propel

CASE STUDY

ASP

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– Brent Lewis, Director of Enterprise IT Quality and Compliance Systems at **ASP**

ABOUT

Advanced Sterilization Products (ASP) is a global leader in developing innovative sterilization and infection prevention products. Healthcare facilities around the world rely on sterilized products and equipment to improve patient care and mitigate infections. Since its founding in 1986, ASP and its 1,500 employees across the globe have focused on providing the best-in-class infection prevention products and solutions for customers and their patients worldwide.

CHALLENGE

Following Fortive's acquisition of ASP from Johnson & Johnson, ASP had one year to deploy its own technology stack to run the business. As part of the process, ASP recognized the opportunity to improve their business processes. Under J&J, ASP's quality management processes and capabilities were spread across multiple systems. "Through this transition, we found that over 6 enterprise-level applications could be replaced with a single solution," said Brent Lewis, Director of Enterprise IT Quality and Compliance Systems at ASP.

ASP's individual systems were all considered industry "best of breed" in their respective functions, but ASP wanted to explore getting this best of breed functionality across the entire QMS in a single solution, as well as one that would help them thrive and support the global quality management system.

"We had solutions that were fine-crafted for their specific function, such as specific PLM or training systems. What we didn't have was a solution that did them all. We desired a system that did everything we needed from our previous solutions plus met the high demand for our global business needs for compliance and top quality," said Lewis. "

"We wanted an interconnected landscape that had our QMS connected with our LIMS system and then tied to our ERP system in SAP," continued Lewis. "We needed the part master managed in the PLM for a consistent data record and any nonconformances from our QMS tied to any lots and batches that could then be identified and from there logged in the ERP system. We also needed a complete integration from Salesforce Service cases to track and manage customer complaints."

Additionally, as a medical device company,

ASP complies with FDA regulations to ensure the safety of its customers and patients. They needed a platform that enabled them to communicate events with the FDA digitally through the FDA's webtrader portal without requiring re-keying of any information captured in the complaint investigation process. "Because of the volume of our install base and the limited time we have to investigate and report complaints, it can be extremely challenging to ensure complaints are investigated, documented, and reported in the required timeframes without any room for error. We needed a solution that allowed us to end-to-end take that data from our customers and evaluate it swiftly and get it reported accurately without it being double-keyed from a secondary system," said Lewis.

"For us, PLM is core to our QMS. We don't separate PLM from QMS. PLM is an integrated part of our Quality System and we required a solution that offered both."

Brent Lewis, Director of Enterprise IT Quality and Compliance Systems

ASP needed an interconnected platform that helped them swiftly intake, investigate, assess, report, and track all aspects of the complaint process, alleviate software overhead costs and gain organizational efficiencies, all while maintaining compliance and quality for the business. ASP needed a platform that empowered leaders to make rapid decisions, address dependencies, and mitigate risks all while removing themselves from Johnson & Johnson's legacy systems in the short timeline they were given.

SOLUTION

ASP chose Salesforce for CRM, SAP for ERP, and Propel for QMS and PLM. In addition to meeting ASP's targeted timeline, the combination of Salesforce, SAP and Propel provided ASP with an integrated solution for all of their product and quality information, effectively integrating customer, supplier and product data across their entire value chain.

Propel is the hub for all ASP quality system data and records; including product lifecycle management, supplier management, QS training, document control, CAPAs, nonconformances, calibration & maintenance, customer complaints, and audit observations.

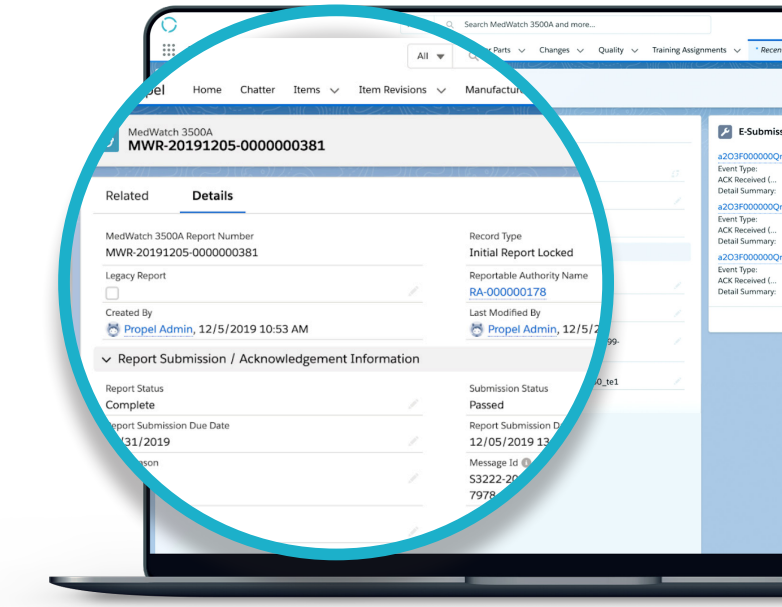
"The speed at which Propel can innovate is really incredible. It was a partnership and not just another sale with them."

