IDBS Polar

Transforming your Bioanalytical Operations

IDBS Polar BioAnalysis could cut your bioanalytical study time by over 55%

Is a lack of insight slowing you down?

Many bioanalytical labs work with a crowded and siloed set of systems and processes. From part electronic to part paper-based workflows, to standalone point-solutions, the result is a lack of insight into data and impediments to reporting and results handling.

So, how you can go beyond 'automating the past' and truly transform your bioanalytical operations? This desired state supports regulatory and operational considerations, and carries high-quality data forward for insight and reporting. That data becomes contextualized within the development lifecycle. And that is just the beginning of how Polar BioAnalysis can drive the success of your lab.

Bioanalysis, the detection and quantitative measurement of drug products in biological samples, is a critical part of biopharmaceutical drug development. It arguably plays the most definitive role in tying therapeutic outcomes to the presence of pharmacologically relevant drug levels in the target biological system – starting with animal models and followed by humans.

The focus of bioanalysis in the pharmaceutical industry is to provide a quantitative measure of the drug and/or its metabolite(s) for the purpose of pharmacokinetics, toxicokinetics, bioequivalence and exposure. Results of such studies are pivotal components of regulatory submissions that tie the drug to a specified therapeutic indication.

As such, the success of the clinical development is heavily dependent on meticulous recordkeeping and reconciliation of the patient response/outcome with the bioanalytical data generated in the lab.

As a vital component of preclinical and clinical drug development, bioanalytical groups are grappling with the pressure to improve efficiency while maintaining accuracy and reproducibility with the regulatory constraints of a compliant environment.

The diverse nature of the individual steps in a given bioanalytical workflow requires a high level of accountability and traceability. As a result, and because they are typically paper based, there are multiple redundant processes that ensure compliance to the study protocol. This level of quality assurance (QA) places a significant burden on an operation and directly impacts the study turn-around time.

While advances in detection techniques and instrumentation have vastly improved sample throughput, there is room for improvement when it comes to the myriad processes that drive sample analysis. This combination of controlled, compliant workflow execution and dramatically streamlined data acquisition is the next phase of innovation within bioanalysis.

The limitations of traditional approaches to lab informatics

Advanced instrumentation and laboratory information management systems (LIMS) have boosted productivity, throughput, and scientific accuracy in bioanalytical laboratories. However, some bioanalytical labs have determined that this level of improvement does not scale without a comprehensive data management strategy.

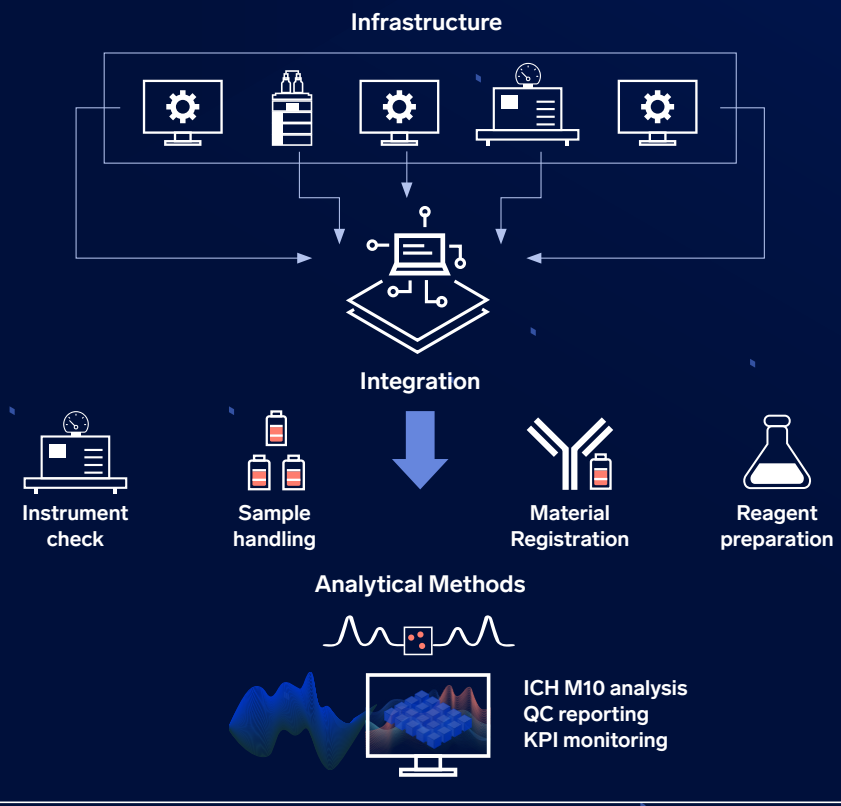
Despite the known benefits of improved analytical instrumentation and sample-based informatics solutions (such as LIMS), the graphic below, showing the evolution of the bioanalytical laboratory throughput, suggests that an order of improvement in productivity is only realized by implementing a workflow management layer that is laser-focused on improving compliance. The transition from "train travel" to "space travel," metaphorically speaking, can only occur if sample testing is tied to quality process improvement.

