

CASE STUDY



Goodier, Skincare Industry's Precision Formulation Leader, Relies on AssurX for Quality Management Compliance





Beauty is more than skin-deep for [Goodier](#), a leader in R&D innovation, precision formulations, product development, and the manufacture of cosmetics and skincare products.

Cosmetics are regulated by the U.S. Food and Drug Administration but the agency does not approve them. It means the FDA may take action against a cosmetic in the market for safety reasons, including cosmetic products that are adulterated, mislabeled or misbranded. As an FDA-registered company, Goodier boasts of its rigorous compliance with Current Good Manufacturing Practice (CGMP) regulations.

Based in Dallas, Texas, the company has been developing and manufacturing cosmetics and over-the-counter skincare solutions since 1922. It is well-known for its innovation and advancements in formulation science.

In 2021, Gryphon Investors acquired Goodier and Revision Skincare to further the mission of developing and delivering clinically-proven and highly-efficacious skincare products for consumers worldwide. Under Gryphon, Goodier has also boosted its contract development and manufacturing capabilities.

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QMS administrator
Goodier

BIGGEST EQMS CHALLENGES

Not too long ago, Goodier was using a manual quality management system (QMS).

“We had a paper-based document management process, and a lot of documents were misplaced,” recalled Jose Castro, Goodier’s QMS administrator. “We had to chase people down for their signatures. When people were out of office, we had to wait for them. Sometimes a document is just forgotten.”

Manual document management was not easy even when the company occupied just one building. It became doubly difficult once the company expanded into two additional buildings.

The paper-based system was not only inefficient, it also led to FDA Form 483 observations during an audit. A 483 lists a manufacturer’s deficiencies, the most common of which pertain to quality documents. In the case of Goodier, paper-based training and quality documents were “all over the place” and not readily accessible back then.

The company was compelled to switch from a manual system to an eQMS. “We wanted a system that would contain all of our documents. We also needed the capability for electronic signatures, so we don’t have to chase people anymore,” added Castro.

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IMPLEMENTING ASSURX EQMS

In 2018, Goodier dramatically improved its quality management processes when it started using AssurX. Castro, who used to be a document control specialist, was promoted to QMS administrator upon the switch to AssurX.

Goodier implemented the AssurX [document management](#) solution first, followed by [training management](#), and then [change management](#), which the company configured to its specific requirements. “The implementation of document management took up a lot of our time because we had so many documents,” explained Castro.

Although he’s the sole dedicated QMS person, Goodier’s implementation proceeded successfully, thanks to close partnership with AssurX’s Professional Services team. He complimented the team, describing it as top-notch. “There were no unexpected issues. The transition was very smooth,” Castro recalled.

However, automation of the paper-based system entailed a huge adjustment for users. “Our users were used to paper. We devoted the first couple of years to get everybody trained properly and get all of them accustomed to the system,” said Castro. “They liked the efficiency once they got used to it.”

BENEFITS OF ASSURX

Under AssurX, document management became easier and faster. The [AssurX eQMS platform](#) facilitates management of the entire document lifecycle, from document creation to obsolescence. It automates routing, review, revision, and approval of documents, making it easy for supervisors and users alike to perform their tasks.

AssurX provides a centralized, secure repository for convenient search and checking-in/checking-out of documents. Users throughout the enterprise can now find all quality-related files and records within the system. They no longer have to chase people down for signatures because all documents-based tasks are automated.

When approvers are not around, the escalation feature means the task moves on to another person who’s authorized to make the approval. “We’ve become more time-efficient. We don’t have to go from one building to another anymore. We can just go online to check document statuses,” said Castro.

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AssurX's electronic signature capabilities comply with 21 CFR Part 11 requirements, including transparency and integrity. AssurX provides a time-stamped archive of all signatures and secures them from any unauthorized use, including modification, transfer, deletion or duplication.

Under AssurX, Goodier was able to automate its CGMP training across the company, including testing. The improvement was immediate and enormous. "Now we can track who's been trained, who's taken the test or not," explained Castro.

CONCLUSION

What's next for Goodier's eQMS? The company is working on implementing [deviation management](#), [nonconformance management](#), and [audit management](#) solutions. It's looking into a possible integration of the eQMS with business processes.

Castro, who has been with Goodier for almost two decades, said he would recommend AssurX to other regulated companies, especially those that require a highly configurable system. He cited the change management solution as an example. "We wanted a process that's about as detailed as you can get to meet our exact needs," he said. That kind of configurability is what differentiates AssurX from other solutions and drives Goodier to expand its usage of the software.

Castro emphasized the importance of having a strong partnership with AssurX, including his participation on the Customer Advisory Board (CAB), which means he provides input on AssurX's product development process. "AssurX is always there for me and always finds the answers for me," he concluded.

ABOUT ASSURX INC.

With decades of expertise built into our extensive quality management and regulatory compliance software, the AssurX Quality Management Software Platform helps companies maintain quality and compliance standards, streamline workflows, and better manage any enterprise. Our configurable software and understanding of users' needs produce a unique system that easily adapts and scales as a customers' business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. [Learn more.](#)

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