IQVIA LABORATORIES

Leading with Science: Trusted Expertise in Small Molecule Bioanalysis

Advancing a small-molecule program requires a bioanalytical partner with deep scientific expertise, modern Liquid Chromatography-Mass Spectrometry (LC-MS) capabilities, and rigorous compliance with global bioanalytical method validation guidance (i.e., International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use | Bioanalytical method validation and study sample analysis M10, known as ICH M10). Our bioanalytical laboratory brings decades of collective experience supporting preclinical through late-phase clinical studies. We combine high-sensitivity chromatographic workflows, proven method development strategies, and robust quality systems to deliver reliable, decision-enabling Toxicokinetic (TK) and Pharmacokinetic (PK) concentration data.

This guide outlines the scientific approach we use to support your small-molecule bioanalytical needs — from initial engagement through method validation and sample analysis. To begin successfully, we encourage clients to share early insights into their program, enabling us to tailor an efficient and scientifically sound strategy.

Initial fact-finding: Building the right bioanalytical pathway

Our initial fact-finding phase is designed to identify and test early analytical hypotheses related to ionization behavior, stability, selectivity, and matrix effects that could impact assay robustness across development.

Study-specific questions

Our team works with you to understand:

- Disease area and therapeutic context
- Phase of development and study design (Single Ascending Dose [SAD], Multiple Ascending Dose [MAD], Bioequivalence [BE], etc.)
- Key timelines and operational milestones
- Clinical site footprint and sample logistics
- Special collection needs (e.g., stabilization, microsampling technologies)
- Concomitant therapies that could affect bioanalytical selectivity

Drug/analyte characteristics

We evaluate:

- Physiologically Based Pharmacokinetic (PBPK) modeling status and known PK information
- Structural attributes (mass, acid dissociation constant (pKa), partition coefficient (LogP)) to anticipate ionization behavior, chromatographic retention needs, and risk of ion suppression
- Requirements for parent-only or metabolite bioanalysis
- Pro-drug conversion or chirality considerations
- Primary and future matrices, including disease-specific matrix effects
- Stability and adsorption risks (whole blood, plasma, extracted samples) and expected concentration ranges to define handling controls and low-end performance needs

Methodology readiness

We assess:

- Availability and quality of existing methods
- Need for transfer or cross-validation
- Instrument platform preferences
- Reference materials and Internal Standards (IS) (including SIL availability)
- Known analytical challenges or specialized needs (High-Resolution Mass Spectrometry (HRMS), chiral, hybrid Immunoaffinity-LC-MS (IA-LC-MS))

This structured intake ensures our approach aligns with ICH M10 expectations for method lifecycle understanding while anticipating potential challenges early in the project.

Timelines

We provide clear, program-aligned timelines covering:

- Method development
- Method validation
- Sample analysis turnaround
- Reporting milestones

Your project manager ensures communication cadence and transparency throughout.

Bioanalytical capabilities and capacity

Core services

- Method feasibility assessments
- De novo method development
- Transfer, adaptation, and optimization of existing methods
- Cross-validation
- Full method validation to ICH M10

Equipment and technology

Our modern bioanalytical laboratories feature one of the industry's largest fleets of state-of-the-art triple quadrupole and Q-Orbitrap HRMS systems, integrated with advanced Ultra-High-Performance Liquid Chromatography (UHPLC), micro-flow, and nano-flow chromatography platforms. Dedicated sample-preparation laboratories leverage comprehensive robotic liquid-handling systems and plate-based workflows to support all bioanalytical operations with precision and efficiency.

Integrated personnel functions

- Dedicated project management
- Sample management and chain-of-custody control
- Method development/validation teams
- Production analysis
- Bioanalytical quality control
- Report writing for study reports
- Independent quality assurance

PK assay: De novo method development strategy

Our de novo development framework blends modern LC-MS analytics with ICH M10 principles to ensure assays are robust, selective, and stability-supported.

Our approach is iterative: feasibility results and early performance data are used to refine sample preparation, chromatography, and calibration strategy until targets are met.

Key steps

- Joint kickoff between client and bioanalytical leads
- Scientific review of structure, chemistry, metabolism, and sensitivity expectations
- Platform selection and sample preparation design
- Feasibility screening (as needed)
- Systematic evaluation of extraction and chromatographic conditions
- Optimization of retention, peak shape, and carryover control

Pre-validation performance includes

- Calibration model selection and range qualification, refined based on observed performance across the curve
- Sensitivity, accuracy, and precision assessments
- Selectivity across donor lots, including hemolyzed/lipemic matrices
- Stability evaluations (bench-top, freeze/thaw, whole blood, light sensitivity) reinjection reproducibility and processed sample stability
- Matrix effect and recovery characterization
- Non-specific binding evaluation
- Carryover and OTC drug interference screening

CLIENT CONTRIBUTIONS TO DE NOVO METHODS

- Matrix information
- Analyte properties and structural data
- Reference materials and CoAs
- Internal standard (as applicable)
- Sensitivity and range requirements
- Historical bioanalytical learnings
- Timeline expectations

PK assay transfer and optimization strategy

For existing assays, we ensure a seamless transition while maintaining scientific and regulatory continuity.

Key steps

- Review of existing method and documentation
- Identification of modifications needed for platform or matrix differences
- Pre-validation testing to confirm performance on our systems

Performance confirmation

Consistent with ICH M10 expectations, we confirm:

- Calibration and accuracy/precision performance
- Selectivity, stability, and matrix-effect alignment
- Carryover, recovery, and IS performance
- Interference and Non-Specific Binding (NSB) profiles

CLIENT CONTRIBUTIONS TO TRANSFERED METHODS

- Existing method package
- Reference materials and IS
- Timelines and delivery expectations

Method validation strategy (ICH M10–Aligned)

Our validation plans are fully aligned with ICH M10 Bioanalytical Method Validation and Study Sample Analysis and tailored to the context of use.

