



**State-of-the-Art and Emerging Technologies for
Therapeutic Monoclonal Antibody
Characterization Volume 1.: Monoclonal Antibody
Therapeutics: ... and Regulatory Space (ACS
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Monoclonal antibodies (mAbs) are an important class of therapeutic that has greatly expanded our ability to treat a variety of indications, including cancer, autoimmune disorders, and infectious diseases. The cost of developing these molecules and ensuring that they are fit for purpose is much higher than for small-molecule drugs. Although some of these costs are due in part to the nature of production, a major cost is incurred because of the complexity of the molecule itself. Extensive analytical testing regimes are needed for in-depth characterization and to ensure product stability, proper in-process controls, safety, and efficacy. The next generation of product understanding will require highly complex, orthogonal technologies to elucidate interdependent structure-function relationships.

The ACS' focus on this field of research represents a defining moment in the development of technologies for characterizing mAbs. A multitude of experts in the field have come together around a single molecule for the first time to demonstrate both current and future practices involved in the characterization of a biotherapeutic. The current series presents an open discussion of current best practices, a multitude of intuitive research, and a collaborative philosophy on where the field needs to move to satisfy future scientific and regulatory needs. Throughout this effort, a first-of-a-kind repository of regulatory considerations, experimental methods, and data--as well as a widely available "reference"--are now available to industry, academia, regulatory personnel, and instrument manufacturers.

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