Charter Global

CASE STUDY – Transforming Regulatory and Compliance Workflow for a Pharmaceutical Giant

A pharmaceutical company specializing in cancer and immunology drugs, aimed to streamline regulatory compliance, enhance the user experience, and reduce operational costs. Charter Global built a Pega-based solution ensured FDA compliance, and provided an intuitive user interface for prescribers, patients, and pharmacists. The scalable solution resulted in an impressive 500% increase in operational efficiency spanning 30+ countries. Charter Global's architectural transformation and expertise in Pega were pivotal in achieving these milestones.

About the Client

The client is a pharmaceutical company that makes cancer and immunology drugs. The major product is used in the treatment of multiple myeloma, and in certain anemias. The company is incorporated in Delaware and headquartered in Summit, NJ with total assets of $35B. The client has a vast medical product portfolio in pipeline and established medical products.

Project Goals

- Establish a regulatory and compliance workflow that can be sold as an industry solution to other Risk Evaluation and Mitigation Strategies (REMS) programs.
- Develop a foundational framework within Pega that is adaptable to specific configurations for medical products in different countries.
- Ability to onboard any new medical drug seamlessly with localization capabilities.
- Reduce operational spend in the call center by 50% with no compromise to customer satisfaction.

Key Challenges

• Avoid regulatory penalties for non-compliance with patient safety.
• Lack of intuitive user experience for prescribers, patients, and pharmacists.
• Inability to track critical business processes and status of patient surveys.
• Channel specific user behavior causes systemic issues throughout the system.

Project Description

• Design, build and deploy a regulatory application that complies with the FDA CFR Part-11 and many critical program requirements as dictated by the FDA REMS (Risk Evaluation and Mitigation Strategies) program.
• Global deployment ensuring availability in over 30 countries, designed to scale for managed services.
• A global platform for Patient, Provider and Pharmacist (PPP) to support EMEA, APAC and the Americas adopted by over 30 countries.
• Integrated with Pega Customer Service strategic solution to expedite the Go to Market offering for the client.
• Ability for client to generate on-demand reporting and ability to change the process flows as deemed necessary by citizen developers.

Results

• Rich customer experience.
• Seamless adoption of the solution by 5 countries in year 1, and 15 countries in Year 2 and 10 countries in year 3.
• Operational efficiency increased by 500%.

Why Charter Global

• Architected a proactive system that implemented the REMS quality management process to mitigate risks around patient safety and allow Prescribers and Patients to perform their tasks.
• Completed an architectural transformation in close collaboration with business and IT that created a cutting-edge experience across all major stakeholders via optimization of REMS process.
• Pega 8 Integration with external systems and databases and authentication services.
• Enterprise customer service solution in omnichannel (Phone, Web, Mobile, and IVR).
• Gathered the requirements and designed the system using Pega Out-of-Box experiences.
• Responsible for business process workflow design and implementation, analyzing requirements and suggesting appropriate architecture to match with the Enterprise Architecture. Managed technical deliverables and led team members. Provided product insight technically and functionally. Interacted with technology team and business users.

About Charter Global

Charter Global drives innovation in IT projects and business operations by defining strategy and providing consulting, digital solutions, custom development, and skilled resources. With an established customer base of Fortune 1000 industry leaders and over 100 successful project implementations, our experience and proven methodologies enable our professionals to deliver industry leading solutions in cloud technologies, open source, DevOps, mobility, CRM, AI/ML, AWS, SAP, Microsoft & Pega BPM.