

Every 1.3 seconds, somewhere in the world, a patient is impacted by a Boston Scientific (BSC) product. With \$8.4 billion in sales and 27,000+ employees, 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, Manger 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.

## Three methods of modernization

### 1/ 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**BSC’s process for moving products from manufacturing sites to distribution centers was outdated, slow, and complex.**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 not 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,” Clarke says, “but we did condense all those forms into one and bring it online.”

### 2/ 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.

## 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 releases form

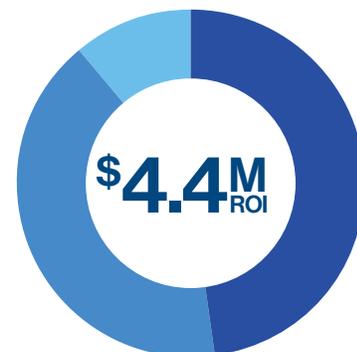
**6**

Automated stages to complete active release form

**78%**

Faster process on average

**Boosting efficiency, improving compliance and adding back to their bottom line**



**48%**

Saved in distribution and product controls

**41%**

Saved in clinical trial administration

**11%**

Saved in regulatory administration

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

### **3/ 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%), and not in the right order.

Working closely with DocuSign, BSC reinvented the process by using DocuSign smart questionnaires 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.

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

**Kevin Clark**  
Manager of Global Clinical Operations

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#### **About DocuSign**

DocuSign helps organizations connect and automate how they prepare, sign, act on, and manage agreements. As part of the DocuSign Agreement Cloud, DocuSign offers eSignature: the world’s #1 way to sign electronically on practically any device, from almost anywhere, at any time. Today, more than 537,000 customers and hundreds of millions of users in over 180 countries use DocuSign to accelerate the process of doing business and to simplify people’s lives.

**DocuSign, Inc.**  
221 Main Street, Suite 1550  
San Francisco, CA 94105

[docusign.com](https://www.docusign.com)

**For more information**  
[lifesciences@docusign.com](mailto:lifesciences@docusign.com)  
+1-877-720-2040