Historically, labs have adopted a strategy that involves multiple systems that individually contribute to aspects of improving the bioanalytical operation. The end result of this strategy is a collection of software applications that need to be individually validated, managed and optimized.

The complexity of systems for defining, testing, analyzing and reporting on sample analysis runs makes bioanalysis a prime candidate for advanced data management and automation of common workflows and reports. Both biopharmaceutical companies and contract research organizations (CROs) require a solution that brings significant efficiency improvements, integrates with other lab informatics and can cope with the specific needs of the broad range of studies performed.

Further, the optimum system must provide an initial layer of quality control (QC) checks that address deviations at the time of execution, and not simply flag them for resolution after study completion. This paradigm, of 'Audit by Exception' has the potential to revolutionize the testing industry.

Digital transformation with Polar BioAnalysis



The power of the platform

Polar BioAnalysis provides a study management and method execution platform that combines electronic data capture with structured workflows that drive standard bioanalytical processes.

These workflows are configured for study definition, sample preparation, data acquisition and analysis, and workflow auditing. Based on best practices defined with the world's leading pharmaceutical, biotech and CROs, Polar BioAnalysis delivers a pre-configured solution specifically developed for both small and large molecule methods. These workflows are deployed within bioanalytical labs at biopharmaceutical companies and CROs across the globe.

Polar BioAnalysis offers powerful material creation, registration and tracking capabilities that are embedded within standard bioanalytical workflow. Data is entered once, and is automatically presented when needed. For example, correction factors for reference standards are made available during the solution preparation step or specific lot numbers resurfaced for assay compatibility. Calibrators and QC samples can be created using built-in templates and referenced within a 'run experiment.' And finally, utilization of a reagent (buffer, stock solution, etc.) or a piece of equipment (pipette, balance or plate reader) can be investigated across all runs in a matter of seconds. Imagine how long it would take you to determine the impact of a suspect reagent or un-qualified instrument during an audit.

Business rules govern all key aspects of the workflow, from ensuring instrument checks prior to use (such as for balances and pH meters) to acceptance criteria for captured measurements. Storage location tracking and solution genealogy (sub-aliquot relationships) are monitored using barcode scans and mandatory input fields.

Labs that use industry standard bioanalytical LIMS can leverage tight integrations to ensure project and study hierarchy and attributes (project name, ID, analyte information, etc.) are automatically created and updated within Polar BioAnalysis. Sample lists and run information can be retrieved and stored for easier referencing at the bench, such as in a specified plate format. Finally, result data can be transferred from LIMS (or even the analytical instrument) to Polar BioAnalysis for downstream calculations and reporting.

