



MANA RBM QUALITY MANAGEMENT POLICY

Commitment to Quality

MANA RBM maintains a Quality Management Policy to ensure we continuously meet or exceed all Regulatory Requirements and standards for good software implementation for our products and services.

Our goal is to produce high quality products and services to support the development of new medicines, vaccines and medical devices by Sponsors and Clinical Research Organizations.

Action Plan

A comprehensive approach to quality management is essential to consistently deliver products and services that meet or exceed regulatory requirements and delight our customers. The following areas are part of the MANA RBM Quality Management approach.

1. Strategic Management

The MANA RBM commitment to Quality starts at the top. Quality is critical to the success of our organization and to the organizations with which we work. That commitment is modeled by all levels of management in the way we lead and our expectations that all operating procedures and process are followed and documented.

2. Aligning with Regulatory Requirements

MANA RBM aligns its processes with Regulatory Requirements from the US (FDA) and Europe (EMA).

3. Operational Management

We uphold the Quality Management Policy and its intent in everything that we do. That includes following Standard Operating Procedures and maintaining good documentation of the set-up, validation, and implementation of any software products we manage.

MANA RBM assures that the customer needs and expectations are clearly defined and met throughout the engagement. MANA RBM maintains timelines and specification documents as defined in our contracts. If there is any deviation from the expected timelines, the Customer is immediately notified and options are presented to remediate any deviations.

MANA RBM often works in cross functional groups, managing the implementation of multiple different vendor software solutions. MANA Consultants facilitate cross-functional discussions, identifying points of interface and critical timelines for delivery of each component. MANA manages the delivery of key information between systems and assures the documentation and testing of any cross system functionality.

We assure that all staff are appropriately trained and managed with the expectation of complete adherence to the Quality Management Policies.

MANA RBM operates as a small business, where contributions of every staff member are appreciated and where all members of the team are encouraged to express their ideas and suggestions on how to improve the business and customer service.

4. Resource and financial management

MANA manages resources to assure that the appropriately trained staff is assigned to each component of the project.

MANA strives to meet all deliveries within the cost and time constraints agreed in the contract.

5. Performance Monitoring and continuous improvement



We review the work that we have done and hold "Lessons Learned" meetings after every engagement to assure that we are continuing to improve in our delivery of products and services and to assure that the lessons are shared throughout our organization.

We conduct debrief sessions after each engagement with our customer to understand how we can better deliver our products and services. We also elicit feedback at least twice a year from customers in long term projects.

All employees have performance reviews at least yearly.

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