Rakuten Medical



Mark Marosz

Vice President of Quality,
Rakuten Medical, Inc.

As Vice President of Quality, Mark leads quality assurance and supply chain operations for the drug and medical device products used in Alluminox® platform-based photoimmunotherapy. He oversees quality management systems across the entire product lifecycle, from development and manufacturing through post-market activities, ensuring the highest standards of quality, compliance, and reliability. Mark also leads supplier qualifications, including due diligence, assessments, and maintenance audits of suppliers worldwide, and oversees Rakuten Medical's global quality engineering organization. He is also committed to fostering a culture of quality and continuous improvement through training and education in GMP, design controls, validation, CAPA, and audit readiness.

With extensive experience in medical device quality management, Mark has led quality initiatives across a broad range of disciplines, including product concept development, design controls, qualification, validation, and technology transfer for mechanical, electrical, and software-controlled systems. Throughout his career, he has built and strengthened quality organizations across diverse regulatory and cultural environments, including Belgium, Switzerland, the United Kingdom, China, Thailand, South Korea, and India. He also successfully led the transition to quality management systems compliant with the European Union Medical Device Regulation (EU MDR) and achieved MDR certification through a Notified Body. He is a certified ISO 13485:2016 Lead Auditor and ISO 17025 Lead Assessor.