PROJECT SNAPSHOT

Medical Grade Functional Safety in Warehouse Robotics

LEVERAGING PROVEN SAFETY FRAMEWORKS TO ACHIEVE ISO 10218 COMPLIANCE AND FASTER TIME TO MARKET

SITUATION

- Functional safety expertise to interpret and apply complex, evolving robotics standards (ISO 10218, ANSI R15.06, IEC 61508) to their warehouse automation system
- Safety-rated system design for autonomous mobile robots and robotic arms operating around humans, including navigation, control, and emergency response mechanisms
- Regulatory compliance support to prepare documentation, validation, and evidence required for third-party audits and certification

SOLUTION

- Performed ISO 12100 safety analysis to identify and prioritize hazards such as collisions, load drops, and system faults
- Defined safety goals and architecture with dual channel controls, redundant sensors, watchdog timers, and real time emergency stops
- Deployed IEC 61508 aligned software modules to reduce development risk and accelerate implementation
- Built a complete safety case with fault injection tests and traceable documentation for third party review

CHALLENGES

- Robotics firms face stricter functional safety rules. The 2025 ISO 10218 update mandates safety rated controls, fault tolerance, and cybersecurity, while new EU Machinery Regulations classify AI robotics as “high risk”, requiring third party review, creating compliance gaps for many teams
- A warehouse automation client deploying AMRs with robotic arms needed to meet ISO 10218 and ANSI R15.06. Key hurdles: safety rated navigation and control, real time fault response, and compliance across mobile and fixed robot standards

RESULTS

- Regulatory Compliance: Achieved full compliance with ISO 10218 and relevant AMR guidance (ISO 3691-4, ANSI R15.08)
- Accelerated Certification: Passed third party audit with a comprehensive safety case
- Faster Time to Market: Reduced development cycle by 6-9 months through standards expertise and accelerators

ABOUT MEDACUITY

MedAcuity, a software engineering firm with over 20 years of experience in safety-critical medical device development, has become a trusted partner for non-medical robotics companies navigating the complexities of functional safety. Their deep expertise in regulated environments (IEC 60601, ISO 14971, IEC 62304) seamlessly translates to industrial and service robotics standards such as ISO 10218, ISO 13489, and IEC 61508. As robotics increasingly operate in human environments, like warehouses, the need for robust, certifiable safety becomes paramount.

Accelerating the pace of innovation while reducing development time and risk.

It’s possible. *Ask us how.*

866.376.1931

medacuity.com

MEDACUITY