

Implementation of 21 CFR part 11 compliant Regulatory Information Portal for a pharmaceutical organization

About the client:

The client is one of the fastest extending pharmaceutical companies engaged in developing, manufacturing, and marketing a broad range of pharmaceutical products globally.

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Business Problem:

- · Manual gathering and collation of data from various sections within the regulatory department
- · Lack of single platform to manage regulatory data
- · Increased waiting time in receiving answers to regulatory queries

Solution:

- Develop and implement single platform to manage regulatory information.
- Implement 21 CFR Part 11 compliance.
- Implement intuitive exploration of published regulatory records allowing expedited response to regulatory queries.

Tools and Technologies:

ASP.NET, Knockout, SharePoint (SQL Server), jqplot, itextsharp(dll), Microsoft openxml SDK Healthcare & Life Sciences