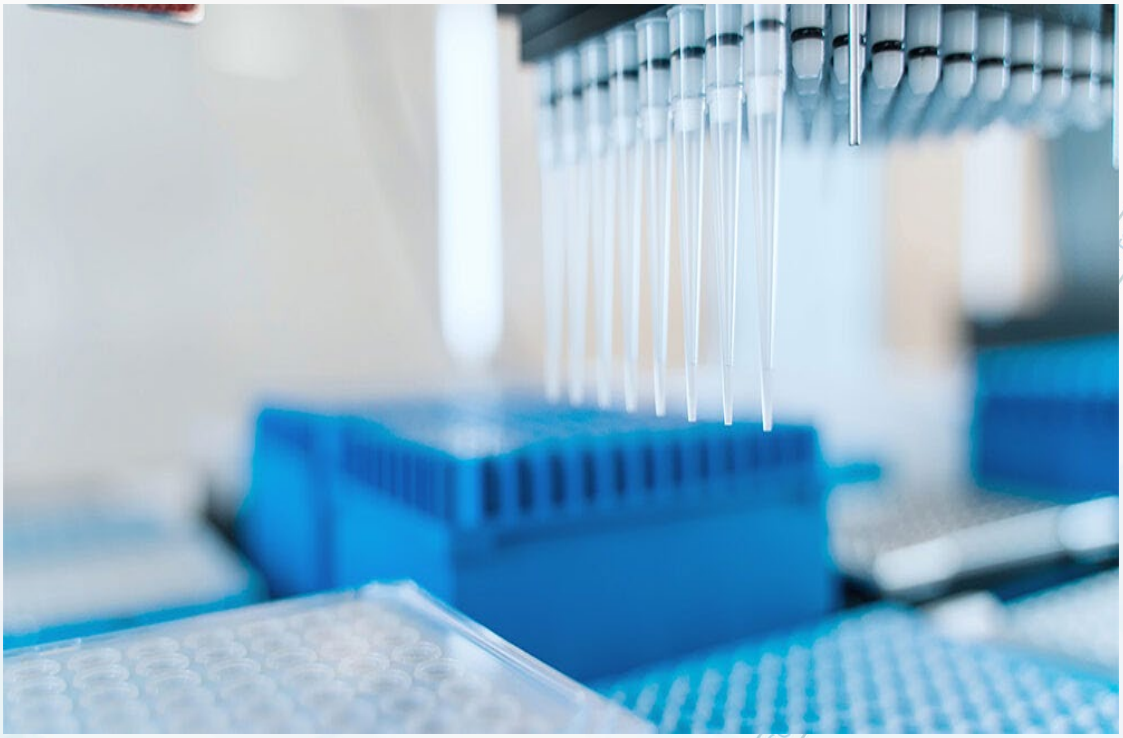

Automating ADME Operations at TCG Lifesciences

Compound Management, bio-inventory Management, and Electronic Laboratory Notebooks

Executive Summary

Automation is central to achieving error-free, high-throughput delivery in modern drug discovery. TCG Lifesciences (TCGLS) has implemented multiple layers of automation across ADME operations to support the end-to-end drug discovery process. These include in-house software solutions for compound handling, inventory management of biological consumables, and electronic laboratory notebooks (eLNBs).

Together, these integrated systems enable superior process flow with enhanced traceability, real-time documentation, accuracy, transparency and accountability. By reducing manual intervention and adopting end-to-end automation, TCGLS has improved operational efficiency, strengthened compliance, and enhanced overall client satisfaction.

Introduction

ADME studies play a critical role in early decision-making and regulatory submissions during drug discovery. These studies typically involve the handling of large numbers of chemical compounds alongside the management of a diverse range of biological materials required for multiple experimental workflows within a laboratory setting.

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Compound management is a core component of DMPK operations and is typically supported by a dedicated team responsible for the systematic handling of compounds across multiple projects. Activities span the full compound lifecycle, including storage, tracking, dispensing, retrieval, and disposal. In parallel, bio-inventory management represents a specialised form of inventory control focused on biological materials such as cell lines, liver microsomes, hepatocytes, plasma, cytosol, recombinant enzymes, and other biological matrices used in DMPK studies. Key aspects include lifecycle management, tracking of storage locations (freezers, shelves, boxes), monitoring of expiry dates, and maintaining comprehensive audit trails to meet regulatory and quality requirements.

