APCER LIFE SCIENCES

BROCHURE

Specialized REMS Web Portal

Purpose-Built REMS Technology

Effective REMS execution is about more than just compliance - it requires a secure, scalable, and inspection-ready digital backbone that ensures controlled access, real-time oversight, and documented regulatory assurance.

At APCER, our REMS Web Portal is purpose-built, shaped, and led by experienced REMS subject matter experts (SMEs). This ensures that every workflow, control, ETASU requirement, and user interaction aligns with practical REMS operations and regulatory expectations.

We take pride in owning, designing, developing, validating, and maintaining our proprietary REMS Web Portals. These portals support the full REMS lifecycle while adapting to each sponsor's unique program requirements. By combining regulatory understanding, risk management expertise, and validated technology, we ensure seamless coordination across all REMS stakeholders.

Designed Around Your REMS Program

Every REMS program is unique, with distinct **Elements to Assure Safe Use (ETASU)**, stakeholder obligations, and reporting requirements. To address these unique characteristics, our portal development starts with extensive discovery and stakeholder engagement.

Our REMS subject matter experts, pharmacovigilance specialists, and risk management data analysts collaborate with sponsors to thoroughly understand:

- Program objectives and regulatory obligations.
- Operational challenges and ETASU workflows.
- Future scalability and assessment expectations.

These insights are carefully translated into a customized REMS portal, designed to integrate seamlessly with either sponsor-hosted or APCER-hosted front-end websites.

Structured Development & Validation Approach

Our REMS portal development follows a proven, inspection-ready framework to ensure quality and compliance:

Planning & Definition

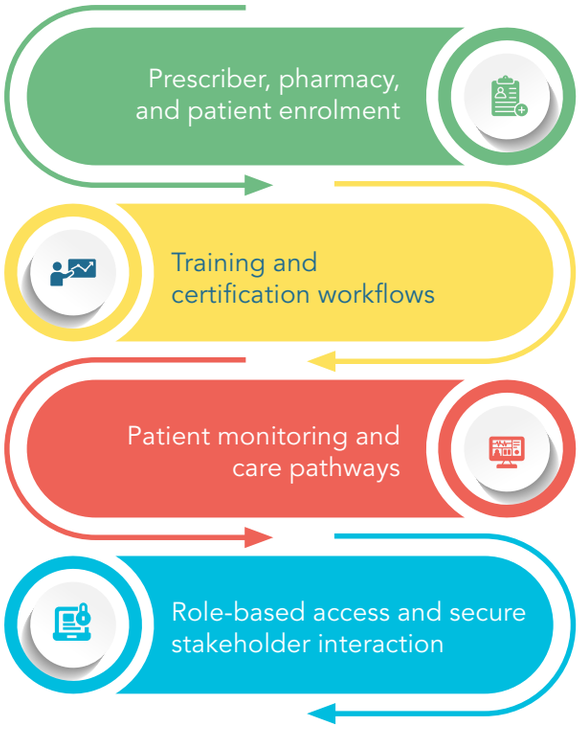
We work collaboratively to define program scope, user roles, workflows, and regulatory expectations.

Requirements Analysis & Compliance Alignment

Sponsor requirements are aligned with FDA REMS expectations, GxP principles, and data integrity standards.

Application Development

Our full-stack development ensures robust functionality, including features such as:



Where possible, we align the portal with existing sponsor design standards to ensure a consistent and unified user experience.

Data Migration & Validation

We provide secure migration from legacy systems (if applicable), covering reconciliation, audit reporting, and validation sign-off in compliance with regulatory expectations.

Testing & Go-Live

Our process includes comprehensive functional, integration, and user acceptance testing (UAT), supported by validation documentation. This ensures a smooth, sponsor-approved go-live phase.

Throughout the lifecycle, we incorporate program-specific needs to deliver a tailored solution.

A Comprehensive REMS Digital Ecosystem

The APCER REMS Web Portal enables efficient collaboration among all REMS stakeholders, including:

- HEALTHCARE PROVIDERS
- PHARMACIES
- WHOLESALERS
- PATIENTS
- ADMINISTRATORS
- CALL CENTER TEAMS

Built with scalability, configurability, and compliance at its foundation, our solution accommodates both single and shared REMS programs.

Key Capabilities

Our REMS Web Portal offers a range of advanced features to streamline program execution:

1 Secure & User-Friendly Interface

Web-based dashboards enable enrolment, certification, patient monitoring, and real-time dispense authorization tracking. The user-friendly interface supports intuitive navigation and real-time data access.

2 Rules Engine (RDA Workflow)

Automated dispense authorization logic is aligned with REMS enrolment, training, and monitoring requirements.

3 AI-OCR & Fax Processing

Intelligent ingestion of faxed documents transforms them into structured digital records, improving efficiency and data accuracy.

4 Automated Notifications

Email and SMS alerts notify users about renewals, deadlines, training requirements, and follow-ups.

5 Training Sandbox

A dedicated simulation environment provides sponsors and call-center teams with a safe space for training without impacting live program data.

