

Preface

Bioanalysis, simply described as the quantitative measurement of the concentration of a drug, its metabolite(s), or an endogenous compound present in a biological matrix, is essential to the discovery, development, and regulatory approval of new medicines. It is also key to modern pharmacokinetics (i.e., the study of what the body does to a drug) and, increasingly, to pharmacodynamics (i.e., the study of what a drug does to the body). Understanding these biological processes is critical to the practice of determining drug safety profiles and efficacy potentials as well as to establishing recommended dosage for new therapeutics that treat disease. Generating this important data to get safe and effective medicine to patients is the work of contemporary bioanalysts. It is the ingenuity of the bioanalysis team that enables development of robust assays to meet increased sensitivity and selectivity requirements across a wide range of chemical entities, from small molecule drugs to protein- or DNA-based therapeutics.

Once considered a branch of analytical chemistry, bioanalysis now spans biology and chemistry. It shows no sign of limitations in furthering drug development in, either the needs it can address or its potential to advance on those requirements. The advances in technology and strategies implemented in today's bioanalytical laboratory are in accordance with the challenges and opportunities presented by new drug therapies. Despite the developments in bioanalytical technology available to today's bioanalyst, an understanding of the fundamentals of this quantitative analytical science remains incredibly important. Whether setting up a new lab, reorganizing an existing lab, considering an investment in new technology or software, writing SOPs or defending data to an auditor, a firm grasp of the fundamentals will serve the bioanalyst well. While there is currently a wealth of information available on advanced bioanalytical approaches, the volume of material can be overwhelming to those new to or considering a career in bioanalysis. Add to this the evolving regulations guiding practice, and the need for a fundamental reference on modern bioanalysis arises, inclusive of the science, technology, and regulations. It is this need that prompted us to approach recognized bioanalysis experts and opinion leaders to write this book. With it, we aim to provide a comprehensive text that puts fundamental bioanalytical science in context with

current pharmaceutical bioanalysis practice, its challenges, and ongoing developments. It expands on existing texts on the subject by covering regulated bioanalysis of both small and large molecule therapeutics. We hope the content will be useful to a wide spectrum of readers: from those new to bioanalysis, to those developing their experience in the laboratory or working in one of the many critical supporting roles, to seasoned practitioners looking for a solid source of information on this exciting and important discipline.

Chapter 1 provides an introduction to the book. Chapter 2 is a primer on regulations affecting bioanalysis, describing what global health authorities require and expect of organizations generating bioanalytical data for new drug applications. An important foundation for the discipline, it also points to the challenge of drafting prescriptive and comprehensive guidance in a variable and rapidly evolving scientific environment. Chapter 3 summarizes the logistics and practice of establishing and running a bioanalytical laboratory. Chapter 4 discusses the documentation needed for such an endeavor. Chapters 5–7 focus heavily on small molecule bioanalysis and liquid chromatography-mass spectrometry (LC-MS) applications, including how LC-MS is now finding niche applications beyond small molecules, including for large molecule and biomarker bioanalysis. Ligand-binding assays (LBA) are noted as the go-to analytical approaches for peptide, protein, and other biomolecule work since the introduction of immunoanalytical techniques. With the surge in protein therapeutics entering pharmaceutical and biotechnology pipelines, we expect this trend to continue. Chapters 8 and 9, therefore, focus on LBA techniques, and also discusses where and how the regulations apply in light of the nuances of these approaches.

This book was made possible by the dedication of the chapter authors. We are humbled by their generosity, both in time and effort, in sharing their valuable knowledge with the bioanalytical community. It is with deepest gratitude that we thank them for contributing excellent first drafts and for sticking with us through rounds of review. These thanks extend to their families, whom we know routinely accept this extra, uncompensated effort beyond the “day-job.”

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