Manual processes in these areas increase the risk of data inconsistency, transcription errors, incomplete audit trails, compromised sample integrity, and delays in study reporting. Increasing regulatory expectations, along with the demand for robust traceability and reproducibility, have driven the adoption of automation. Within this context, the electronic laboratory notebook (eLNB) has emerged as a critical advancement, replacing paper-based documentation with structured digital records of experimental procedures, observations, and results.

TCGLS has developed an integrated automation framework that connects compound management, bio-inventory management, and eLNB systems. This unified approach ensures consistent execution, traceability, and transparency across ADME studies conducted for multiple clients.

In drug discovery environments managing multiple global projects, manual compound handling and biological material management are inherently complex, time-consuming, and error-prone—particularly when dealing with temperature-sensitive and high-value materials.

Challenges of Manual ADME Operations:

1. Compound Handling Challenges

Manual compound handling presents several risks and limitations:

- Increased complexity due to multiple projects and multiple clients
- Risk of cross-contamination or compound mismatches
- Requirement for project-specific storage locations and accurate tracking
- Stringent storage requirements due to temperature sensitivity
- Periodic and compliant disposal of compounds

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Consumables and Biological Materials Management

Managing biological consumables manually is challenging due to:

- Handling of diverse biological materials, including liver microsomes, hepatocytes, plasma, S9 fractions, cytosol, recombinant CYP450 enzymes, vesicles, and cell lines across multiple species
- Storage across multiple temperature-controlled environments, including −170°C (liquid nitrogen), −80°C, −20°C, 4°C, and 0°C
- Need for unique identification using catalogue and lot numbers
- Dependence of experimental accuracy on product specifications such as protein concentration, CYP450 content, and enzyme activity
- Cumbersome manual record keeping and retrieval

2. Laboratory Notebook Limitations

Manual laboratory documentation introduces additional inefficiencies:

- Difficulty in segregating records for multiple assays and clients running in parallel
- Delays in assay status tracking and responding to client queries
- Labour-intensive inclusion of instrument-generated data into hard-copy records
- Increased paper usage and long-term storage requirements

TCGLS' Automation Framework for ADME Operations

To address these challenges, TCGLS has adopted a set of integrated automation solutions that reduce manual intervention, improve accuracy, and enable real-time project tracking across ADME operations.

1. Automated Compound Handling: BioCMPM Software

TCGLS utilises an in-house developed BioCMPM application to enable accurate, project-specific compound tracking. All compound-containing tubes, vials, and plates are labelled with barcodes to ensure precise identification and full traceability throughout the compound lifecycle. The application supports compound storage under defined conditions, including nitrogen desiccators, room temperature, 0°C, 4°C, −20°C, and −80°C. Dedicated, project-specific storage positions are maintained for both solid compounds and stock solutions, ensuring controlled access and minimising the risk of mix-ups.

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Figure 1. Compound Handling Workflow Automation

2. Automated Consumables Management: BIO-Inventory Software

The BIO-Inventory application captures catalogue and lot numbers for all biological materials procured, stored, and utilised across projects. Certificates of Analysis (COAs) are available for every item, with historical COA records securely archived for reference. The system tracks storage locations, batch details, and reorder levels, ensuring biological materials are maintained under specified conditions, including cryocans and freezers at −80°C, −20°C, 0°C, and 4°C. This automated approach minimises manual handling, reduces errors, and prevents sample misplacement or the inadvertent use of incorrect catalogue or lot numbers.