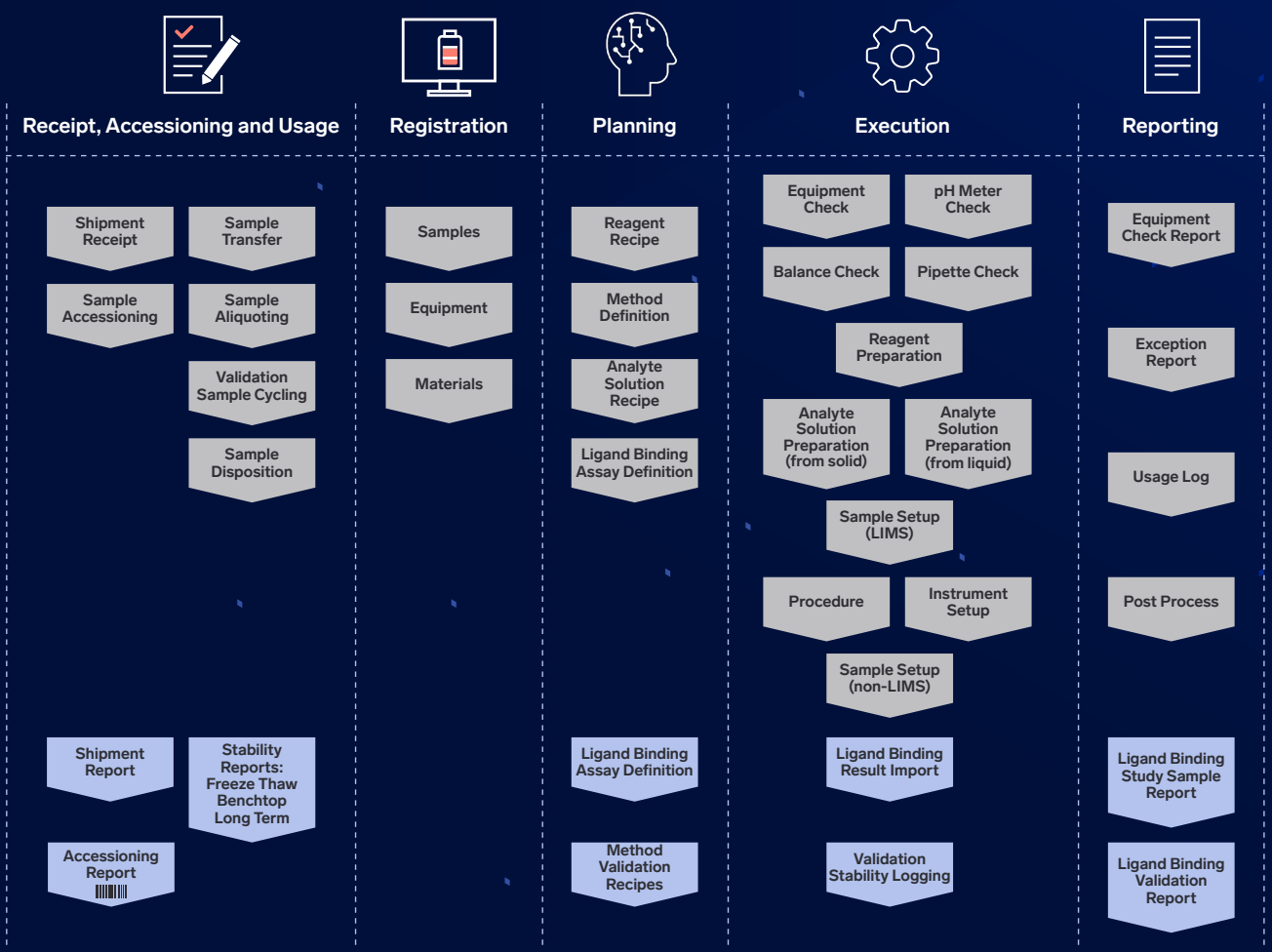
All aspects of Polar BioAnalysis are geared toward improving compliance and reducing QC burden. Polar BioAnalysis eliminates transcription errors by directly accepting raw data and performing statistical analysis and curve fitting within a workflow. The built-in audit log monitors data input and GxP settings can be adjusted to full compliance mode where authentication credentials are mandated at each step of the process. QC of a study can move from manual checks of date/time stamps, cross-reference checks of metrology logs, expiration date checks for all materials used and revisiting calculation to an exception-based auditing methodology.

