

GENMAB'S COMMITMENT TO QUALITY

Commitment to Quality

Genmab develops, manufactures, and delivers investigational antibody therapeutic products for clinical testing that provide significant benefit to patients and to our customers. A company-wide quality policy has been defined and implemented to ensure that these products meet current regulations promulgated by the Danish Medicines Agency, the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), International Council for Harmonization (ICH) Quality guidelines, Health Insurance Portability and Accountability Act (HIPAA) as well as customers' expectations.

Genmab has a strong culture of quality with dedicated senior management leadership and commitment of employees at all levels to achieve and maintain a quality minded approach to everything we do.

Management Responsibility

Senior management is responsible for securing a company-wide commitment to quality and for the performance of the Pharmaceutical Quality System (PQS). Senior management defines the quality objectives and commissions the appropriate qualified employees and resources to achieve these objectives.

Senior management has established the PQS and organized a Quality Assurance (QA) unit to maintain and develop the PQS. This is to secure compliance to current regional and global regulatory requirements to meet industry standards and Genmab's quality objectives. Quality Performance Indicators (QPIs) are defined and monitored. Senior management will periodically review the quality of Genmab products and the performance of the quality system during Quality Management Review (QMR) and advocates a continuous improvement of quality.

Senior management has ensured that processes are in place for a timely and effective communication and escalation of critical quality issues to the appropriate level of management.

Quality Management

Genmab has established a PQS that includes quality policies and procedures that employees must follow. The PQS is process-oriented and encompasses all relevant product lifecycle phases and GxP activities including Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Vigilance Practice (GVP) and Good Distribution Practice (GDP). The PQS covers the company's activities in pre-clinical development, clinical development and manufacturing and supply of products for clinical studies and eventually for commercial use. The research area within Genmab has established an independent quality system to secure quality performance in the non-GxP area.

The Quality Manual is the top-level quality document, and it is implemented to define and communicate the quality policy and how the PQS is organized. The Quality Manual applies to all Genmab employees and is approved by the Chief Executive Officer, Chief Financial Officer and Chief Development Officer.

Operational Quality

Genmab has established a training program to ensure all employees in GxP areas are properly trained and qualified to perform their work. This is facilitated using defined job descriptions, C.V., training plans, and training documentation to demonstrate compliance and qualification. Genmab has a knowledge-sharing culture. Competencies needed for job functions are continuously reviewed and deficiencies are mitigated by hiring, contracting, training and/or educating employees.

Quality risk management is applied throughout all operational activities to consider risk to patient safety, patient rights, regulatory compliance, product quality and data reliability and integrity when making decisions related to the lifecycle of a product including product development, manufacture, distribution and all stages of clinical trials. Risk assessment is used to assess hazards and defects to reduce redundant and non-value-added efforts and keep the focus on efforts that have optimal impact on patient safety, product quality and data reliability and integrity.

A system for quality deviations and Corrective and Preventive Actions (CAPA) is in place ensuring that deviating products or processes are well identified, described and handled, that root causes are well understood, that actions are taking to avoid recurrence and that measures are taken to ensure that the quality, safety and efficiency of the products remain intact.

Recall and complaint procedures are in place for patient safety to ensure that non-conforming products are not used by patients. Recall procedure is frequently tested.

External partners

Genmab utilizes an outsourcing business model for the production, testing and distribution of products and for conducting clinical trials. Through the vendor assessment and onboarding process as well as operational and quality oversight, Genmab ensures that the Contract Manufacturing Organizations (CMOs), Contract Research Organizations (CROs) and other service providers meet both Genmab and applicable regulatory requirements and operate with adequate standards of quality and service as per industry standards and best practices, e.g. HACCP, ISO, ICH, etc.

Quality oversight

A quality audit program has been established for all GxP areas where internal as well as external partners are audited at predefined intervals. Genmab is furthermore subject to inspections from authorities and audits from partners.