



ORIC Pharmaceuticals, Configurability is the Cure

THE COMPANY



ORIC Pharmaceuticals was established in 2014 with a bold vision of Overcoming Resistance In Cancer. The company's mission is to discover and develop innovative therapies that benefit patients with cancer, including making existing therapies more effective over a longer period of time.

Located in San Diego and South San Francisco, ORIC engages in rigorous, hands-on work in pursuit of that mission. They maintain an unwavering focus on improving the lives of patients by tackling the problem of cancer treatment resistance.

THE PROBLEM

As an FDA regulated company, ORIC is required to maintain strict controls with respect to quality management and employee training. Like many rapidly growing startups, they initially developed their QMS processes around spreadsheets, paper documents, shared network folders, and other manual systems. Unfortunately, those processes quickly grew unwieldy, wasting significant time and leading to considerable frustration among the company's employees.

Melody Puckett, ORIC's Senior Manager for Quality Assurance, was charged with finding an eQMS solution that could help the company improve the efficiency and effectiveness of its quality management processes. Puckett is a veteran in the

QMS space, having worked extensively with established vendors like Veeva, MasterControl, and Documentum. She has taken the lead in multiple eQMS implementations, so she clearly understands the challenges and pitfalls that can arise throughout the process.

Puckett and her team wanted to look beyond the "usual suspects" within the eQMS space to find a software solution that could conform to their unique way of doing things. In fact, widespread market adoption was the least important factor in their list of seven key criteria. Above all, ORIC wanted a product that was highly configurable.

"I can't tell you how many different times I have seen that a fundamental lack of flexibility has been a huge pro-

blem," Puckett said. "You can have the most well-known, most expensive system out there, but if you don't have the ability to configure it to meet your unique needs, it just sits there unused."



THE SOLUTION

The ORIC team created a prioritized list of selection criteria to guide their decision. As noted, configurability was at the top of that list. “We really didn’t want a so-called ‘out-of-the-box’ solution,” Puckett commented.

“A lot of eQMS vendors are pushing what they call ‘out-of-the-box configurations,’” she added. “They tout those configurations as the ‘industry standard,’ – but regardless of whether you’re in a small company or a very large one, – nobody ever has the same workflows. The regulations may be the same, but even if you have the same system across multiple companies, nobody’s configuration or workflows are exactly the same. It really bothers me when I hear salespeople tell me that their out-of-the-box configuration is the best for my company.”

ORIC’s executive management team was very much on the same page. Having been through a number of eQMS rollouts themselves, they understood that an out-of-the-box configu-

ration can take three to four months to validate, another six months to align with the company’s internal processes, and even more time to retrain employees. Their experience told him that rigidly defined eQMS configurations simply don’t work in the real world.

“Configurability was our number-one priority, because we knew it would help us avoid wasted time, eliminate the need to restructure our business processes, and prevent our users from having to deal with frustrating workarounds.”

said Puckett

Cost was also a key factor, of course. Many of the established players in the eQMS space offer reasonable licensing costs for entry-level customers, only to increase their fees quite substantially as the number of users grows. ORIC wanted a more scalable, affordable pricing model that could help them to avoid that kind of sticker shock.

The ORIC team also wanted a system that could accommodate the company’s growth as they expand, and as their business processes become more complex. “I’m not really a big fan of

having multiple eQMS systems or multiple platforms,” noted Puckett. “When it comes to validation and keeping track of multiple systems as you grow, it becomes quite cumbersome from both a quality and an IT validation standpoint. We were definitely looking for a system that had a large number of QMS models that we could roll out over time.”

Ease-of-use was high on ORIC’s priority list as well.

“If users can’t get in and figure out how to do their trainings,” noted Puckett, “or how to route their documents without extensive instructions, then they’re not going to want to use it in the first place.”

Aesthetic appeal was also important. Melody Puckett admits this might not sound like a big deal, but when she saw some of the complex, overcrowded screens within some eQMS products, she intuitively understood it would be a turn-off for many users.



THE RESULTS



After spending countless hours viewing demos, talking to industry peers, and exploring the detailed capabilities of various eQMS platforms, Melody Puckett and her team chose the Intellect QMS platform. They loved the product's design philosophy of "extreme configurability," – but Intellect's simple pricing model, capacity for expansion, and white-glove service were also important factors. Puckett also noted that Intellect is the only eQMS product she's seen that offers Periodic Review as a built-in workflow.

Quality Assurance Specialist Brooke Jackson was a key player in ORIC's rollout of Intellect QMS. She arrived at the company with previous experience using Intellect, so she had unique insights to offer throughout the implemen-

tation process. With the assistance of Intellect's white-glove service team, Jackson, Puckett, and others at ORIC were able to successfully implement document control and training applications that conform to the company's unique requirements.

"With the launch of our document control and training applications," Jackson said, "we have eliminated ten separate spreadsheets. With just these two processes, we anticipate a reduction in cycle times and errors, as well as a cleaner and more efficient system overall. So far, we have not had to change any of our internal processes, our document numbering, or any of our SOPs aside from the procedures that pertain to the use of the software itself."

Looking to the future, – Puckett, Jackson, and the rest of the ORIC team see a host of opportunities for further improvement. They plan to implement Change Management next, followed by phase 2 of their Document Management rollout. Deviation management, CAPA, EHS, and a host of other modules will add further value as the team at ORIC take full advantage of the Intellect platform's capabilities.