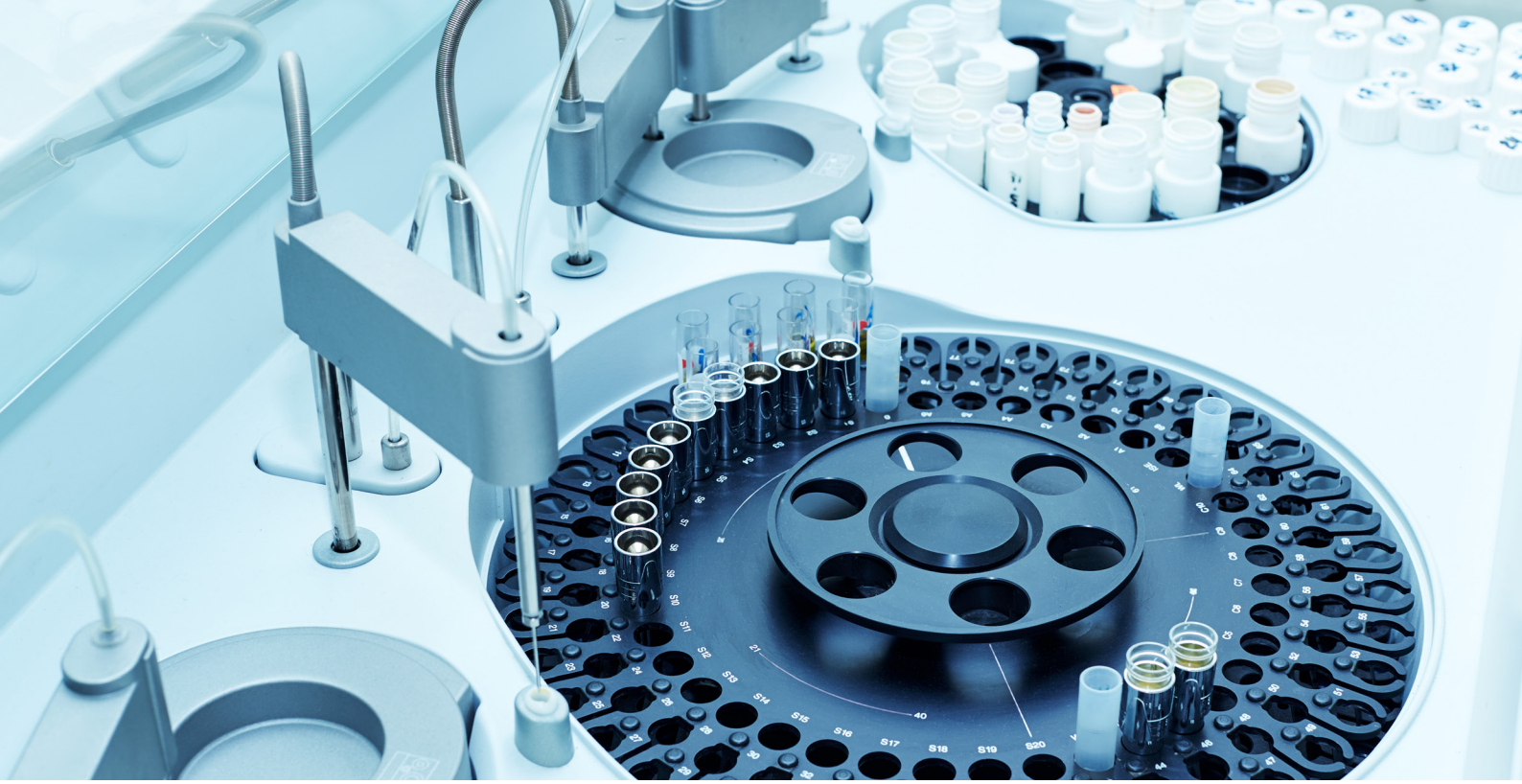
Polar BioAnalysis is a single platform that facilitates documenting balance checks, recording of sample information for the analytical run, development and validation of analytical methods, preparation of reagents and solutions, integration with existing LIMS as well as tracking compliance issues.

The single platform approach facilitates the following steps:

- Lifecycle management of instruments and equipment (usage logs and maintenance schedules)
- Comprehensive electronic methods
- Management of samples, reagents and buffers (creation, storage, control and disposal)
- Integration with instruments and systems (LIMS, CRM, statistical software, etc.)
- Compliance and quality assurance using 'Audit by Exception'
- Results reporting in compliance with the ICH M10 standard.

Workflows: Polar BioAnalysis





Method development

For each lead small molecule or biologic, and the associated biological matrix to be analyzed, a specific method must be developed and subsequently validated. Part of the process of method development is often to build on previous experience by re-using an existing protocol as a starting point for the new method.

