

Customer Success: **Bio SB**



About Our Client

Bio SB develops, manufactures, markets, and distributes a portfolio of products for laboratories, clinicians, researchers, and patients. The company's products are used worldwide for applications in molecular pathology, cancer diagnostics and research, microbiology, immunopathology, immunology, and immunotherapy. Bio SB's products meet the highest national and international regulatory standards in accordance with FDA 21 CFR Part 820 cGMP, ISO 13485:2016, and In-Vitro Diagnostic Directive 98/79/EC.

"What really separated AODocs from the other solutions we looked at was that Validation as a Service of our functional requirements was included. This allows us to update to new releases and features as soon as they are validated, which saves us time, effort, energy, and burden. This has been a huge benefit and will save us thousands of dollars per year in validation costs,"

Hector Solano

Bio SB Automates Document Control and Workflows with AODocs for Life Sciences

As an emerging player in the life sciences space, Bio SB needed to implement a modern and more effective solution for document control. Bio SB required a platform that would enable the company to manage documents and records in a manner that was compliant with the several industry regulations, and that also integrated with the G Suite.

"We were storing all of our files on a network file server, and all of the workflows and processes related to these documents were conducted manually," said Hector Solano, COO of Bio SB. "When changes needed to be made to a record, someone would make a copy of the file, change the name, and manage the rest of the process in a painfully manual manner. We needed a solution to help us automate this process and enable more collaboration among our team and partners."

AODocs for Life Sciences: A Validated Platform

Bio SB looked at several options to address the company's needs. The company considered building their own solution, and also looked at a host of quality management systems (QMS) such as MasterControl and Greenlight Guru, but ultimately Bio SB selected **AODocs for Life Sciences.**

"AODocs was unique from other offerings we evaluated in that it was a platform versus a solution. This distinction was key for us because we knew we could configure it to meet our specific needs and requirements," noted Solano. "And since we're shifting our IT stack from Microsoft to the Google ecosystem, going with AODocs made even more sense for us. With AODocs for Life Sciences, we've been able to add enterprise-grade workflows, document control, and quality management on top of Google Workspace"

Another important aspect of Bio SB's decision to select AODocs was its Validation as a Service approach.

Low Code Platform Makes It Easy to Set up Libraries and Workflows

"One of the first things I noticed when I tested AODocs was that we could configure our libraries and workflows in a way that enabled us to manage the entire lifecycle of our documents and records," said Solano. "We were able to build new document classes within AODocs templates, and we configured strictly-controlled workflows in which certain users were provided with unique UIs based on their access permissions. We were able to accomplish all of this ourselves because the AODocs platform is extremely easy to use."

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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"With AODocs, we now have control over the quality documentation and processes associated with our experimentation and production activities. These controlled documents serve as a template for the creation of new records, which can often occur daily. Being able to enforce strict document control procedures on this process with AODocs ensures efficacy and consistency,"

Hector Solano

QMS with Enterprise-Grade Document Control and Records Management

Prior to deploying AODocs for Life Sciences, Bio SB's records management and document control functions were paper based, which presented numerous efficiency, security, and compliance challenges.

AODocs for Life Sciences is now Bio SB's official QMS, and the company leverages the platform for records management, document control, change management, and process control. Because Bio SB must adhere to numerous industry regulations the company has automated its records management and document control processes with AODocs in a manner that meets regulatory requirements. The company manages all of its business critical QMS content in AODocs, such as SOPs, technical procedures, CAPAs, forms, and product specifications, training materials, safety guides, validation reports and equipment manuals – with workflows configured for each of these content types.

Bio SB has also built a separate AODocs library for managing materials requests (between their R&D and production teams, for example), and another for managing contracts and agreements with its partners and distributors. The company was able to configure workflows within each of these libraries for managing reviews and approvals complete with electronic signatures (via the DocuSign connector in AODocs).

Being Part of the Google Ecosystem Has Benefits, Especially When Collaborating with International Partners

While Bio SB is an emerging player with most of its employees residing in the US, the company sells its solutions via a network of distributors around the world. AODocs for Life Sciences has not only enabled a higher level of collaboration with its partners, but the fact that the platform is seamlessly integrated with the Google Workspace has delivered additional benefits.

"We sell via distributors, and when we work with our distributor partners in Germany, France, or in other non-English speaking countries, our documentation must be in those languages," stated Solano. "Because AODocs is a part of the Google ecosystem, we have access to other automation tools via the Google Workspace, such as language translation. We use Google translate API when our content must be in other languages, and then we use AODocs to collaborate with language translators to make edits, reviews, and approvals – as well as for publication. This saves us hundreds of hours and thousands of dollars. We couldn't do this if AODocs wasn't a platform that was so closely aligned with the Google Workspace."

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