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Shaping Healthcare Possibilities

Accelerating REMS health cloud implementation for a healthcare Life Sciences organization

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Client Profile

The client is an American company that specializes in the distribution of pharmaceuticals at the retail level, as well as the provision of health information technology, medical supplies, and care management tools. The company works with various health care organizations to enhance the health of their businesses, helping them control costs, develop efficiencies, and improve quality.

Background

According to the U.S. Food and Drug Administration (FDA), a Risk Evaluation and Mitigation Strategy (REMS) is a federally mandated drug safety program that may be required for certain medications with serious safety concerns to ensure that the benefits of the medication outweigh its risks. Drugs that are subject to REMS control must meet certain requirements with respect to how their manufacturers manage communications and interactions between patients, health care providers, pharmacists, and health care settings. In this regard, the client offers REMS services to assist pharmaceutical companies in complying with FDA drug development, launch, and ongoing safety reporting requirements while ensuring that patients have appropriate access to drugs and biologics. To support this effort, the client needed a contact center application to manage a REMS program for the drug Xiaflex, which is indicated for the treatment of adult patients with Peyronie's disease (PD) and Dupuytren's contracture (DC).

INDUSTRY	**HOW WILCO SUPPORTED**	**SALESFORCE TOOLS UTILIZED**
Healthcare and Pharmaceuticals	REMS Health Cloud Implementation	Health Cloud

The Challenge

- The client desired to move a Risk Evaluation and Mitigation Strategy (REMS) application from a custom-developed full stack application to the cloud. To do so, they had to ensure that the application met REMS standards and 21 CFR part 11 requirements.

- The application was required to meet several high-level requirements. These included the ability to receive forms by fax or mail, store the forms as images, and attach the images to the appropriate stakeholder records within the application. It also needed to provide tracking capabilities for all inbound and outbound communications for stakeholders who interacted with the program.

- In addition, the application needed to be able to enroll Healthcare Providers (HCPs) and Healthcare Settings (HCSs) into the REMS program and map provider affiliations to healthcare settings. It also needed to validate HCP and HCS enrollments by verifying that all required information was received and that required identifiers were provided and valid, such as the NPI, NCPDP, SLN, and DEA number.

- The application was also required to manage escalations, such as invalid identifiers, suspected noncompliance, duplicate identifiers, and sponsor escalations. It needed to capture potential adverse events, product complaints, and medical information for reporting to the manufacturer. Additionally, it needed to manage all REMS requirements for the PD indication and manage the distribution list for the DC indication. Finally, it needed to manage notifications related to enrollment, such as complete/incomplete notifications, as well as other notifications, such as enrollment expiration, cancellation, deactivation, re-enrollment, and affiliation changes.

The Solution

Wilco Source assessed the client's requirements and customized Salesforce Health Cloud to capture different stakeholder details, including Healthcare Providers (HCPs), Healthcare Settings (HCSs), Patients, Pharmacies, and Authorized Representatives (ARs) for the HCS. To meet the requirements of 21 CFR Part 11, a Salesforce object specific audit trail was enabled for all fields. The contact center application was integrated with zPaper for incoming and outgoing fax communications. zPaper allowed agents to view faxes as images in Salesforce and easily attach these forms/documents to stakeholder records. Standard Health Cloud data repositories captured stakeholder information, with cases created to manage enrollments, communications, and services. The application differentiated between enrollment, re-enrollment, safety event, service, and fulfillment cases. Dynamic Lightning forms would appear based on the unique combination of stakeholder, service type, and indication. The application handled complex validation rules and managed task queues for agents. Automated follow-up tasks were created based on the logic defined in task schedules. As per REMS requirements, the Salesforce application tracked every single status change, including the date of the change and who made it. The application was integrated with a data warehouse to track these changes for every single field. Enrollment summary data was accessible to users through historical snapshots. Over 80+ outbound communications were configured to be sent from the application automatically or manually upon user request. The application was integrated with third-party databases to validate NCPDP, NPI, SLN, and DEA identifiers.

The Outcome

- The contact center application built on Salesforce Health Cloud met REMS standards and 21 CFR Part 11 requirements. Wilco Source successfully helped the client manage REMS programs in the cloud. The data model designed for the Xiaflex program met all Xiaflex requirements and could be easily scaled to other REMS and non-REMS programs.

- The application facilitated a smooth program enrollment process for providers and settings and enabled agents to send out program-relevant communications in a timely manner. Agents were delighted with the Lightning capabilities and appreciated how easy it was to perform their daily operations in Salesforce compared to their previous application. By involving the application users in the change process and gaining buy-in from the leadership team through design discussions and demos, Wilco Source contributed to successful change management.

- The solution developed for the Xiaflex REMS program was implemented quicker than the previous REMS application. THe project was delivered on time and within budget, enabling the client to meet their customer's deadline.

  - Contact center application met REMS standards and 21 CFR Part 11 requirements

  - Wilco Source helped the client manage REMS programs in the cloud

  - Data model for the Xiaflex program met requirements and could be scaled to other REMS and non-REMS programs

  - Application facilitated smooth program enrollment and enabled timely communication

  - Solution for the Xiaflex REMS program was implemented faster than expected and delivered on time and within budget.

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Thank You

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