



Risk Evaluation and Mitigation Strategy (REMS) Compliance Audit Services



KPMG REMS Experience

KPMG's Life Sciences professionals work closely with drug manufacturers operating under a Risk Evaluation and Mitigation Strategy (REMS) program to understand:

- ▶ The REMS requirements and auditing considerations
- ▶ The contractual relationship between the drug manufacturer and the vendor(s) it selected to manage the REMS programs
- ▶ The current governance and oversight structures at the drug manufacturer, vendor(s) and relevant third parties involved in the REMS program

KPMG, LLP has extensive experience supporting both single and shared REMS programs by conducting REMS audits on behalf of the Program Sponsor(s), of REMS programs with multiple Elements to Assure Safe Use ("ETASU") for all types of stakeholders. KPMG conducts audits in-person, via phone or by survey, leveraging KPMG Concert, our propriety digital enablement tool.

As a REMS audit provider, KPMG understands that successful audits go beyond mere execution. We emphasize the importance of:



Providing clear program status communication to **meet timelines** and **drive accountability**.



Enhancing stakeholder experience with focused audit scopes aligned with REMS requirements, reducing burden.



Gaining real-time **insights for continuous improvement**.



Supporting **timely responses** to regulatory requests like inspections and inquiries.



Efficiently scaling programs to adapt to changing needs.

Our in-depth knowledge and experience with REMS programs of all sizes, uniquely positions us to assist your organization in assessing compliance with REMS requirements, and assisting in meeting required audit and reporting obligations.



How Can KPMG Help?

As a leading provider of regulatory and compliance services for the Life Sciences industry, our team provides support for compliance, clinical, R&D, medical affairs, QA and commercial functions; and specializes in REMS program support. KPMG's REMS services include:

01

REMS Stakeholder Audits. We conduct detailed assessments of REMS stakeholders, including pharmacies, healthcare settings, wholesalers and distributors. The audits focus on compliance with REMS requirements, such as product ordering, prescriber/patient verification, drug dispensing or shipment practices, training and awareness and more. KPMG reviews relevant policies, procedures, systems and controls and conducts dispense and distribution testing to identify gaps that may not align with REMS requirements.

02

REMS Program Vendor Audits. We audit through interviews and document reviews to understand current policies, procedures, SOPs, business rules, workflows, systems and controls for applicable services. We also review applicable systems and workflows for functionality and regulatory compliance, and report findings and recommend actions.

03

Project Management Framework. We develop audit program governance materials, including the audit protocol with defined audit activities and milestones, template reports and communication letters, and designate points of contact for transparent and responsive communication.

04

FDA Inspection and Inquiry. We support audit-related responses to FDA inspections and inquiries, preparing audit statistics, metrics, audit documentation and providing an overview of the audit processes as outlined in the program's audit protocol, as needed.

05

Assessment Report Support. We offer a development of the annual audit summary presenting: audit processes, methodology and audit metrics.

06

Trend Analysis and Program Insights. We regularly analyze program trends by reviewing audit metrics, such as outcomes by stakeholder type, annual results, and remediation timing.

07

Identify Opportunities for Continuous Improvement. We leverage our experience across programs to identify opportunities to enhance the program, including clarity with program documentation, stakeholder resources, and streamlined communications.



KPMG Concert: Streamlined REMS Audits from Start to Finish

KPMG Concert is a proprietary digital platform which simplifies REMS audits end-to-end **with AI-enabled workflows** from initial notification to final closure. Concert brings everything together in one place: stakeholder communication, questionnaire distribution, document collection, and data capture.

With **real-time dashboards**, you gain instant visibility into audit metrics by stakeholder type, frequency, and year-over-year trends—empowering timely, informed decisions.

Our experienced team combines **proven, standardized processes** with **tailored delivery** to fit your program's unique needs. The result? Enhanced communication, predictability, and efficiency that scales effortlessly with audit volume.

We prioritize a **smooth, user-friendly experience** with clear requests and timelines, minimizing disruption for REMS stakeholders while emphasizing **efficiency, responsiveness, and sensitivity to competing priorities**.

Ready to strengthen your REMS program?

Our KPMG Life Sciences team is here to help you navigate REMS compliance with confidence, efficiency, and insight. Connect with us today to discuss how our tailored audit methodologies and digital accelerators can support your organization's goals and regulatory requirements.

Contact us to schedule a consultation or learn more about our REMS Compliance Audit Services.

- **John Gitas**
Principal, Healthcare and Life Sciences, Advisory, KPMG LLP
T: 908-723-7672
E: johngitas@kpmg.com
- **Erin Movall**
Director, Healthcare and Life Sciences, Advisory, KPMG LLP
T: 312-665-5231
E: emovall@kpmg.com



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