

Autolomous achieves ISO 27001 and ISO 9001 certification for cell and gene therapy management systems and services

Autolomous Ltd., a developer of critical manufacturing management systems for cell and gene therapies, announced it has achieved ISO 9001:2015 and ISO 27001:2013 certification from QMS International.

A central part of Autolomous' client engagement strategy is to surpass the current quality and security requirements expected of critical suppliers to the sector. Autolomous will join a select group of cell and gene therapy suppliers with ISO certification. This will provide an additional incentive to companies across the cell and gene therapy supply chain to partner with Autolomous to strengthen existing cell and gene therapy collaborations. It will also help to accelerate the growth of Autolomous' early adopter client base with Autolomous' business-critical digital platform, AutoloMATE(R). The integrated ISO certification demonstrates that Autolomous' management systems, covering AutoloMATE and its IT services, complies and operates under internationally agreed standards. This includes both Quality Systems (ISO 9001) and Information Security Management (ISO 27001).

Obtaining certification for ISO 27001:2013 involves implementing 114 specific security measures, organised into 14 sections, followed by an ongoing 3-stage audit process. The ISO 9001:2015 standard complements the above, requiring seven key areas to be addressed to achieve continual improvement: Context of the organisation, Leadership, Planning, Support, Operation Performance evaluation and Improvement. Autolomous operates in a highly regulated environment. The AutoloMATE platform is designed to be compliant with U.S. and EU regulations for electronic systems (FDA 21 CFR Part 11 and EU Annex 11). Autolomous' integrated certification is the latest successful achievement in its commitment to maintaining the security of sensitive data. As Autolomous is deploying leading-edge technologies, ISO accreditations will provide reassurance for customers and patients that its services are implemented to the highest quality and digital security standards.

“Autolomous achieving its new ISO certification will provide all clients and prospective clients with the assurance that Autolomous and its services are in compliance with current and future international standards. This certification is essential for organizations throughout the cell and gene therapy sector to demonstrate the highest possible standards and compliance for this clinically advanced sector,” said Alexander Seyf, CEO, Autolomous. “The 2 ISO certifications are a continuation of the rapid progress Autolomous has been making over the past 2,5 years. This will enable us to quickly build on the 8 platform deployments, two UK government supported projects, 8 integrations with CGT eco-system suppliers and a completed investment round we have achieved within this short time frame.”

About Autolomous

Autolomous LTD is the market leading developer of critical manufacturing management systems for cell and gene therapies. The company, located in London, was founded in 2019 by four professionals with combined experience covering 50 years in advanced therapies and medical practice and 35 years in technology, software and business. Autolomous internationally deploys fully integrated, digitized and automated supply chain software solutions. These solutions utilize emerging technologies such as Distributed Ledger technology and Internet of Things (IoT) to ensure compliance with current and future regulatory requirements. As a result, Autolomous enables manufacturers to reduce costs and deliver cell & gene therapies to more patients. AutoloMATE(R) is a business-critical robust digital solution increasing efficiency, scalability and process streamlining of the GMP manufacturing and product release of cell and gene therapies.

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