

COMPANY SNAPSHOT

LMK Clinical Research Consulting is a leader in document management solutions to the life sciences industry. From study start through completion, our TMF experts can help you develop, plan, and implement processes that will engage stakeholders and mitigate risks. LMK's comprehensive and detailed approach to TMF management will ensure that you are able to collect and maintain your clinical trial content cost-effectively without jeopardizing quality, enabling your TMF to become inspection ready from day one. Don't let your content be a collection burden at the end of a trial!

CORE COMPETENCIES



Functional Service Provider

As a premier TMF Functional Service Provider (FSP), LMK offers comprehensive TMF services specializing in the strategic development, project management, and quality control of documents and content that support clinical development. We offer the flexibility to support you with whatever tasks you choose – from staff augmentation to full support of your TMF, we can provide what you need, when you need it.



Document Quality Control

TMF Document QC is the core of successful TMF management. Our TMF Professionals can help you assess your document QC standards and provide document QC services for some or all of your TMF documents and files.



TMF Quality Control

The quality of the TMF as a whole is often overlooked as part of the ongoing management of the Trial Master File. LMK's TMF Professionals can help you implement a cycle of QC that continuously monitors the condition of your TMF to ensure continuous inspection readiness.



TMF University

TMF University is the first and only internationally recognized training program for TMF Professionals. The program is accredited by IAOCR (International Accrediting Organization for Clinical Research), the world's only organization that qualifies Clinical Research Professionals to international standards.



SOP & Process Development

LMK's TMF experts know that your TMF can be complete, accurate, and inspection ready at all times with a foundation of sustainable SOPs, work instructions, and processes. We can provide custom and comprehensive solutions tailored to the specific needs of your business through the development of meaningful SOPs that ensure the System of Record for all of your content is complete and accurate.



eTMF Selection & Implementation

Change is good. Whether transitioning from a paper to an electronic TMF, or between two eTMF systems, LMK's team of experts are ready to ensure a smooth transition with detailed processes that will provide guidance for your team. LMK can support you with eTMF training and empower your team to turn TMF drudgery into TMF mastery—transforming your TMF into a competitive advantage.



TMF Reference Model Implementation

As TMF Reference Model Subject Matter Experts, LMK's TMF Professionals specialize in indexing documents within the TMF Reference Model framework. LMK can work with your team to develop a complete TMF 'Table of Contents' that will establish clear expectations across your organization.



Document Filing & Indexing

LMK's TMF Professionals understand the need for flexibility when it comes to conquering document management challenges. Our TMF experts quickly pivot in response to changing document management resource needs, eliminating document handling latency and ensuring your TMF is always inspection ready.



Training & Stakeholder Engagement

Training and Stakeholder Engagement are the cornerstones of every optimally functioning TMF department. LMK's accredited and non-accredited training programs can re-energize teams and help instill a refreshing new perspective on TMF accountability.



Metrics Driven Process Improvement

"If it wasn't written down, it never happened." LMK will put the appropriate metrics in place to guarantee the success of your TMF so that you will be 100% Inspection Ready.

TMF CORPORATE EDUCATION

Training is a key component of a well-developed, well-run TMF Operations department. Organizations looking to elevate the knowledge and skills of their TMF staff will benefit from LMK's portfolio of non-accredited training courses designed to address common gaps or deficiencies within groups that manage Trial Master Files. The Corporate education program is designed for all experience levels, from introductory to advanced. Courses can be customized to make the learning experience relevant to the company's real-world environment.

Introductory Courses

- TMF Overview
- Document Quality Control (QC)
- TMF Indexing

Intermediate Courses

- TMF Quality Control
- Audit and Inspection Readiness

Advanced Courses

- Current Regulations
- TMF Process Best Practices
- TMF Metrics

DIFFERENTIATORS

TMF Professionals: All LMK employees hold certifications from TMF University, Six Sigma, SoCRA, and/or the Project Manager Institute.

Experienced Staff: We have experience in all therapeutic areas. Skilled in clinical operations and multiple eTMF technologies, we are "eTMF agnostic," enabling us to work across all platforms.

Established Company: Highly flexible and adaptable to meet our client's needs; every engagement is customized.