



"With Hexaware's advanced platforms, regulatory complexity becomes an opportunity for strategic advantage, driving efficiency and ensuring safety in product development."

Rohan Sinha

Hexaware

Overview

Hexaware is headquartered in Mumbai, India. It has more than 31,500 employees across 28 countries. In FY24, the company generated \$1.4 billion in revenue, with Financial Services as its largest segment. Hexaware is dedicated to ensuring compliance with essential standards such as FDA regulations, ISO certifications and Good Manufacturing Practices (GMP) for clients in the U.S. By fostering strategic collaborations with industry organizations and technology providers, Hexaware enhances its domain expertise and keeps abreast of regulatory changes, offering significant value to the medical device industry.

Strengths

AI-driven regulatory Co-Pilot: Hexaware's medical device Co-Pilot is an AI platform that helps manufacturers navigate complex regulatory landscapes. It synthesizes regulatory data, enabling precise content extraction and regulatory synthesis while ensuring submission readiness and compliance with QMS.

Innovative regulatory intelligence platforms:

Hexaware utilizes platforms like RAQA.AI and ReguFlow.AI to streamline submissions across over 65 markets, adhering to FDA and EMEA guidelines. These cloud-native solutions leverage AI to anticipate regulatory changes, improve document collation and provide real-time compliance checks.

Integrated quality management solutions:

QualiVerse, Hexaware's electronic QMS, helps manufacturers achieve audit readiness and streamline document control and training. With AI-driven regulatory intelligence, it ensures proactive adaptation to evolving EU MDR and ISO 13485:2016 requirements, enhancing patient safety.

Post-market surveillance automation:

Hexaware automates post-market surveillance processes using AI, allowing clients to monitor device performance and detect adverse events, ensuring compliance with FDA and MDR/IVDR standards. Its AI and blockchain-powered remote audit solutions further enhance compliance readiness and efficiency.

Caution

Hexaware's AI-driven compliance and quality solutions boost efficiency but may not fully capture nuanced regulatory requirements. Organizations should strengthen internal regulatory expertise alongside leveraging automation to ensure accurate interpretation and implementation.