System flexibility is paramount during method development and Polar BioAnalysis enables a user to quickly and easily clone methods to create new ones. A free-form environment can be used to develop protocols from scratch, while links to existing protocols give users the best of both worlds.

As methods are developed, Polar BioAnalysis instruction sheets are developed alongside them; these provide documentation for users to follow when performing the experiment and include links to the appropriate worksheet for data entry.

Method validation

Method validation is the process by which a method is verified to meet key requirements such as precision, accuracy, linearity and robustness. Unlike method development, method validation processes are subject to rigid controls relating to the analyte being investigated.

Once a method has been developed, control substances of known quantities will be used to verify the method and determine detection sensitivity. All information relating to the method validation process can be captured within the context of the study and re-purposed as new methods are developed. Once methods have been validated, Polar BioAnalysis data-entry spreadsheets can be locked-down to control data entry, thereby reducing the possibility of errors and deviations.

The deployment of business rules within the bioanalytical workflow and the enforcement of workflow audit tools (such as counter signatures and reason for change codes) supports Good Laboratory Practice (GLP).

Ensuring accuracy and precision in bioanalysis

Polar BioAnalysis provides a series of components to capture all the contextual information associated with bioanalysis workflows. These can be customized in order to meet specific standard operating procedures (SOPs) and business rules. Divided into four groups, these include:

1. Instrument tracking and calibration check

Often, instruments within bioanalysis laboratories are attributed with a unique reference, and these can be entered and tracked in Polar BioAnalysis. Each instrument or asset can be associated with specific accuracy and precision acceptance criteria. If the calibration of an instrument falls outside the acceptance criteria, the user is automatically prompted accordingly and the potential issue is logged centrally, or remediated in real time.

Components are available for weight sets, pH meters, pipettes and balances. By incorporating these workflows within the study, labs can eliminate the need for paper documentation such as balance use logs. Further, audits of reagents and solutions can be tied directly to the balance or pH meter used during its preparation.

2. Sample handling

Users have the option to use a sample receipt and discrepancy tracking component (e.g. missing or damaged samples within shipment). Stability monitoring covers freeze-thaw, benchtop, and long-term stability. Stability monitoring covers freeze-thaw, benchtop, and long-term stability. A sample disposal record can be used to authorize and track sample disposal events.

Additionally, integration with email systems can facilitate the routing and approval process for disposing samples. Samples can also be tracked from their storage location, say a freezer, and monitored for freeze-thaw cycles.

3. Material registration

The material receipt component can be used to record and track referenced standards and critical reagents. The component also includes the option to associate a Certificate of Analysis (CoA) that ensures appropriate correction factors and purity values are incorporated during reconstitution or solution preparation steps.

4. Solution and Reagent preparation

All stock solutions and resulting working stocks used in a specific assay are recorded and traced. Furthermore, information relating to reagents (e.g. Control of Substances Hazardous to Health COSHH assessments) can be stored and handling instructions can be communicated to users. Reagent recipes are displayed from the method, however, daily preparations are scalable on the fly for current study needs.

Weights and pH meter measurements are directly retrieved from instruments and electronically monitored for accuracy and compliance. These values can then be incorporated within calculations being performed during the preparation steps. This direct input of data prevents errors and increases the workflow efficiency.

Changing the face of method execution

The effort invested in setting up the templates described above really pays off during method execution. For the analyst performing these experiments, Polar BioAnalysis provides significant advances in day-to-day activities and delivers a major timesaving boost by generating sample preparation worksheets electronically. From an operational perspective, setting up experiments is largely automated, with pick lists ensuring accurate data entry and integration with LIMS, ensuring folder structures and results are kept synchronized.

Integrating with LIMS

Major bioanalytical laboratories use a LIMS, such as Watson, for sample tracking within a study and to ensure tests are conducted in a consistent manner. Nevertheless, there is a large amount of critical information associated with projects, studies and daily runs, which is not captured or tracked in the LIMS but is still required to complete study reports – for example, analytical instrument setup, method validation documentation, sample QC and system calibration records. Typically, this information resides in paper lab notebooks or study binders.

Polar BioAnalysis has a number of specific tools for integrating with LIMS that can help streamline and enforce synchronization. For instance, Polar BioAnalysis can automatically synchronize with the hierarchy setup (and security model) so that users have a familiar workspace within their electronic study.

