This workshop takes a different approach to understanding the foundation of the GLP principles and regulations.

- **Practical Understanding of Fundamental GLP Components**
  Grasp a unique approach to understanding GLP regulations, by focusing on the fundamental premises and learn how to apply this foundation to incorporate GLPs instinctively into daily functions.

- **GLP Culture and Values**
  GLP study execution especially at multi-sites can be complicated. Potential hurdles with planning, performance, monitoring, and reporting must be proactively addressed to ensure the study is not compromised. Developing a robust GLP culture is Key to study success.

- **Quality and Compliance – Are They One in the Same?**
  Compliance is only one component of Quality. While compliance addresses the regulatory requirements; quality encompasses much, much more. Learn other fundamentals that also have a substantial impact on the success, profitability and quality of the overall study.

- **Requirements vs. Reality – Welcome to the Real World**
  The regulations tell us WHAT to do, but not HOW to do it. “Real life” situations play a large part in GLP studies. A gamut of trials and tribulations are covered to congeal the workshop training into the reality of the GLP world.

- **Elements of Technical Writing**
  Learn fundamental skills for writing effective study documents - elements of good technical writing, important principles of organization, format and structure, and “Writing for the Reader”.

- **Protocols**
  A clearly-written protocol is a fundamental requirement for a successful and reconstructible GLP study. This session covers techniques for writing detailed, yet flexible protocols that avert being “painted into a corner” and prevent unwarranted deviations.

- **Amendments, Deviations, and Unforeseen Circumstances**
  Documentation of deviations and unexpected events can be problematic and jeopardize study integrity. Learn how to avoid study “pitfalls” with proven strategies for the prevention and minimization of unnecessary deviations.

- **Quality Documentation & Reports**
  This session emphasizes good writing skills to effectively convey the study results and conclusions. It also covers how to tactfully and truthfully handle inconclusive and problematic results and conclusions.

- **Study Reconstructibility - Life After GLP Study Conduct**
  Reconstructibility is critical to study quality and compliance. This session summarizes the practical approaches to assure study reconstructibility from cradle to grave (and beyond).