

Boston Scientific

Every 1.3 seconds, somewhere in the world, a patient is impacted by a Boston Scientific (BSC) product. With \$8.4 billion in sales, 27,000+ employees, and a presence in 100+ countries, the company has a vast footprint and a massive impact on human health.

Managing the design, production, and distribution of 13,000+ products is a tremendous task—and manual processes were jamming the gears.

“We needed a better solution,” says Kevin Clark, Manager of Global Clinical Operations.

And not just any solution, but one that complied with FDA 21 CFR Part 11, the regulation governing electronic signatures in records. When Clark discovered DocuSign’s Part 11 Module, he knew it could be a game-changer.

Results

Before
DocuSign

After
DocuSign

48%

Rate of not in good order on key regulatory form

0

GDP errors

36

Manual stages to complete active release form

6

Automated stages to complete active release form

ROI

\$4.4 million in savings

\$2.1 M

Saved in distribution and product controls

\$1.8 M

Saved in clinical trial administration

\$500K

Saved in regulatory administration

“When we talk about workflow, DocuSign is the epitome of how to streamline and gain efficiencies.”

Kevin Clark
Manager
Global Clinical Operations PMO

Three Methods of Modernization

From three manual forms at separate sites to one automated form online

BSC's process for moving products from manufacturing sites to distribution centers was outdated, slow, and complex.

"We had three forms. Multiple people reviewing. Multiple people signing. And no automation," says Clark. As a result, products weren't getting to market quickly enough.

DocuSign streamlined, centralized, and automated the entire chain of custody.

"We can't eliminate stakeholders," Clark says.

"But we did condense all those forms into one and bring it online."

From a complex, manual process to a simple online experience

When bringing patients into clinical trials, BSC struggled with a process that required too many actions on the part of medical staff.

"Someone on our team would have to email each form," Clark says. "On the physician side, they'd have to print it out, get a signature, scan it, and email it back." Delays were putting the success of the trials—and ultimately the development of new products—at risk.

Now, the process is streamlined within DocuSign, and patient consent flows in.

"In the clinical group, DocuSign spread like wildfire," Clark says.

From a 48% error rate to an intelligent, guided process

BSC's regulatory assessments (DRA) process was plagued by complexity, slowing time-to-market and putting BSC at risk of non-compliance.

"This was a 23-page form," Clark says. "Over 150 questions. Zero logic. No drop-downs." The error rate was high—48% Not in Good Order.

Working closely with DocuSign, BSC reinvented the process, using DocuSign's smart questionnaire with conditional logic and advanced formulas to digitize preparation and submission.

Now the compliance team can instantly determine which submissions are required just by interacting with the form. Version control isn't an issue, and errors have dropped dramatically.

An average of 78% faster processes

By modernizing their System of Agreement with DocuSign, Boston Scientific is boosting efficiency, improving compliance, and adding \$4.4M back to their bottom line.

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About DocuSign

With its System of Agreement Platform, DocuSign helps organizations connect and automate how they prepare, sign, act-on, and manage agreements.

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