

Diatranz Otsuka Limited

Quality Policy Statement



With a combined experience of over 35 years in all aspects of xenotransplantation, Diatranz Otsuka Limited (DOL) is in a unique position to share its knowledge and experience. Our expertise includes provision of xenosafety testing for both animal donors and human patients. We also provide guidance and expertise in animal husbandry to achieve designated pathogen-free (DPF) herd status, development and execution of xenosafety monitoring strategies, GMP production and quality control testing of porcine cell therapy products, research and development, product development, pre-clinical studies and strong proficiency in diverse cell and molecular laboratory technologies.

It is the commitment of DOL to:

- Maintain a high-level quality management system that is compliant with all aspects of ISO 15189:2012 and accredited by International Accreditation New Zealand (IANZ) through annual internal and external audits.
- Provide meticulously researched, evidence-based materials which are practical, value adding and based on our extensive professional experience.
- Develop and maintain staff competencies, empowerment and accountability at all levels of the business through training programs and strong management involvement and commitment.

Purpose:

- Requirements of ISO 15189:2012 are continuously upheld or exceeded across all aspects of testing and quality management.
- Needs of the clients are fully understood and met through comprehensive communication.
- Test methods are fully validated as fit for purpose to ensure the accuracy and reliability of our test results.

Objectives:

- Ensure the continued development, implementation and maintenance of the quality system and to continually seek improvements in the effectiveness of the quality system.
- Report results accurately and unambiguously in a timely manner; to seek improvements in the service provided to clients; to continually review the determinations offered to clients to continue to meet the needs of the industry.
- Ensure tests are performed by suitably trained and qualified staff and to provide opportunities for staff to extend their knowledge.
- Ensure equipment used is fit for purpose, properly maintained and calibrated and to seek improvements in the equipment and methodology used.
- Ensure full traceability throughout the sample handling process and to ensure sample handling procedures and environmental conditions do not affect the result.
- Use a stringent audit program to ensure the quality system continues to comply with constantly developing requirements of the ISO 15189 standard.
- Comprehensive checks during all testing procedures ensure that problems are identified, investigated promptly, the root cause established, and effective actions are taken to prevent recurrences.