Key components

- Full, partial, or cross-validation
- Validation plan drafting and approval
- Evaluation of sensitivity, accuracy, precision, and selectivity
- Disease state testing
- Concomitant drug and matrix-effect assessments
- Comprehensive stability evaluations
- Dilution integrity
- Carryover assessments
- Internal standard performance and robustness
- Reinjection reproducibility and run-length suitability
- Processed sample stability

Validation concludes with data release and a complete validation report.

Application of validated method to PK sample analysis

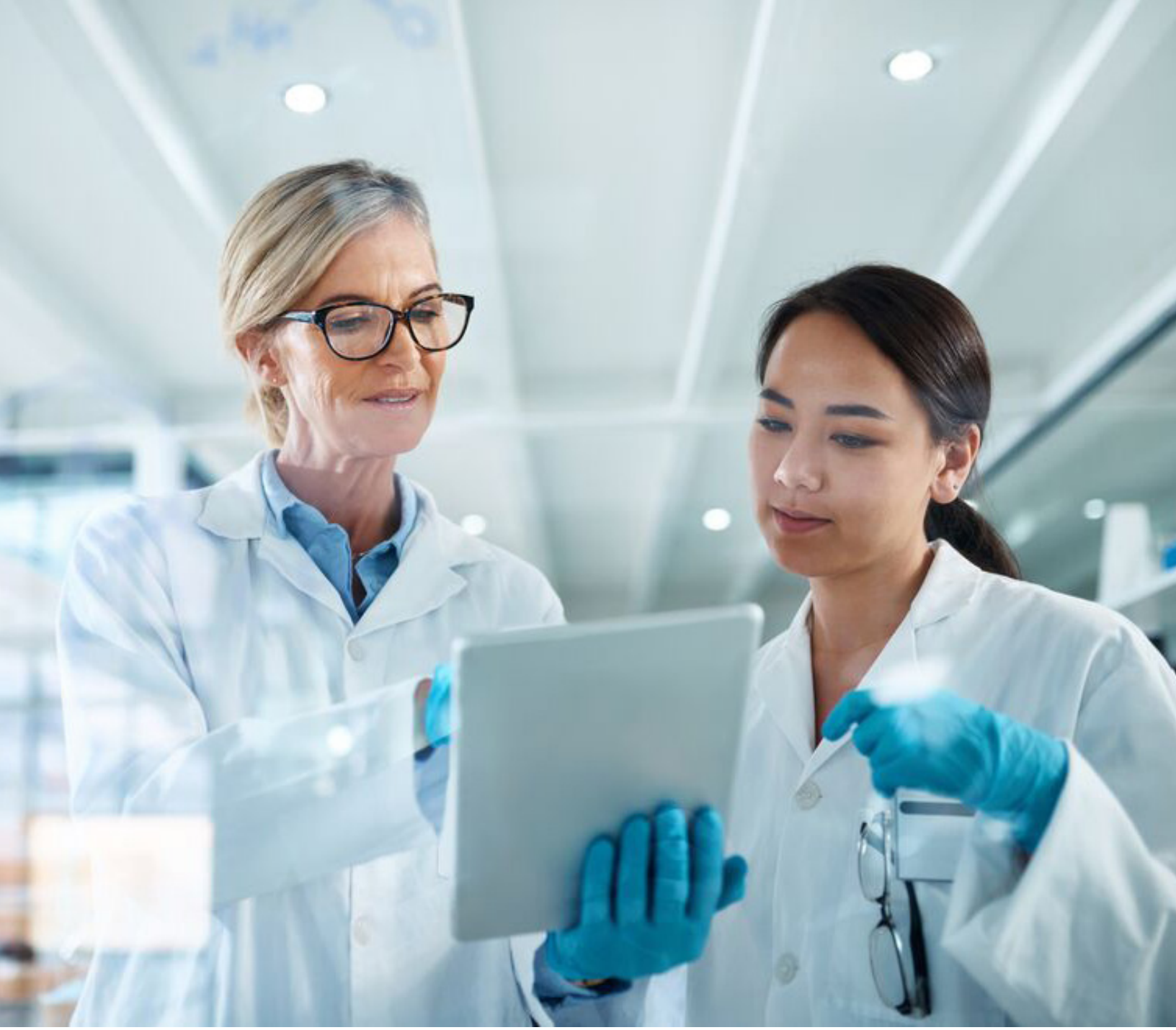
Our regulated sample analysis processes ensure full compliance with ICH M10, SOPs, and method-specific requirements.

Key steps

- Development and approval of sample analysis plan
- Verification of calibration and QC material readiness
- System suitability and long-term stability oversight
- Daily monitoring of method performance and chromatographic integrity
- Compliance with reinjection, reanalysis, and dilution rules as per ICH M10
- Incurred Sample Reanalysis (ISR) performed in accordance with regulatory expectations and used diagnostically to assess reproducibility in real study sample matrices
- Clean, well-documented data packages and reporting

CLIENT CONTRIBUTIONS TO SAMPLE ANALYSIS PROCESS

- Sample shipment, manifest details, and CoAs
- Reference materials, IS, and CoAs
- Data delivery expectations



Rely on an experienced laboratory that supports the full LC-MS bioanalytical lifecycle

From preclinical feasibility to late-stage clinical PK support, our laboratory combines scientific rigor, regulatory compliance, and operational excellence. We help you accelerate development with high-quality, decision-ready data built on a foundation of modern LC-MS science and ICH M10-aligned methodology.

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