A record of the sample sequence, plate layout and instrument settings can also be extracted from Watson and presented as part of the daily run worksheet. Using the run ID, data can be retrieved without the need for manual file transfer or copy/paste functions. This can significantly reduce the QC burden and simplify the analyst's day-today workflow. To maintain the integrity of the validated environment, Polar BioAnalysis can be restricted to 'read-only' rights within the LIMS.

As data analysis for non-compartmental studies is often done in LIMS, the study result can be imported directly into Polar BioAnalysis. In addition, users of Polar BioAnalysis have the option to exchange information with third-party analysis tools and include output results in analysis reports. Polar BioAnalysis includes a comprehensive statistical engine as well as extensive graphic capabilities, giving users the option to use this native functionality rather than third-party software, i.e. do the non-compartmental analysis directly in Polar BioAnalysis.

Utilizing existing laboratory infrastructure

The effort invested in setting up the workflows described above really pays off during method execution. For the analyst performing these experiments, Polar BioAnalysis provides significant advances in day-to-day activities and delivers a major timesaving boost by generating sample preparation worksheets electronically. From an operational perspective, setting up experiments is largely automated, with pick lists ensuring accurate data entry and integration with LIMS, ensuring folder structures and results are kept synchronized.

Issue tracking and KPI reporting

The need for accuracy, reproducibility and compliance with GLP demands accountability and traceability at every part of the workflow. In order to continually optimize processes in the laboratory, as well as meet the regulatory demands of bioanalysis results, a 'top level' view of assays and projects is required.

Polar BioAnalysis captures any deviation from the defined method, as well as tracking the progress of every experiment. This operational data is provided as KPI dashboards, such as the number of assays performed, average duration per assay, assays requested and flagged issues (such as calibration errors). This vital business intelligence enables the performance of the laboratory to be carefully monitored and optimized.

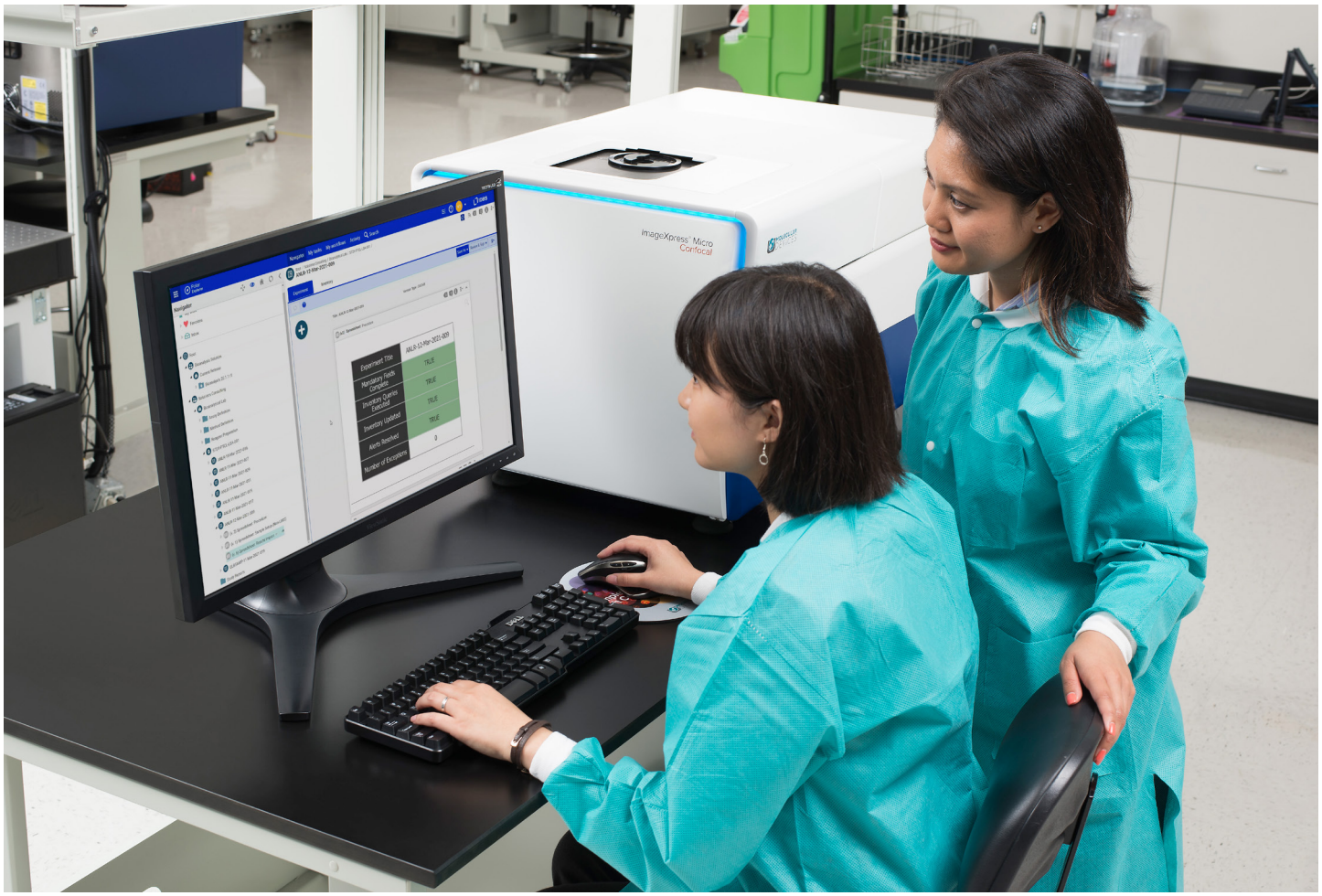
As all data in the Polar BioAnalysis environment is linked, it's simple for managers to drill down into any aspect of the method, analysis or results to better understand the issues. The linking of data also allows flexibility in the pivoting and display of analysis and enables data entered during test assays to be related to business rules and SOPs. For example, in the event that a non-calibrated pipette is used during an analytical test, the event is recorded, along with the full calibration history of that apparatus. The study director can view all issues captured against analytical runs and make a judgement whether or not these constitute as invalidation of that experiment.