Brent Lewis, Director of Enterprise IT Quality and Compliance Systems

In their search, ASP approached the platform selection process using a points system. "We needed one platform that could do it all," said Lewis. "Propel was the clear champion coming ahead in all of the numbers. It had everything we were looking for when we put it into a quantitative state," he added. "Some of these out-of-the-box solutions would have met the aggressive one-year deadline but it would have forced us to change our process. We needed a solution that could adapt to us versus us adapting to them. With Propel we can mistake-proof our processes to gain business efficiencies and at the same time ensure compliance," Lewis added.

Furthermore, the other platforms considered did not offer ASP a complete interconnected PLM and QMS system in one platform, nor one that tightly integrated with SAP or Salesforce. "For us, PLM is core to our QMS. We don't

separate PLM from QMS. PLM is an integrated part of our Quality System and we required a solution that offered both," said Lewis.



Propel provides ASP their much-needed unified platform with full PLM functionality and the ability to tie the bill of materials (BOM) to their quality records. "Thanks to Propel we have all of our design controls around part quality in one system," he added. "This helps us ensure specifications are linked to respective parts and part lifecycles can be used to track the design evolution from engineering to production. We can associate suppliers to the parts that are qualified, giving us end-to-end connectivity. The PLM solution being part of the QMS was core to us picking Propel. We can place our process in workflow controls to facilitate compliance."

"Propel is fast to deploy, easy to use and has the flexibility to support our processes in a single solution."

Brent Lewis, Director of Enterprise IT Quality and Compliance Systems

Because Propel is completely built on Salesforce, ASP is utilizing the fully integrated Propel platform to tie their quality information to the product record throughout the lifecycle from engineering to marketing and sales to manufacturing to customer service and complaints, allowing for R&D full end to end visibility and feedback from the product lifecycle. "Salesforce is a tool that businesses are choosing to use and it is actually enabling a lot of functionality and efficiencies in the business so when you put a QMS inside of that, you get the usability and the UI which gives you a solution people actually want to use, not one that they have to use," said Lewis.

Propel's feature-rich product success platform includes Digital FDA Submissions, allowing ASP to create and submit MedWatch 3500A

adverse event forms electronically within Propel. Propel's Digital FDA Submission capabilities help regulatory and quality teams easily and efficiently manage the entire process with FDA within one single platform. Propel removes the work of double keying or worry around possible transcription errors. "It's fantastic." said Lewis. "Electronic adverse event reporting is the latest advance in Propel offering end to end capability connecting early design to customer feedback and regulatory reporting. This enables incredible insight intelligence and ensures compliance for our business," he added.

Throughout the entire process, Propel worked with ASP to ensure that the platform was tailored to fit their business goals. "This wasn't another sale with Propel. It was all a conversation around how we can work best together and how Propel wants to partner with us to help our business. And also take feedback and evolve the Propel product. The speed at which Propel can innovate is really incredible. It was a partnership and not just another sale with them," he added.

RESULTS

By choosing Propel, ASP was able to consolidate all 6 enterprise QMS applications into one fully integrated PLM and QMS solution. “With Propel we implemented over ten years of QMS innovation in six months,” added Lewis. “Propel is fast to deploy, easy to use and has the flexibility to support our processes in a single solution.”

Propel was a key solution in enabling ASP to meet their required timeline of standing up an entirely new technology stack within one year. Since Propel is built on Salesforce, ASP was able to launch CRM, PLM and QMS on a single platform within eight months. Integrating the Salesforce platform with SAP also allowed ASP to create a true integrated platform with single sources of truth and eliminate double data entry.

“Propel being in the Salesforce ecosystem was very unique and exactly what we needed. We can take the part metadata, then have it flow to our ERP and then to our service calls and then have our sales and marketing teams leverage that same data across the board. And because 80% of our complaints are triggered from Salesforce Service cases, we needed close connectivity there as well.” Propel helps ASP achieve true connectivity from concept to customer by tying product, customer and quality data together in one platform.

Increasing product complexity, service-based models and globally interconnected supply chains need to be carefully managed to ensure quality and compliance. Propel’s product success platform seamlessly connects all product, customer, quality, and service records to provide a true closed feedback loop that helps companies like ASP get products to market faster, maximize customer satisfaction, and comply with all regulatory agencies. Propel delivers an innovative, cloud-based, single-platform approach to producing safe, high-quality products for ASP’s customers and their patients. “The technology that’s in Propel comes from the legacy of other companies that came before it. Except it’s been taken to the next level and packaged in a cloud solution,” said Lewis. Because of the technology behind Propel, ASP is able to easily configure the platform to fit its processes and help them ensure compliance, contextual collaboration and high quality throughout the product lifecycle. “Propel is bringing efficiencies and insights across the enterprise that we couldn’t have without it.”

