

Surmasis Pharmaceutical optimizes quality & compliance with Dot Compliance Xpress

The Challenge

Surmasis was managing their document and training management using a paper-based system. Unfortunately, this left them exposed to compliance risks. Other QMS systems previously piloted were not Part 11 compliant or they required advanced training for system administrators and software developers. They needed a simplified electronic quality management system (eQMS) to provide compliance but also visibility into their quality data, real time, with dashboards and reporting capabilities.

The Solution

Implementing a pre-validated, off the shelf eQMS was their top priority. Dot Compliance's cloud-based, ready to use quality and compliance management system with preconfigured best practices enabled Surmasis to deploy their processes within 30 days and within budget. To avoid any customization, they were able to leverage the capabilities of protocols (electronic forms) which added critical data to records without having to generate required fields and revalidate their QMS.

Next Steps

Surmasis continues to take advantage of Dot's extensive set of quality processes by successfully deploying Changed Control, Complaints and Corrective and Preventive Actions (CAPA) solutions as well as maintenance activities. Currently they are working on Electronic Batch Record trials and design. Next on their schedule is to roll out Supplier Quality, Audits and Quality Events processes.



Employees

450+

Industry

Medical Device

Location

USA

About

Surmasis is a pharmaceutical contract manufacturer with a passion for bringing ideas to life. From process design, to manufacturing and logistics, the desire to deliver innovation is the driving force behind everything they do.



"The support and responsiveness of the Dot Compliance team makes me feel like a valued customer. I have already seen improvements in the product based on earlier feedback."