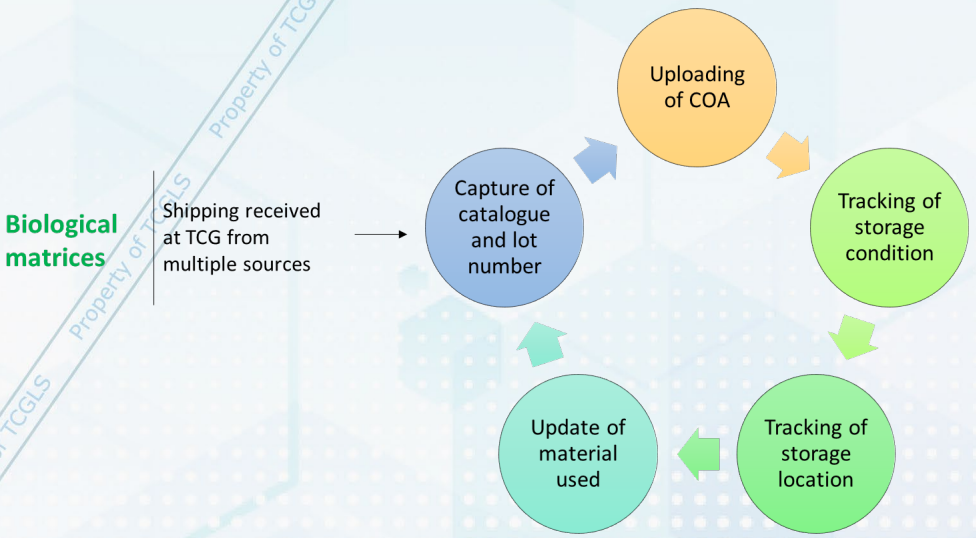

Figure 2. Bio-Inventory Management Workflow Automation

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Integrated Electronic Laboratory Notebook (eLNB)

The integrated eLNB system enables real-time project tracking across assay execution, bioanalysis, data analysis, review, and approval. It provides instant access to historical studies and associated study protocols, supporting consistency and continuity across projects.

Automatic data capture from analytical instruments improves data accuracy and eliminates manual transcription errors. Controlled sponsor access supports real-time monitoring, transparency, and efficient communication.

Figure 3. eLNB Management Workflow Automation

Advantages of ADME Automation

The integrated automation framework ensures process integrity and traceability across every stage of the DMPK workflow.

Key benefits include:

- **Accuracy and data quality:** Reduced manual errors and operational bottlenecks, leading to improved accuracy and reproducibility
- **Efficiency and timelines:** Streamlined inventory management and documentation result in faster study execution and reduced turnaround times
- **Client outcomes:** Transparent reporting and high-quality ADME data support increased client trust and long-term collaboration
- **Sustainability:** Reduced paper usage contributes to a lower environmental footprint

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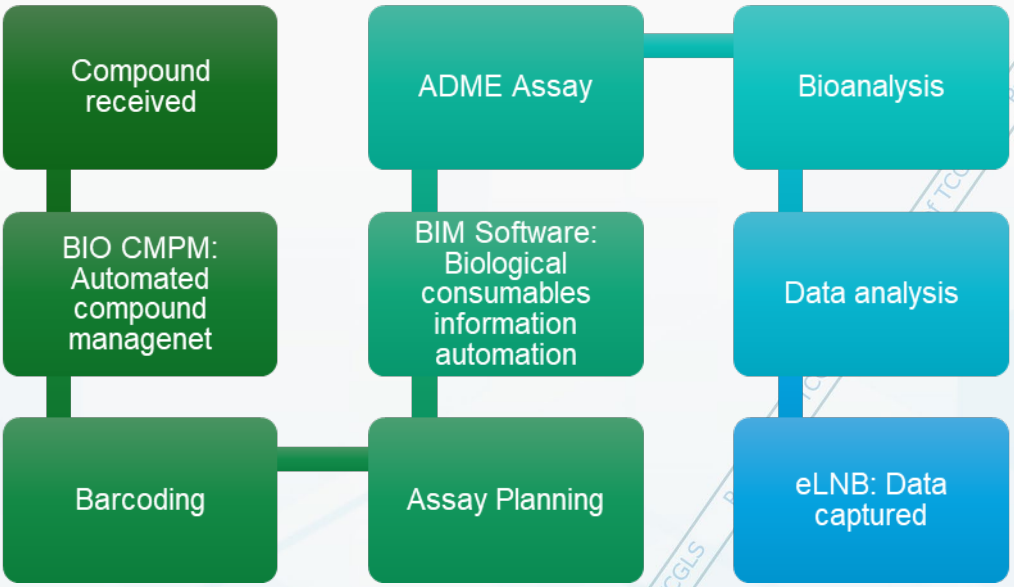

Figure 4. DMPK Workflow Automation

Conclusion

Scalable and interconnected workflows are most effectively managed through automation. The integrated systems implemented at TCGLS provide user-friendly interfaces to manage records, store and retrieve data, capture study details, embed raw data, and archive documentation securely.

Together, automated compound management, consumables management, and eLNB integration contribute to improved governance, higher operational efficiency, and enhanced delivery of ADME services. These capabilities support TCGLS' commitment to accuracy, compliance, and reliable execution across drug discovery programmes.

Property of TCGLS