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Leveraging Agile Methodology: Building an FDA-Compliant REMS Contact Center

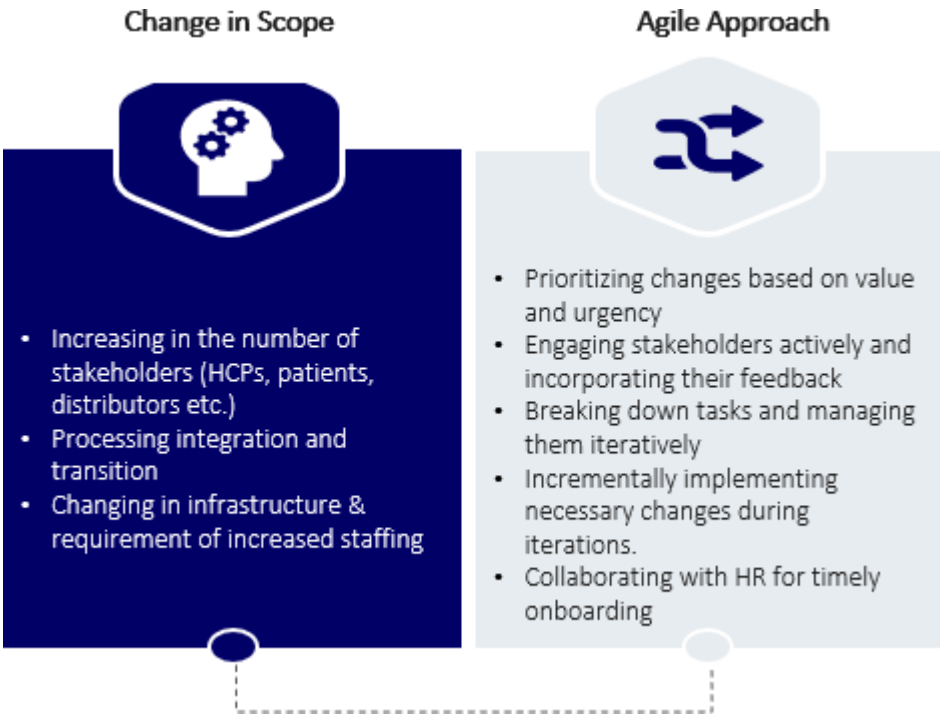
Infinite Scientific Innovations

Situation

The presented case study examines the dynamic implementation of a Risk Evaluation and Mitigation Strategy (REMS), highlighting how an Agile approach was crucial in responding to unforeseen project challenges.

Initially, patient and pharmacy volumes were underestimated by the project management office due to re-enrolment in the REMS update, leading to a sudden surge in required resources. This unexpected increase in the number of pharmacies raised significant concerns regarding staffing, training, and compliance, necessitating rapid adjustments to address safety and operational issues for REMS contact center.

The Agile methodology provided the flexibility to realign the project effectively under pressing timelines and compliance needs, ensuring a scalable and compliant REMS program.



Case Overview

The initial REMS plan estimated patient and pharmacy participation to guide resources, staffing, and training. However, the number of pharmacies increased exponentially, far beyond projections, due to high uptake of products and understanding REMS needs from end-user stakeholders, causing significant challenges in managing workflows, compliance, and staff training.

In response, the COD contact center adopted an Agile approach to redesign the REMS program quickly. By restructuring priorities, constant communication with FDA for right strategy, reallocating resources, and scaling training processes. Agile methodology allowed efficient handling of these challenges. Its iterative framework enabled continuous adjustments, real-time feedback, and enhanced communication with the FDA for regulatory alignment.

Step 1 Crafting the benefit-risk profile and guiding drug development

Cultivating a 'Risk aware' culture in the organization during drug development and post-market phase ensures market success, as patient safety is an important parameter for maintaining product's benefit-risk balance. Utilize the benefit-risk profile to craft the risk management strategy.

Step 2 REMS strategy for regulatory compliance

Organization should consult and understand the requirements to evaluate the most appropriate elements for REMS and risk minimization programs. They should also strategically plan actions that facilitate effective and appropriate risk mitigation for both current and future products.

Step 3 Executing risk management strategies

By efficiently utilizing tools such as strategically selecting vendors and technology, highly skilled implementation team (e.g., hiring experienced consultants) envisions long-term sustainability with the adaptation of risk messages. This will minimize go-to-market delays, prevent unexpected costs related to REMS or safety issues, and enhance regulatory compliance.

Step 4 Compliance strategies to monitor and improve risk mitigation

REMS program compliance by leveraging new tools for monitoring, assessment, and reporting will ensure ongoing drug safety management, improve market position, and drive industry-wide advancements in REMS maintenance. The information gathered in the market should also be used for continuous updates to the drug's benefit-risk profile.

Step 5 Portfolio management - an eye on product risk

A 'Risk aware' culture in the organization will allow performing risk assessments regularly across both in-development and in-market product portfolios, and prioritizing the creation of risk mitigation plans based on potential risks and benefits.

