



Quality Policy

Omixon is a global molecular transplant diagnostics company established in 2011 with a mission to provide histocompatibility laboratories with innovative technologies to improve transplant outcomes.

At Omixon we are committed to quality in order to

- Improve transplant outcome
- Provide safe and efficacious devices and
- Ensure continuous compliance with customer and regulatory requirements.



We have established and maintain suitable, effective and adequate Quality Management System processes which provides framework for continual improvement and for achieving our quality vision especially by

- relevant and measurable Quality Objectives aligned with business goals
- training and development of our employees
- regular internal audits
- systematic operation of Corrective and Preventive Actions
- regular Management Review Meetings
- operating Post-Market Surveillance including feedback management and complaint handling processes
- applying a risk-based approach for the control of processes, determining acceptable risk and maintaining a risk management procedure
- evaluation, selection and performance monitoring of suppliers against set criteria and
- effective communication to all stakeholders.

Although Top management has ultimate responsibility for Quality, all employees have responsibility within their own areas of work to help ensure that Quality is embedded throughout the company.

Managing Directors

Revision and Change History

Version	Date	Author	Summary of changes	Approved by
1.0	14/04/2015	Tim Hague	initial issue	Tim Hague
1.1	01/12/2015	Tim Hague	Correct English wording	Tim Hague
2	06/09/2017	Zoltán Simon	Add CAPA and internal audit as means of maintaining effectiveness of Omixon QMS	Peter Meintjes
3	06/09/2019	Gabriella Adlovits, Peter Meintjes	Add PMS and risk approach to Quality Policy, and rephrased according to the company values (QMS-428)	Zoltán Simon, Peter Meintjes
4	10/06/2021	Gabriella Adlovits	Add policy for determining acceptable risk (QMS-604)	Attila Bérces Zoltán Simon 
5	20/09/2023	Gabriella Adlovits, Elmar Schilling, Zoltán Simon 	Align Quality policy with company values and 5 quality principles	Zoltán Simon Attila Bérces