6 System Integrations

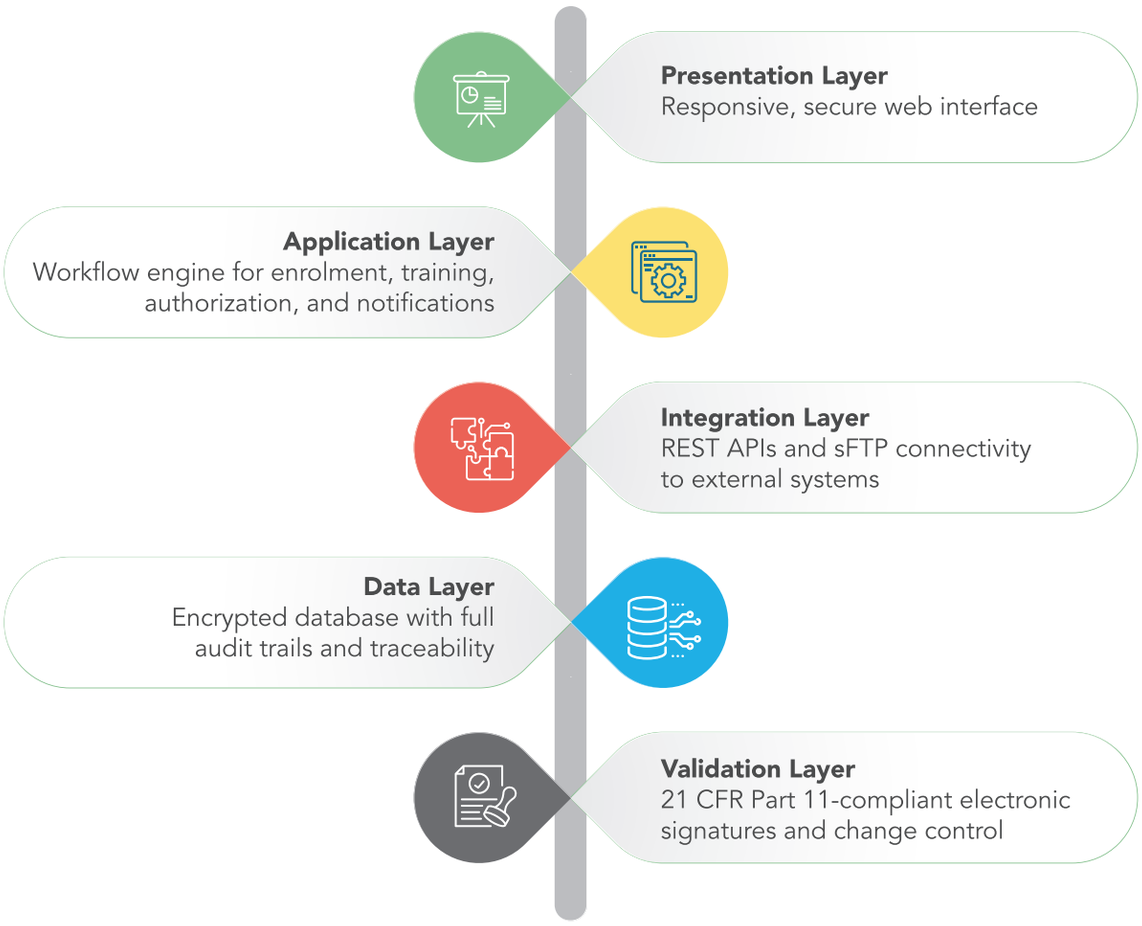
Seamless connectivity with NPPES, DEA, sFTP pharmacy lists, and telephony systems ensures real-time validation and communication.

7 Compliance & Validation Support

Fully aligned with FDA 21 CFR Part 11 requirements, our portals include comprehensive validation documentation such as URS, IQ/OQ/PQ, and traceability matrices to support audits and inspections.

Robust Technical Architecture

The REMS Web Portal is built on a modular, secure architecture to ensure flexibility and reliability:



Data Protection

We maintain strict data protection standards:

- Personally Identifiable Information (PII) is redacted prior to model input.
- Processing occurs in secure, HIPAA-eligible cloud environments.

Strategic Value for Sponsors Like You

Our platform provides sponsors with unmatched strategic benefits:

- Rapid deployment using APCER's validated REMS foundation.
- Our configurable architecture evolves with your program and accommodates FDA feedback.
- Built-in governance, audit trails, and traceability to ensure inspection readiness.
- Integration-ready design for future REMS expansion and multi-program management.

A REMS Portal Built for Regulatory Reality

With validated technology, risk-focused design, and regulatory alignment, APCER's REMS Web Portal delivers a reliable digital foundation for compliant, scalable, and efficient REMS program execution.

Why Partner With APCER?

Partnering with APCER means choosing a trusted ally in REMS program execution. Our commitment to innovation, compliance, and customer-centric solutions ensures that your REMS programs are equipped to meet regulatory requirements with precision and efficiency.

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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