RadBee

eQMS on Jira

Case Study

How RadBee helped one medical device organisation improve their regulatory compliance processes & save over $150,000 annually

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*"Everything is streamlined,
and the time savings have been incredible.
Now, compliance-related tasks are getting done
in 1/5th the time they used to take."*

**- Raymond,
Vice President of Regulatory Affairs and Quality**

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HIGHLIGHTS

The client is an in vitro diagnostics (IVD) medical device organization and a clinical laboratory located in Massachusetts.

CHALLENGES

- Reliance on an inefficient paper-based QMS to manage a large body of core documents
- Difficulty standardizing documents across multiple geographic locations
- High learning curve training new personnel to use QMS
- Risk of non-compliance whenever documents weren't up-to-date or approved in a timely fashion

SOLUTION

- Established a new document control module with easy user interface
- A training module to promote consistency and compliance
- Created a staging environment which allowed client to see new modules before implementation
- Migrated existing documents and approval forms (including historic ones) into the new system
- A managed installation of Jira within RadBee's Amazon Web Services (AWS) environment

RESULTS

- 75 users actively using new eQMS on a regular basis
- Over 700 documents processed through the new system between Feb–Nov 2017
- 500+ training records uploaded to the system across 51 training modules in less than a month
- 1/5th time needed for compliance-related tasks
- Resource cost savings of $150,000–200,000 annually

Our client graciously allowed us to share their story but requested anonymity. We're happy to respect their wishes. Client names have been changed.

CHALLENGES

A paper-based QMS which made it difficult to create standardised documents and train new personnel

When Raymond, our client's Vice President of Regulatory Affairs and Quality, first contacted RadBee he already had a backlog of challenges that needed solving.

First and foremost, he needed a way to standardise the documents and modules his team relied on.

> *"The standardisation process was a nightmare. We used to get a lot of internal complaints—'this document isn't approved,' or 'these instructions aren't clear,'"* **Raymond says.**
>
> *"Solving these issues was challenging because we were using a paper-based system. We were wasting a lot of time tracking down printed documents and making sure everyone had the latest revisions,"* **he adds.**

To make matters more complicated, the company has two offices—one in the US and one in Europe. Ensuring that both were using the same standardised procedures and meeting necessary compliance requirements was a daily challenge.

> *"We were often at a standstill over small things, such as a signature or an approval. When key people were out of the office, on holiday, or in a different time zone, we sometimes had to wait days for someone to sign a piece of paper,"* **Raymond laments.**

Other everyday necessities, such as internal complaint tracking, corrective action tracking, resolution, and personnel training, were also needlessly complicated by their paper-based quality management system.

"" *"Our biggest issue was probably training new personnel to use our quality management system. It was so complicated,"* **Raymond grimaces.**

"For example, we have hundreds of documents and each document also had an associated approval form it was linked with. Changing a process meant managing both simultaneously. Then you needed to track down printed copies to make sure they matched," **he elaborates.**
"These were the problems in a nutshell and they all stemmed from our paper system."

The final hurdle for Raymond and his team was that they'd tried using other quality management systems before, and none of them had met their needs.

"" **Raymond recalls,** *"We found that most off-the-shelf quality management systems are very rigid in implementation and difficult to program. You either can't change things after installation, or changing things is so complicated that you need to pay extra for additional training."*

Raymond needed a way to make compliance-related processes easier for his team; he needed an electronic quality management system he could trust.

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SOLUTION

A user-friendly electronic quality management system

Raymond examined his options thoroughly before deciding that RadBee and their suite of Atlassian-based products was the best fit for his company.

> *"We knew that we needed to switch to an electronic quality management system,"* **he explains.** *"We chose RadBee because they use Jira as their base software—and Jira is the biggest name in bug tracking in the software industry."*

> *"Atlassian is updating and improving their software all the time. In most other eQMS systems, upgrading the base software takes four to six months. But, on RadBee eQMS, which is based on Jira, it is easy to upgrade the Jira base software without losing functionality. And the upgrade is a piece of cake that can be done over the weekend,"* **he adds.**

Any fears he might have had about user-friendliness were quickly assuaged by RadBee's transparent implementation process.

> *"RadBee was very frank with us about the system settings, and they showed us how to customize it so we can easily change the workflow if needed,"* **Raymond says.**

> *"Plus, they were always happy to help,"* he adds. *"If we ran into problems, their team was ready to help. If a particular solution didn't work for us, they came up with an alternate proposal. If we had questions, they had answers. That kind of support is invaluable."*

To give Raymond even more peace of mind, RadBee agreed to install Jira onto their own managed environment on Amazon Web Services (AWS). This system has continued running without any downtime ever since the first production day.

