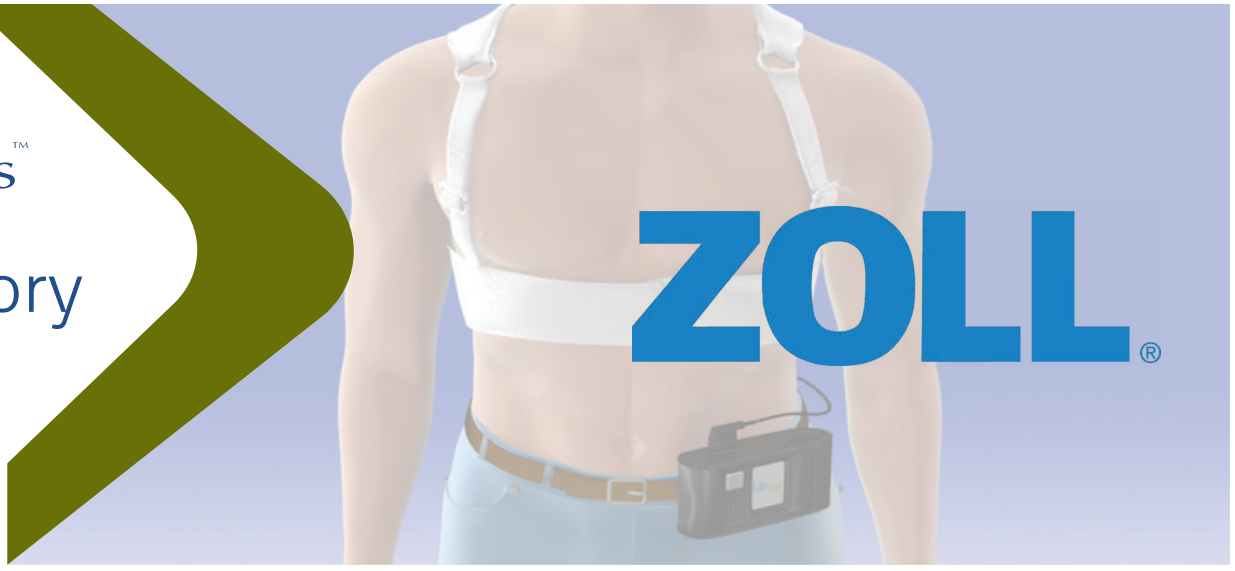
DocuClass™

Success Story

- Compliance
- Quality Assurance
- Workflow Processing



When Zoll Medical Corporation, a leader in medical products and software solutions that help advance emergency care and save lives, was searching for a solution to automate several of their FDA 21 CFR Part 11 compliant processes, they diligently sought a solution that could fulfill their complex needs and reduce the strain the manual process placed on their rapidly growing company.

Business Situation

Zoll's process handling of Non-conforming Material Disposition Forms (NMDF), Incoming Inspection (II), as well as Unsatisfactory Condition Report (UCR), was entirely paper based as well as labor intensive. Due to the fact that the current process followed FDA guidelines, there was no need to alter the process itself, but streamline it by automating and digitizing. In this process Zoll created a form in MS Access, and then routed the form with related documentation to relevant individuals for sign off. Once signed off, the appropriate steps could then be performed, like sending back a defective part, repair it, etc. The process from the point of creating the form to the sign-off could take up to 35 days (depending on the particular form).

Additionaly, for compliance reasons, the integrity of the individual records and the databases themselves had to be safeguarded with several layers of security.

Solution

After researching and testing other software solutions, ranging from Document Management providers to software marketed directly towards FDA compliance, Zoll decided on the DocuClass solution from CIMA Software Corporation; DocuClass met all their compliance and IT requirements and Cima collaborated with Zoll to adapt their software to Zoll's procedures and fully understood their process and requirements for compliance with FDA 21 CFR part 11.

Chiefly, Cima emulated the manual paper process with a robust Workflow that met FDA 21 CFR Part 11 requirements in particular the use of electronic forms (DC eForms) and application of electronic signatures with a forced double authentication.

Furthermore, the DocuClass solution meets the compliance requirements by providing several layers of document and access security as well as audit trails that track all activity within the system. Cima bolstered record security by designing their software to write to a second database with different authentication credentials.

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Solution - continued

Due to CIMA's unique flexibility to customize the solution, the eForms module is directly integrated with Zoll's MS Access databases. Zoll creates a form in Access, DocuClass picks up this form, uses the related information to generate and populate its own form, triggering the appropriate workflow process.

In order to comply with all required verification and system testing Cima first designed the entire system as a prototype. This ensured that once the solution went live, any unforeseeable issues were resolved. To overcome any issues, CIMA and Zoll's IT department worked seamlessly together, ensuring that all IT mandates where met. Since avoiding downtime during transition was critical for Zoll, the prototype ran parallel to the paper-based system for testing, once validated, the system went live without any downtime.

Benefits

Gene Partin, the Director of Quality Assurance expects to see significant savings in cost and labor. After the system has been live for only 2 months, the early results have shown an immediate improvement compared to the original paper-based system. Some early measurable results are the reduction of processing time of Material Disposition Forms (from 23 to 4 days) and other key metrics by up to 81%. This translates into reduced labor costs for scanning and filing; subsequent benefits are increased throughput of material and production as well as a significant reduction in paper consumption.

Overall the process is now entirely transparent with full insight of the process status at any given time. This should make future FDA audits run very smooth. Furthermore, Gene Partin expressed an increased confidence in the overall process, because of access and security controls, signatures with double authentication, and added transparency.

Future Expansion

After successful deployment, Zoll is currently evaluating a DocuClass expansion to cover more workflows with electronic signatures, future projects include web-based access locally hosted within their own network. As Zoll experiences rapid growth, they incur an increased strain on their QA staff, so there is an inherent need to further automate and streamline processes to reduce this burden. Gene Partin is looking forward "to continuing the very good relationship with Cima, because Cima was committed to make the project successful within the FDA 21 CFR Part 11".