Dot Compliance

CASE STUDY

Driving CDMO Excellence: Dalton's Journey to an Integrated Quality Platform

The Challenge: Beyond the Incumbent Cloud

As a sterile manufacturing CDMO, Dalton Pharma Services (Dalton) requires high-performance quality systems to support its 150 employees and global client base. While already utilizing a cloud-based QMS, Dalton determined that their evolving operational requirements necessitated a partner better aligned with their technical needs and long-term growth.

Following significant organizational shifts at their previous provider, the team experienced technical hurdles, including unresolved software bugs and inconsistent support responsiveness.

Saif Mia, Associate Director of IT Informatics, noted that these issues "added up over the years."

Beyond service levels, Dalton identified a need for expanded functionality that was not integrated into their incumbent system, specifically regarding Asset Management and Electronic Protocols. To improve operational efficiency, the team sought a solution that would eliminate manual data handling and provide a more cohesive environment for managing their quality processes.

The Solution: A Seamless Transition to Dot Compliance

Dalton chose Dot Compliance to unify their quality, asset management, and electronic protocol needs into a single platform.

During the implementation, Dalton's team worked with "power users" to identify pain points and optimize workflows rather than just migrating them. "If we found some things redundant, we made them more streamlined and shorter in Dot Compliance," Mia noted.

Key technical wins during the rollout included:

- **Automated Workflows:** Redesigning Change Control and Investigations to remove manual steps.
- **Digital Calibration:** Moving from paper-based forms to electronic protocols within the Asset Management module.
- **Unified Data:** Consolidating QMS and asset management to ensure that equipment deviations are tied directly to the quality record.

DALTON Pharma Services

Industry Pharmaceuticals / Contract Development and Manufacturing (CDMO)

Location Toronto, Canada

About

Dalton Pharma Services is a leading North American Contract Development and Manufacturing Organization (CDMO) providing integrated drug discovery, development, and manufacturing services. Dalton specializes in sterile filling and finishing, API manufacturing, and formulation development. With over 30 years of experience and a team of approximately 150 employees, Dalton supports global pharmaceutical and biotechnology clients through every stage of the drug development cycle, maintaining rigorous compliance with Health Canada and FDA standards. For more information, please visit **www.dalton.com.**

Despite migrating a tremendous amount of data during an active Health Canada audit, the transition remained on track.

Huyen Bui, Senior Specialist for QMS and Lab Informatics, highlighted the support they received:
“Implementation went really smoothly. The professional services team was on their game. Even during our audits, they were there. If I sent an email, they would get back to us immediately. I was very impressed with that. It was a tremendous amount of data, and they were really responsive when it came to giving us what we needed or changing anything.”

The Benefits: Visibility and Time Savings

Since going live, Dalton has seen immediate improvements in day-to-day efficiency. The most significant change for end-users has been the introduction of personalized home dashboards.

These user-friendly tiles allow employees to see exactly what records they are responsible for without running manual reports.

Bui stated, "Everything’s connected. Everything’s traceable. It’s really easy to work with."

The shift to digital asset management has also eliminated the paper trail delays common in CDMO environments. Previously, calibration forms had to be physically printed and issued by QA, a process that risked lost documents and wasted time.

"The time saving is in not having to physically print it out," Mia said. "Now, everything is online. You can find the record right away within seconds and see who is responsible."

For the 150 employees at Dalton, the familiar Salesforce UI meant the transition was smooth. Within a month of the rollout, the initial new system confusion had quieted, and even light users found it easier to navigate their training and documents.

Looking Ahead: Expanding the Digital Footprint

For Dalton Pharma Services, the transition to Dot Compliance builds the foundation for a fully integrated digital enterprise. The team is already planning to automate environmental monitoring data and streamline supplier management through direct ERP integration. Dalton also intends to launch a transparent community portal to improve client collaboration.

With these initiatives, Dalton continues to prioritize operational excellence and patient safety as they grow.

"If you want a very comprehensive eQMS system with different streams of requirements, quality, asset management, and electronic forms, this is a very good platform."

Saif Mia,
Associate Director of IT Informatics