

Customer Success: Omni Neuro



About Our Client

Omniscient Neurotechnology (Omni Neuro) delivers software solutions to connect pioneers in neurosurgery, neurology, and neuroscience with subject-specific brain analytics. The early-stage startup builds solutions specific to the needs of neurosurgeons, neurologists, psychiatrists, clinical researchers, and academics that can be easily integrated with existing diagnostic, therapeutic, and surgical workflows. While o8t is a relatively small company, the startup employs a globally dispersed workforce with staff members residing in the US, Canada, China, and Australia.

“The nature of our business requires strict adherence to regulatory requirements. Our existing systems weren’t ideal long-term solutions for document control, and they also created validation challenges for us.” “We needed a scalable long-term solution that would allow us to meet our evolving compliance requirements.”

Arie Henkin

Director of Quality and Regulatory Affairs at o8t

Rapid AODOcs for Life Sciences QMS Deployment Enables Omniscient Neurotechnology to Meet Compliance and Submission Requirements

O8t needed a quality management system (QMS) that could address their document control needs and help them meet compliance requirements. Specifically, the company was looking for a system that could help comply with ISO 13485:2016 requirements, as well as the country-specific regulatory requirements of Canada, USA, and Australia. The solution had to be 21 CFR Part 11 compliant, and had to be able to facilitate meeting the stringent needs of the Medical Device Single Audit Program (MDSAP) which allows medical device manufacturers to be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets (Australia, Brazil, Canada, Japan, and the US).

New QMS Selection Criteria: Collaborative, Agile, and Easy to Validate

Since o8t was on a Google-based IT infrastructure, it was vital that the solution the company selected worked within this environment and that it was as easy to use as Google’s collaborative tools. It was important that the new system was agile and flexible so it could be customized to meet evolving needs and requirements and included an easy path to a validated software state.

“AODOcs quickly rose to the top of our list because of its integration with the Google Suite, which simply wasn’t the case with other platforms and solutions we evaluated,” said Henkin. “Our staff is very familiar with the Google stack, so we knew user adoption would be very straight-forward.”

o8t selected [AODOcs for Life Sciences](#), which is a dedicated solution for life sciences from [AODOcs](#).

“We immediately recognized the value of AODOcs for Life Sciences not only to help with our immediate document control and compliance needs, but we also saw how our organization would benefit from its innovative and evolving roadmap,” added Henkin.

About AODOcs

AODOcs for Life Sciences is a Quality Management platform for organizations to confidently build their Quality Program and reduce the cost of Computer System Validation & Assurance (CSV&A) while accelerating time to deliver business solutions.

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"AODOcs for Life Sciences was the first system we validated within our environment. Their continuous validation approach saved us a tremendous amount of time and internal resources. Our auditors appreciate that we take IT system changes seriously, and that we mitigate the risks of those changes with a continuous software validation model!"

Arie Henkin

Director of Quality and Regulatory Affairs at o8t

Low Code Customization Capabilities and AODOcs Support Team Enables Fast Deployment

O8t has several unique document control and process requirements, and the ability to quickly customize AODOcs for Life Sciences to meet these needs resulted in an incredibly fast deployment. Within about a month after selecting the solution, the company was already leveraging the quality management system for audits. The company quickly configured document libraries and workflows for the management of business-critical documentation such as records, SOPs, training documents, design history files, device master records, and more.

"We purchased and began implementing AODOcs for Life Sciences in April, and by May we were already using the platform to complete an internal audit. In July and August, we were heavily using the system to complete both stages of our MDSAP certification. We're planning to use AODOcs to compile all of our regulatory submissions, including our FDA submission," said Henkin.

O8t quickly and easily configured AODOcs for Life Sciences internally and worked with the AODOcs support team to help customize their training and incident management modules.

"Working with the AODOcs team was great. Their support staff was instrumental in helping architect our configuration for security incident management and training request workflows. The ability to create our own training request workflow module has been huge in our ability to complete audits," noted Henkin.

Seamless QMS Software Validation

Cloud solutions must be validated for life sciences companies to use them, and every time a cloud vendor makes an update to their software, it needs to be re-validated. Unfortunately, many life science firms still conduct validation testing manually, which is time consuming and prone to error. However, AODOcs (in collaboration with its partner, xLM) employs a continuous validation approach for its offerings, which alleviates the headaches typically involved with meeting validation requirements.

An Eye Towards the Future

O8t believes it has just scratched the surface with what the company can accomplish with a modern and innovative quality management system.

"We're currently in the beta stage for another AODOcs for Life Sciences module that will enable us to better manage our corrective and preventative actions (CAPAs) and audits, as well as expand our incident management module as a future service engagement. We're also looking at integrating the QMS with our Customer Relationship Management (CRM) system and other existing systems," added Henkin.

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