Migrating controlled documents

To Raymond's relief, implementing the new quality management system was fast and painless. RadBee took care of the entire process in three to four short months.

> *"Implementation was very quick and straightforward,"* **Raymond says.** *"We gave RadBee our paper system and a flowchart of how we wanted the electronic system to behave, and they made it happen. It was by far one of the smoothest software system implementations we've ever done."*

The first thing RadBee did was create a customised document control module that would standardise their client's controlled documents into one easy process.

> *"Our document approval forms were very specifically laid out, detailing changes made with each revision as well as a big picture look at the possible impact from a product risk management perspective,"* **Raymond explains.** *"RadBee created a new process for us that ties all these crucial elements together into one document online."*

After creating the module, uploading the company's documents took practically no time at all.

> *"It only took us two days to upload all of our documents up and online,"* **Raymond marvels.** *"The old documents were uploaded into the new system on a Sunday, we tested it on a Monday, and the system went online on a Tuesday."*

The resulting system has already made day-to-day operations for Raymond and his team far smoother.

> *"Now, we can easily track where a document is at any given point, view attached documents, and update our procedures instantly if needed,"* **he adds.**

And, best of all, Raymond knows that his company is meeting compliance requirements better than ever before.

> *"Meeting compliance standards is the most important thing for us,"* **Raymond says emphatically.** *"RadBee's software development process and our organisation's validation process made sure the new system met all compliance requirements. We're very confident in our new system."*

Customised training modules

Once the new electronic quality management system was up and running, the final step was to develop a solution that would solve Raymond's training challenges.

To do this, RadBee created a custom training module extension that could be added to their client's quality management system.

" *"RadBee helped us create a new training management module in under two months from start to finish,"* **Raymond says.**

As of the end of 2017, 75 employees have access to the electronic quality management systems and rely on it daily.

And, in less than a month, Raymond and his team have added more than 500 training records to the system—a testament to how desperately they needed this system.

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"Our new electronic quality management system is so efficient, and implementing it was by far one of the smoothest software system implementations we've ever done."

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RESULTS

$150,000+ annual savings in resource costs & 500% more regulatory compliance efficiency

Raymond noticed the difference between his old paper-based system and his new electronic quality management system immediately.

> *"Getting a signature used to be difficult,"* **he reminds us.** *"With RadBee, they just log into their computer, read the document and approve it. The issue is solved right away. And the system is compliant with electronic signature regulations and directives, which is an added plus."*

And while Raymond expected to save some time by switching to the new system, the results have exceeded his expectations.

> *"Everything is streamlined, and the time savings have been incredible,"* **Raymond emphasizes.**
> *"Now, compliance-related tasks are getting done in 1/5th the time they used to take—that's a 500% increase in efficiency."*
>
> *"If you were to translate that into resource-saving terms, RadBee's simple system has replaced two full-time resources. From a cost saving perspective, it's probably saved us between $150,000–200,000 per year,"* **he adds.**

On top of these savings, Raymond's happy to know that his company is meeting necessary compliance regulations more efficiently than ever before.

> *"We don't print documents anymore. Now, if we need a document, we go into RadBee, pull it up, and work from an electronic copy. Everyone's using the same documents, all the time,"* **he says.**
>
> *"It's saved us time and money."* **Raymond pauses.** *"And paper,"* **he laughs.**

In less than a year, over 700 documents have been processed through the new system—and Raymond has tangible evidence that his team finds the new system easier to work with.

> *"We've had no more internal complaints; there's no better indicator that our new system is working,"* **he says.**

> *"We have people with high school diplomas using the same system as people with advanced PhDs. They're all using it in the same manner, and finding the documents they're looking for and the processes they need to know,"* **he elaborates.**

Raymond's collaboration with RadBee has been so positive, in fact, that he's become a repeat customer. As of this study, they're already in the process of creating three new modules.

And Raymond is more than happy to share his experience with the electronic system that forever improved his company's quality assurance processes.

> *"We deployed our new quality management system from start to finish over a few months, for a fraction of what other systems cost,"* **he says**. *"RadBee has solved our current problems and set us up for future success."*

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Streamline your quality assurance processes and controlled documents.

**RadBee makes Quality Management easy, by standardising
and improving all of your regulatory processes
with the help of Jira and Confluence.**

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* Jira is a registered trademark of Atlassian

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