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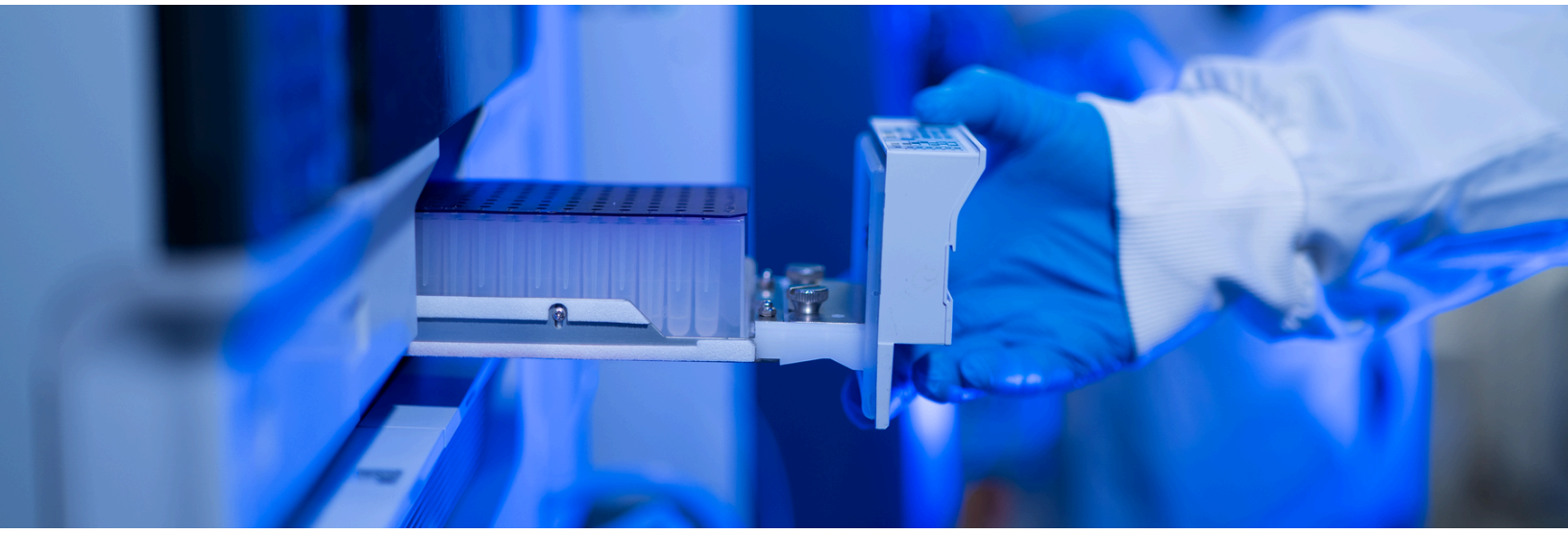

GCP Considerations in the Bioanalytical Laboratory

Why it Matters

Chris Tudan, PhD
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OVERVIEW

Good Clinical Practices (GCPs) are foundational to ensuring the integrity of clinical trial data and the safety, rights, confidentiality and well-being of trial participants. While GCPs are often associated with clinical sites and investigators, their application in the bioanalytical laboratory is equally critical.

With the lines between clinical and bioanalytical domains increasingly blurred—particularly in the analysis of pharmacokinetic (PK), pharmacodynamic and biomarker data—it's imperative for bioanalytical laboratories to fully integrate GCP principles into their systems and procedures. In response to evolving regulatory landscapes, we actively evaluate and refine how these principles are applied across our projects.

In his 2023 *Bioanalysis* article, Dr. Chris Tudan, Director of Biochemistry and QA at Veloxity Labs, initially examined how GCPs intersect with bioanalytical workflows.

Integrating Good Clinical Practices (GCPs) into bioanalytical laboratories is more critical than ever as the boundaries between clinical research and bioanalysis continue to blur, demanding rigorous standards to ensure data integrity and regulatory compliance.

This report revisits the key themes from Dr. Tudan's article, and provides updated insights, recommendations and Veloxity Labs-specific practices.

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GCP CONSIDERATIONS IN THE BIOANALYTICAL LABORATORY

Data Retention: FDA guidance mandates that data collected up to the point of a subject's withdrawal must remain in the trial database to preserve scientific integrity. Bioanalytical labs must be instructed clearly on handling such data to ensure compliance.

Veloxity Labs retains the data for a period that exceeds the E6(R3) GCP requirements to ensure data integrity.

