As a biotechnology company evolving from research and development into the more regulated arenas of FDA and USDA manufacturing requirements, the management team at Morphogenesis, Inc., recognized the necessity of implementing a comprehensive Quality Management System (QMS) that would facilitate the company's transition into a regulated and licensed manufacturer of biotechnology derived cancer therapeutics. The management team approved a QMS draft design based on an adaptation of Clinical Laboratory Standards Institute (CLSI) Guideline QMS01-A4. Management then assigned the task team members Quality System Essentials (QSEs) as per each member's area of relevance and expertise for policy, process, document and record drafting. Over a 6-month period the task team completed all assigned drafts and obtained management’s approval for implementation. A QMS implementation plan was designed and executed by management spanning a 3-month period that included in-service training, continuous education, regulatory compliance and personnel development sessions. In conclusion, the design and implementation of the QMS ultimately streamlined the company’s efforts towards obtaining industry-specific regulatory licensure, it improved company morale by aiding in personnel development and provided the vital functional framework on which the company will build future improvements. The success of this project at Morphogenesis, Inc., and its implications on all scientific, manufacturing, regulatory and business operations has been profound and emphasizes the universality of clinical laboratory quality management systems.