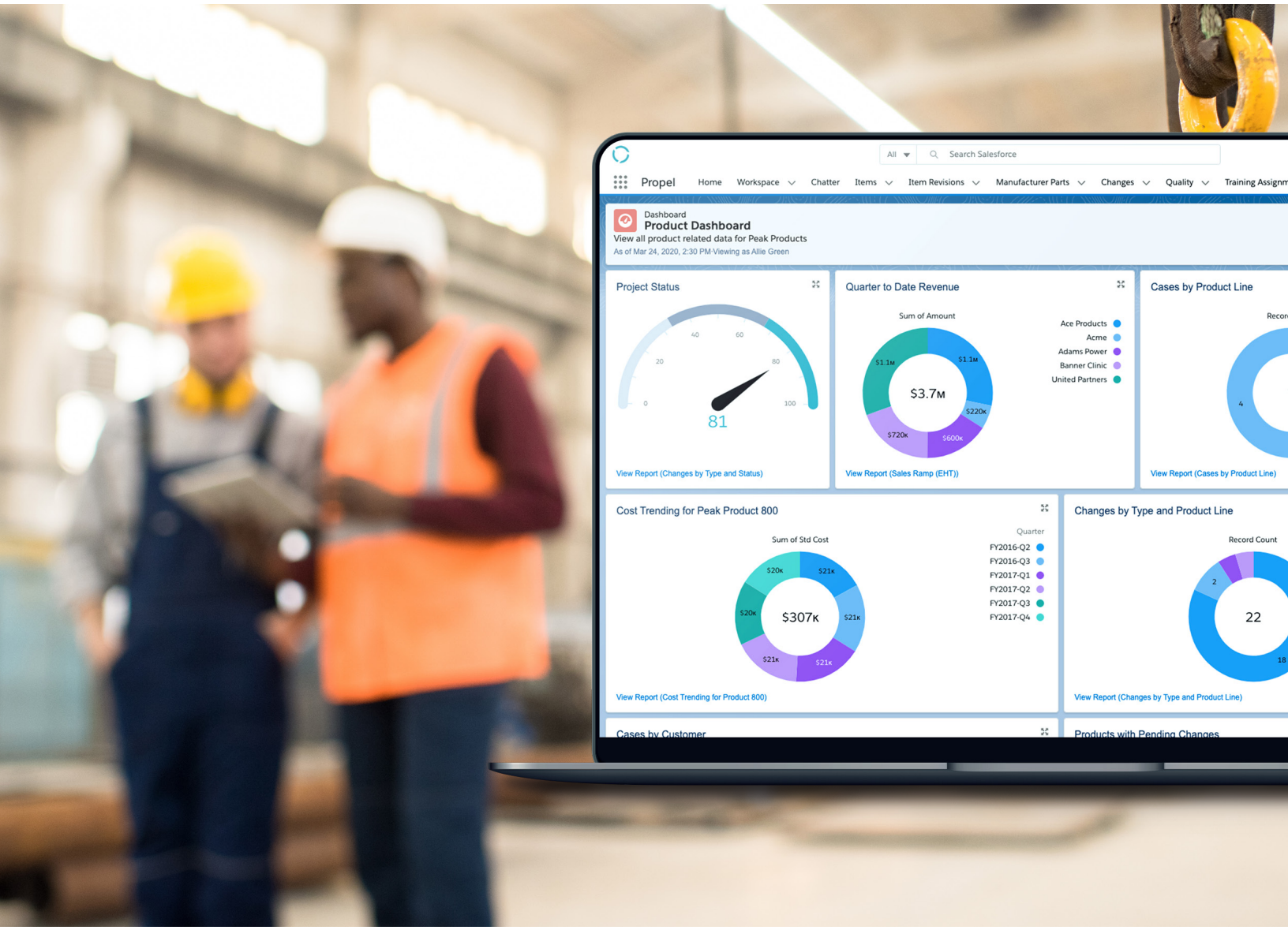
PRODUCT SUCCESS DELIVERED

CHALLENGE

- Required separation from J&J systems within one year
- Difficult to manage 6 different quality applications
- Long timelines required to close FDA warnings
- Needed a tool that met high demand for compliance and top quality
- Required “best in breed” application that interconnected with existing tools

SOLUTION

- Integrated PLM, QMS and CRM platform
- FDA connectivity with Medwatch Form 3500 submissions
- Quality incorporated into product design process
- Feature rich solution with end-to-end visibility from design to customer
- 10 years of QMS innovation in 6 months



Propel helps companies achieve product success by connecting the people, systems, and processes needed to deliver products from concept to customer.

Learn more and watch a guided tour at propelPLM.com

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