

Omniscient Neurotechnologies meets Compliance and FDA requirements with AODocs

AODocs was the natural fit for Omni Neuro considering its seamless integrations with Google Workspace. The company provided a scalable, long-term solution that would allow Omni Neuro to meet its evolving compliance requirements.

The challenge

Omni Neuro needed a quality management system that could address its document control needs and help them meet their compliance requirements. The company had challenges in ensuring its processes adhered to FDA regulatory and 21 CFR Part 11 requirements in addition to looking for a solution that would help them fulfill requirements of the Medical Device Single Audit Program (MDSAP).

The solution

Since Omni Neuro was on a Google-based IT infrastructure, it was vital that the solution the company selected worked within this environment. Omni Neuro selected AODocs for Life Sciences, which is a pre-configured template from AODocs that's designed as a stand-alone QMS offering for life sciences customers.

The results

Within only a few weeks of deployment, AODocs' QMS solution allowed Omni Neuro to pass an internal audit, and in a few months, the company was ready and successfully passed external certification 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, and more.

“ AODocs for Life Sciences was the first system we validated within our environment...Their Validation as a Service 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 Validation as a Service software model. ”

Arie Henkin, Director of Quality and Regulatory Affairs, Omniscient Neurotechnology



About Omniscient Neurotechnology

Omniscient Neurotechnology delivers software solutions to connect pioneers in neurosurgery, neurology, and neuroscience with subject-specific brain analytics. The company builds solutions specific to the needs of neurosurgeons, neurologists, and others that can be easily integrated with existing diagnostic, therapeutic, and surgical workflows.

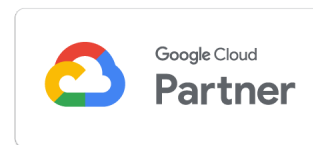
Industry: Healthcare & Life Sciences

Primary project location: United States



About AODocs

AODocs is a Content Service Platform, completed built GCP, bringing together real-time collaboration and best-in-class AI capabilities.



Products

Google Cloud Platform