Randomization & Blinding: Procedures for blinding, including handling randomization and managing unblinding events (e.g., safety-driven unblinding), are crucial. Labs must document processes to limit accidental unblinding, especially in placebo-controlled trials where treatment identity may be revealed during analysis.

We follow randomization and blinding procedures which are adhered to by the principal investigator.

Reporting Adverse Events (AEs) & Deviations: While the identification of AEs is rare in the lab setting, expedited analysis and deviation documentation remain critical. Labs must follow protocols for expedited reporting and document all protocol deviations, with particular attention to adverse events.

Any deviations related to the protocol, blinding processes or subject confidentiality are reported to the Sponsor within 24 hours, in accordance with Veloxity Labs' SOPs.

Investigational Products: Traceability and accountability of investigational products, including Certificates of Analysis (CofA), are essential for both regulatory compliance and scientific accuracy prior to starting method validation or sample analysis.

Veloxity Labs requires a current CofA prior to study initiation. The CofA must include all data required under GCP guidelines.

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GCP CONSIDERATIONS IN THE BIOANALYTICAL LABORATORY

Data & Sample Integrity: From chain of custody to data security and system validation, maintaining data integrity, confidentiality and appropriate metadata control is non-negotiable. This includes validated computerized systems, robust sample tracking and adherence to labeling and storage requirements that ensure sample traceability and subject anonymity.

To ensure the highest standards of integrity, we use validated systems supported by QC checks and auditing throughout the study. Sample accessioning processes are guided by documented procedures that safeguard subject confidentiality.

Pre-Study Facility Inspections & Audits: Pre-study inspections and audits by independent, qualified personnel are key checkpoints for ensuring readiness and alignment with GCP expectations. Pre-study inspections must be facilitated by the laboratory, and compliance with both internal SOPs and external regulatory standards is critical.

Veloxity Labs facilitates sponsor audits with transparency and preparedness. By proactively sharing SOPs and applicable records, we help ensure auditors receive everything they need to conduct thorough and successful reviews.

Fit-for-Purpose Approaches in Biomarker Analyses: With the growing use of biomarkers intended for exploratory to pivotal studies, laboratories must adapt assay validation to context-of-use. GCPs encourage risk-based, fit-for-purpose (FFP) strategies tailored to the clinical study's data criticality. This is especially relevant in biomarker assay validation, where context-of-use determines the extent of method qualification.

We perform FFP qualification and validations under real-world clinical sample conditions based on context-of-use that is derived from exceptional communications between the lab and the sponsor.

Future Perspectives: Evolving technologies like decentralized trial models, e-labs and advanced biomarkers require flexible, modern approaches to trial conduct. For example, the new ICH E6(R3) Guidance seeks to address these modern complexities, reinforcing the need for integrated, adaptive quality systems in bioanalytical research.

We're always expanding our technical approaches, procedures and quality management system to accommodate the bioanalysis of newer therapeutics including larger molecules, innovative trial designs and rapid PK support.

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CONCLUSION

At Veloxity Labs, we're committed to applying GCP principles in every facet of our bioanalytical operations. As regulatory expectations evolve, so too do our practices – ensuring our clients receive scientifically robust, compliant and actionable data.

REFERENCE

This summary is intended to provide a practical overview for sponsors, CROs and clinical research professionals engaging with bioanalytical laboratories. For the full peer-reviewed article, please refer to **"Good Clinical Practices in the Bioanalytical Laboratory"**, *Bioanalysis*, 2023.

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ABOUT VELOXITY LABS

Veloxity Labs is a leading bioanalytical contract research organization (CRO) dedicated to advancing therapeutic development and improving patient outcomes. With deep expertise in both non-regulated and GxP-compliant analysis of non-clinical and clinical samples, we provide high-quality, fast-turnaround services to support the pharmaceutical, biotech and animal health industries.

At Veloxity, we specialize in innovative solutions that address the most complex bioanalytical challenges. Our capabilities span a wide range of modalities, from small molecules and peptides to large molecules, antibody-drug conjugates and beyond. We are pioneers in microsampling and patient-centric sampling, utilizing cutting-edge technologies such as Mitra®, Tasso and dried blood spot (DBS) to collect precise data in even the most challenging settings.

Our clients rely on us to initiate projects quickly and deliver results with unmatched speed and accuracy. We help companies accelerate the development of life-changing therapeutics by **moving at the speed of bioanalysis**! Learn more at www.veloxitylabs.com.

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