CASE STUDY

KDG
KeystoneDental**Group**

Keystone Dental Saves More Than 1,000 Labor Hours Per Year with AssurX Complaint Handling and FDA Reporting

AssurX

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Manager of Business Intelligence
Keystone Dental

OVERVIEW

As an FDA-regulated company, Keystone Dental recognized the need to move beyond paper-based complaint handling processes that were hurting efficiency and increasing the complexity of reporting. By automating complaint management with AssurX, Keystone Dental was able to increase efficiency and accuracy while reducing the backlog of complaints and time to closure.

The Company

Keystone Dental is an innovator in dental implant solutions, offering a wide range of advanced dental implants, prosthetics, and biomaterials used by dentists and specialists worldwide. Due to stringent FDA regulations around complaint handling, the company needed a robust complaint management system that could keep pace with its growing product offerings while helping maintain compliance.

PAPER PROCESSES CREATE INEFFICIENCY AND SCALABILITY CHALLENGES

When Paul Juliano, Manager of Business Intelligence, joined Keystone , the company was still relatively new. Like many companies, they used a paper-based process to manage complaints.

As the company's product portfolio grew, so did the volume of complaints that needed to be managed in compliance with FDA regulations.

Not only was the process time-consuming in terms of the effort required to input, track, and analyze complaint data, it also created challenges around consistency and accuracy.

"Just looking at the volume and number of products that we had, it was an easy decision to move away from paper," says Juliano.

DEPLOYING AN AUTOMATED COMPLAINT HANDLING SOLUTION

After going through the vendor selection process, Keystone chose AssurX for complaint management due to its ease of configurability and its flexibility to adapt to the company's processes.

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Over time, the company has expanded its use of AssurX to include features such as MedWatch and FDA electronic complaint submissions. The AssurX complaint system integrates directly with the company's Oracle database to automate data collection and populate complaint forms with accurate, uniform data.

To ensure a smooth implementation, Keystone dedicated two full-time employees to oversee the AssurX deployment. Because complaints are regulated by the FDA, Juliano says it's essential to bring the right team members together for implementation.

"You need a project manager who understands what the regulations are and how they impact what you need to do, while also having an understanding of the technology," he says.

IMPROVING EFFICIENCY AND ACCURACY OF COMPLAINT HANDLING AND REPORTS

Since automating its complaint handling process, Keystone has seen significant improvements in efficiency and accuracy across its complaint management process.

Time Savings and Efficiency

One of the biggest wins came when Juliano recently identified an opportunity to automate high-volume tasks for a group that handles complaints from international distributors.

"Because of the way we're regulated and the processes that we follow, there are a lot of little steps that need to be completed for each complaint," says Juliano. He adds that the team was very excited when he told them the process could be automated.

"We created event hooks in AssurX based on form data that would code everything from the implant and assessment data to MedWatch forms that we submit to the FDA," he says.

That has resulted in several key improvements for the company. First, it eliminates several minutes the team must spend on entering data for each complaint, saving several hours a day and over one thousand labor hours per year.

Consistency and Accuracy of Reporting

The second improvement, he says, has been the consistency and accuracy of the data captured.

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"We're not having someone mistype a specific code or anything like that. It's all uniform," Juliano says.

That has also made reporting easier, since the team is able to group complaints that meet specific criteria without having to manually correct errors such as misspellings.

"It's saved them time, and it's also made the complaint process as a whole more streamlined," says Juliano.

Reducing the Complaint Backlog

Because of the automated complaint handling process, Keystone has seen an overall decline in the number of open complaints and the average time to closure.

"The time that complaints have been open has been going down consistently since our team has gotten better at using AssurX, as is the backlog of complaints," Juliano says. "That's a huge improvement for the team."

FINDING A TRUE PARTNER IN KEYSTONE'S QMS SUCCESS

One big factor in Keystone's success with the AssurX platform, Juliano notes, has been the responsiveness of the AssurX team.

"The personalized service that we get from AssurX is absolutely second to none," he says."

He points out that where other vendors often have [a revolving door of contacts], he's been working with the same AssurX team members for years. He compares this with other vendors that are replacing phone support with chatbots.

"Anytime I send a message to AssurX, I get a reply within minutes, and typically they're asking me if I want to hop on a call," he says. "It's truly a breath of fresh air."

ADVICE FOR COMPANIES LOOKING TO AUTOMATE QMS PROCESSES

One strategy Juliano recommends for companies looking to implement an automated system like AssurX is to start by getting your process down on paper, such as with a flowchart.

"If you can map out every part of your process before you start to implement, you're not going to paint yourself into a corner by making design choices that will limit you in the future," he says.

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AssurX

SEE ASSURX IN ACTION

He adds that the most important part is making sure you have a very clear understanding of the process outside of any technology, and that you have places to expand your process as needs change over time.

"You need to make sure your process is scalable so you aren't impacted when and if you have an uptick in complaint volume," says Juliano.

FUTURE PLANS WITH ASSURX

Keystone is currently exploring how to use AssurX's web services API to build an interface where users can directly submit complaint information, rather than having to send in paper forms.

"We want to create an electronic form that allows us to validate the complaint information and then send that data to AssurX automatically to create the complaint and all relevant subtasks and subforms," Juliano says.

He adds that every day he discovers new ways to use AssurX, whether it's adding new automations for the complaint process or even entirely different areas the company could use the software.

Document management is one key area where he hopes Keystone will expand its use of the AssurX system in the future. The biggest potential improvement he sees here would be the ability to collect signatures digitally rather than having to get manual approvals on documents.

As for why he recommends AssurX over other solutions, he says the flexibility of the product and its simple user interface are what really make it stand out.

"Pretty much everything is in HTML, so it's a technology that speaks to all different levels and skill sets," he says.

He notes that he was impressed with how quickly AssurX was able to create a mockup of the customer interface for submitting complaints in a short amount of time.

"It speaks to the ease of development of the product," says Juliano. "It's like having a Lego set—if you want to build a castle or even just a horse, you have the building blocks to do it. That's where AssurX's real strength is."