Incorporating quality across the bioanalytical operation

IDBS Polar Bioanalysis provides a method execution and data management layer that spans metrology as well as material preparation and tracking. By incorporating business rules into each workflow, labs can enforce compliance and more importantly manage deviations.

QC moves from retrospective manual cross-checking of lab notebooks to 'real-time' confirmation that methods were executed according to plan. Polar BioAnalysis' single platform approach eliminates the need for disparate study binders and instrument logbooks:

- Quality control checks are embedded into every step
- Deviations can be eliminated by incorporating business rules
- Separate 'exception-handling' layer allows for QC audits while the study is on-going, not just at the completion of validation and sample analysis



Increasing capacity by shortening study time without compromising quality

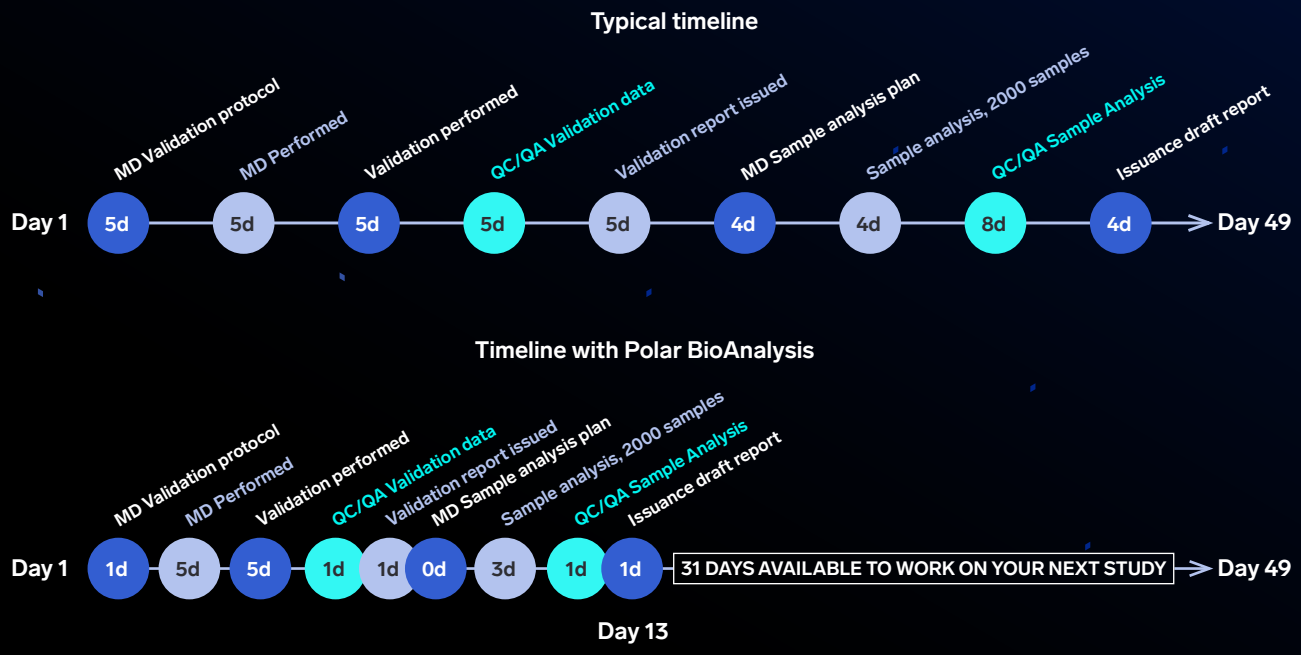
Polar BioAnalysis has been shown to impact the time it takes to review data prior to releasing a final study report. Especially within the CRO industry, the operational aspects of the study (actually generating data) are tremendously efficient. However, there still remains a breakdown in efficiency when it comes to reviewing data for quality and compliance. The current process of handing-off paper notebooks to a QC team for manual cross-checks can hinder the release of results data.

