

7 WAYS TO AVOID INSPECTION FINDINGS



1.

GO PAPERLESS TO ENSURE ALL TMF RECORDS ARE MAINTAINED ELECTRONICALLY.

WHY IT MATTERS

Going paperless ensures that all documents are easily accessible remotely and retrievable and searchable in real-time.

HOW IT PREVENTS INSPECTION FINDINGS

With a contemporaneous TMF, your TMF remains inspection ready instead of requiring active preparation ahead of inspections.

HOW LMK CAN HELP

LMK's TMF experts keeps all of your TMF records organized, accessible, visible, and controlled in real-time across all of your studies with reports and dashboards to monitor TMF health.



2.

CONDUCT REGULAR INTERNAL AUDITS

WHY IT MATTERS

An internal audit with more of a GCP focus will assess procedures as well as essential documents anticipated for review as part of a GCP inspection. Mock TMF audits help identify and address any potential compliance issues.

HOW IT PREVENTS INSPECTION FINDINGS

Allows companies to proactively address any issues before they become problems during an inspection

HOW LMK CAN HELP

LMK's Complete TMF Solution services can help you conduct effective internal audits.



3.

CREATE STANDARD OPERATING PROCEDURES FOR TRIAL-RELATED ACTIVITIES

WHY IT MATTERS

Ensures consistency and compliance in all study-related activities and streamlines change management.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW LMK CAN HELP

LMK's SOP development service can help you create effective, compliant SOPs. It helps you navigate the complexity of change management when new SOPs are needed for new processes.



4.

OBTAIN TMF EXPERT CERTIFICATION THROUGH TRAINING

WHY IT MATTERS

Ensures that your organization's TMF team members have the necessary knowledge and skills.

HOW IT PREVENTS INSPECTION FINDINGS

Helps prevent non-compliance issues during inspections.

HOW LMK CAN HELP

LMK offers two educational programs TMF University (TMFU) and TMF Corporate Education. TMFU is accredited by the IAOCR the world's only organization that qualifies clinical research professionals to international standards. TMF Corporate Education is LMK's portfolio of nonaccredited training courses designed to address common gaps or deficiencies within groups that manage Trial Master Files.



5.

CENTRALIZE INVESTIGATIVE SITE FILE MANAGEMENT AND MONITORING.

WHY IT MATTERS

The ability to conduct remote site monitoring with paperless site file management helps CRAs work more efficiently and meet regulatory requirements.

HOW IT PREVENTS INSPECTION FINDINGS

Maintain digital site files that update in real time in one central location that supports inspection readiness

HOW LMK CAN HELP

LMK's Consultants eISF reduces administration and improves speed and compliance for site personnel.



6.

IMPLEMENT A SOLUTION FOR CLINICAL STUDY DOCUMENT COLLABORATION.

WHY IT MATTERS

Centralize collaborative authoring and approval processes for your clinical study documents in an FDA 21 CFR Part 11 compliant system.

HOW IT PREVENTS INSPECTION FINDINGS

Helps reduce risk of inspection findings by aligning document work streams with regulatory compliance practices for document authoring, approval, control, and related training. It also adheres to FDA requirements for electronic records and signatures, 21 CFR Part 11.

HOW LMK CAN HELP

LMK's complete TMF solution also adheres to FDA requirements for electronic records and signatures, 21 CFR Part 11.



7.

CENTRALIZED TRAINING REQUIREMENTS FOR ALL STUDIES THROUGH A LMS WITH REAL-TIME TRACKING.

WHY IT MATTERS

Ensure that all study-related training at site level are conducted and documented in compliance with regulations.

HOW IT PREVENTS INSPECTION FINDINGS

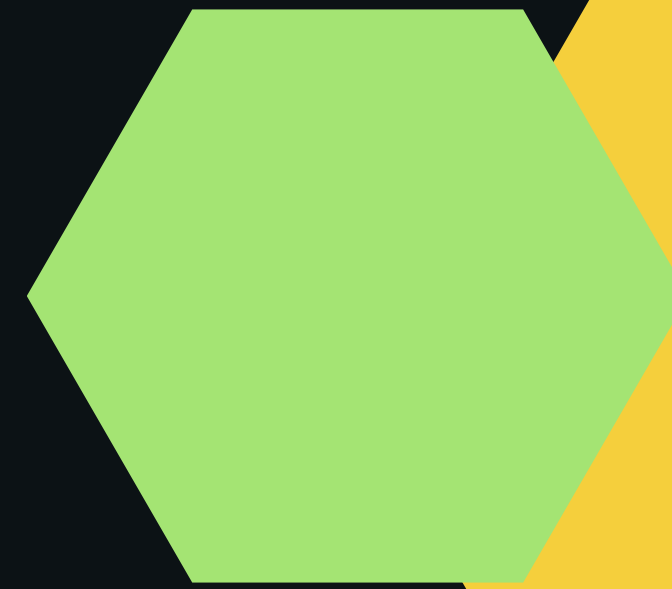
Helps prevent non-compliance issues during inspections.

HOW CAN LMK HELP

LMK's complete TMF solution and training provides a regulatory compliant system to track training on regulatory requirements and best practices for site staff.



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