Challenges and Learnings

Realign Resource Allocation	Adjusting staffing, training, and workflow capacity to handle the increased pharmacy volume and ensure compliance
Address Safety Concerns	Working closely with the FDA to manage potential safety risks associated with the sudden increase in pharmacies, focusing on patient enrollment and adverse event monitoring
Ensure Continuous Compliance	Maintaining full alignment with FDA requirements for prescriber certification, pharmacy training, and patient management under the revised REMS structure Creating FAQs – placing them on website for reducing queries

Our Methodology

- Forming an Agile cross functional Team
- Defining user stories
- Prioritizing Features and Deliverables
- Iterative Approach
- Stand-up Meetings
- Continuous Stakeholder Engagement
- Embracing Continuous Improvement
- Agile Document Management
- Testing Early and Often
- Regular Retrospectives

Rapid Agile Project Restructuring

- **Revised Sprint Planning and Prioritization:** Focused on critical tasks like pharmacy certification, staff onboarding, and rapid training. The backlog prioritized safety and compliance to meet FDA standards.
- **Emergency Cross-Functional Collaboration:** Coordinated with HR, training specialists, and regulatory teams to expedite hiring and training. Ensured new hires were quickly certified to manage REMS workflows.
- **Continuous Stakeholder Feedback:** Integrated real-time feedback from project management office, sponsors, and FDA to make rapid adjustments and address safety concerns.

Contact Center Adaptation and Workflow Scaling

- **Pharmacy and Prescriber Certification Surge Management:** The contact center shifted to a scaled-up workflow for certifying the newly enrolled pharmacies. Agile's incremental approach allowed the team to deploy revised certification processes in phases, ensuring pharmacies were compliant without compromising safety or response times.
- **Streamlined Training Protocols:** New training modules were developed to expedite onboarding for additional staff. Agile's flexible structure allowed for real-time adjustments to training content based on feedback from trainees and supervisors, ensuring that staff were adequately prepared to manage REMS requirements.
- **Automated Compliance Checks and Monitoring:** With the increased data flow from the higher pharmacy count, automated compliance checks were integrated to monitor pharmacy certification statuses and adverse event reporting. These automations reduced the risk of manual errors and improved regulatory oversight.

Enhanced Risk Management and FDA Engagement

- **Proactive Safety Measures and Risk-Based Testing:** Agile's risk analysis techniques allowed for continuous testing and monitoring of new pharmacies' compliance. This ensured that any gaps in safety protocols or patient monitoring were addressed swiftly
- **Regular FDA Check-Ins:** Emergency meetings were scheduled with the FDA to discuss the increased volume, explain the revised REMS structure, and address safety and compliance adjustments. Agile's emphasis on flexibility enabled the contact center to respond to FDA feedback efficiently, ensuring regulatory concerns were managed in real-time.

Agile Project Management Tools and Practices

- **Daily Stand-Ups for Rapid Deployment**: Address new challenges, align priorities, and ensure progress on essential REMS functions
- **Sprint Retrospectives on Scalability**: Evaluate process effectiveness, focusing on scalability and regulatory alignment, and inform immediate adjustments.
- **Real-Time KPI Monitoring**: Track KPIs such as pharmacy certification rates, adverse event reporting times, and compliance check response times to meet operational and regulatory benchmarks.

Results

Despite the unexpected increase in pharmacy involvement, the Agile approach allowed the contact center to realign resources and maintain compliance:

Improved Certification Efficiency: **Enabled rapid pharmacy certification to meet the surge while ensuring FDA compliance**

Increased Operational Scalability:
Efficiently scaled training and certification workflows, reducing new pharmacy onboarding times by

35%

Enhanced Safety Oversight: **Proactive risk management and continuous FDA check-ins addressed safety concerns with no compliance gaps**

Positive Feedback:
Stakeholders, including the FDA, praised the contact center's effective adjustments to ensure safety and compliance

Key Highlights

This experience provided several critical insights into managing REMS programs using an Agile framework:

- **Scalability and Flexibility:** Agile's adaptability allowed the contact center to scale up workflows, training, and certification processes in response to an exponential increase in pharmacy participation.
- **Risk Mitigation Through Proactive Oversight:** Agile's risk-based testing approach enabled early identification of potential compliance risks, ensuring patient safety despite increased demand.
- **Stakeholder Satisfaction Through Real-Time Engagement:** Agile's iterative feedback loops fostered transparent communication and swift responses to FDA concerns, reinforcing the REMS program's commitment to safety and regulatory compliance.

Conclusion

The current REMS case study illustrates the critical role of Agile project management in addressing unanticipated challenges within a high-stakes regulatory framework. By adapting to increased pharmacy volumes and ensuring FDA compliance through iterative adjustments, the Agile approach enabled a responsive and scalable REMS program that met regulatory standards while safeguarding patient safety.

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