At a specialized bioanalytical CRO, The Director of Quality Assurance GxP, reported a 31-day reduction in study duration after implementing Polar BioAnalysis for bioanalysis within a validated bioanalysis CRO setting.

Key benefits to a CRO include:

- Permission-based access to protocol and study data
- Direct access to study data from instrument and LIMS from electronic notebook
- Elimination of Excel-based spreadsheets for data analysis
- Streamlined approvals using electronic signature-driven workflows for study sign-off
- Expedited QA review of study data and supporting processes

Study cycle time with Polar BioAnalysis



Re-evaluate productivity within your bioanalytical lab

Most bioanalytical operations look to headcount and instrumentation when evaluating areas for improved sample throughput. While increasing throughput may reduce your sample backlog, it only moves your bottleneck over to the QA review stage. A comprehensive solution for productivity improvement must also consider mechanisms to identify and eliminate deviations. The alternative will be to either repeat samples or justify the exception, both of which are costly and can jeopardize the entire study.

As an extension, some may consider addressing inefficiencies inherent to paper-based processes as a way to raise productivity. Our experience indicates that a primary problem is not paper replacement but raw data review and 'exception handling.' The bottleneck is no longer one of lab or instrument capacity (i.e., operations) but one of data review (QC). Polar BioAnalysis provides a mechanism to address both these obstacles.

Unbeatable insight and control of your bioanalytical operations

There is no arguing that laboratory informatics solutions such as LIMS, scientific data management systems (SDMS), electronic document management systems (EDMS), and instrument control software have significantly advanced the quality and quantity of bioanalytical data being generated. However, modern bioanalytical labs require a robust data management solution that improves workflow efficiency, simplifies the application landscape for the scientist and addresses the significant QC burden of each study.

Polar BioAnalysis is a single platform for comprehensive capture, storage and reporting of bioanalysis study data that integrates with existing laboratory infrastructure, thereby adding value rather than support burden to an organization. Implementing Polar BioAnalysis has been shown to dramatically reduce the QC burden in bioanalytical laboratories whilst increasing quality. Furthermore, overall study times are dramatically reduced (upwards of 55% time savings) resulting in significantly faster study turnaround and therefore increased capacity, without the need for more instruments and people.

In this way, implementing Polar BioAnalysis can take a lab far beyond the mere digitization of their current processes and lead to a revolution in how data and processes are managed.

IDBS Polar

Would you like to know more?

Talk to one of our experts today

CONTACT US TO FIND OUT MORE.

IDBS
contact@idbs.com
www.idbs.com

Discover Polar BioAnalysis

UK (HQ) USA JAPAN GERMANY FRANCE INDIA