

Quality Commitment Statement Posted July 2024

Ensuring the highest levels of quality in our work is crucial to our patient-centric approach. Quality assurance is a key part of our Code of Conduct, which requires employees to raise quality concerns as a matter of urgency, with all issues addressed transparently. Issues are investigated and if needed corrective and preventative action (CAPA) implemented.

At Insmed, we adhere to a systematic decision-making approach utilizing risk-based scientific methodologies. This ensures that sound decisions are made at every stage of product development, manufacturing, and distribution, with a focus on instilling quality into our processes. This commitment fosters a culture dedicated to data integrity, patient safety, and product quality across all facets of our business operations. This policy and corporate culture were developed by the Insmed Quality Organization, which has direct oversight from the Chief Legal Officer.

Our Quality Management System (QMS) applies to all activities related to the development, manufacturing, packaging, analysis, and distribution of Insmed products (including activities undertaken by our contract partners), regardless of location. The QMS ensures all products meet and conform to regulatory standards of quality, purity, efficacy, and safety in all applicable global regions. Senior management receives accurate, independent assessments of QMS compliance through regular management reviews and surveillance audits conducted at Insmed manufacturing/testing sites, country offices, and global functions.

Insmed is committed to ensuring clinical studies are conducted in accordance with regulations prioritizing patient safety and data integrity. In collaboration with our partners, we establish robust systems and processes aimed at managing and mitigating risks inherent in clinical trials. Monitoring and audit programs are in place to periodically evaluate these systems and processes, ensuring ongoing compliance and adherence to best practices.