TRIAL MASTER FILE INSTITUTE SAN FRANCISCO

Enhance TMF Professional Competencies and Knowledge Base Through Targeted Learning and Skill Development

MAY 14-15, 2019 // HYATT REGENCY SAN FRANCISCO AIRPORT // SAN FRANCISCO

COURSES

TMF FOUNDATIONS: Understand TMF Fundamentals, Challenges and Regulations and Explore TMF Management Best Practices

- List the fundamentals of the TMF management process
- Elucidate essential elements for success as outlined in regulations
- Describe roles and approaches of TMF management-process stakeholders

REMEDIATION STRATEGIES: Best Practices to Achieve Inspection Readiness and GCP Compliance

- Build and manage cohesive cross-functional teams to drive remediation
- Conduct gap assessments and implement process improvements that justify resource allocation
- Use metrics to develop KPIs with the intent to identify most relevant risk factors through quality reviews

eTMF SYSTEM: Understand Needs, Strategy, and SOPs to Choose and Utilize an eTMF

- Establish milestones for the project which will select, evaluate, and implement an eTMF system
- Use the industry-available tool for assisting with the selection and evaluation of an eTMF system
- Prioritize and communicate your company's needs and other factors that may influence your choice of eTMF system

TMF ALLIANCES & COLLABORATIVE PARTNERSHIPS: Improve Quality and Inspection Readiness

- Tailor a TMF Management Plan with streamlined processes throughout the study life cycle
- Surmount obstacles to oversight and QC in third party-owned systems
- Know the essential requirements for machine-to-machine exchange of TMF content

WHO SHOULD PARTICIPATE

Professionals from pharmaceutical, biotech, and medical device companies as well as CROs and eTMF/TMF service providers having or seeking responsibilities in the following areas:

- TMF/eTMF Systems Management
- Clinical Document Management
- Clinical Trial Documentation
- Clinical Trial Administration
- Clinical/TMF Project Management
- Quality Control/Quality Management
- Clinical Research Management
- Clinical Operations
- Regulatory Affairs/ Operations
- Clinical Trial Coordination
- Business
- Trial Records Management
- Clinical Process
- Clinical Trial Compliance
- Clinical Development
- Quality Assurance/Control/ Operations
- R&D Quality Management
- Strategic Operations and Planning
- Global Development
- R&D IS Management
- Archives

FEATURED INSTRUCTORS

Donna Dorozinsky
President
JUST IN TIME GCP

Lisa Leete
Clinical Research Associate
XENCOR

Alex Markiel
Director, Clinical Operations, Head of Clinical Document Control
PHARMACYCLICS

Wendy Trimboli
Director, Head of TMF Management and Compliance
EISAI

Stephanie Viscomi
Associate Director, Clinical Trial Office
IMMUNOGEN

EDUCATIONAL UNDERWRITER

Just in Time GCP

For more information, please call 212-400-6240 or visit **www.tmfsummit.com/inst-sanfrancisco**

DAY ONE TUESDAY, MAY 14, 2019

*9:00-5:00

TMF FOUNDATIONS: Understand TMF Fundamentals, Challenges and Regulations and Explore TMF Management Best Practices

Instructors:

Lead - Wendy Trimboli, *Director, Head of TMF Management and Compliance,* **EISAI**

Evelin Baez, *Clinical Document Management Specialist,* **BECTON DICKINSON**
Lisa Leete, *Clinical Research Associate,* **XENCOR**
Jolanta Strus, *Associate Principal Clinical Scientist,* **MERCK**
Stephanie Viscomi, *Associate Director, Clinical Trial Office,* **IMMUNOGEN**

The TMF professional has adapted from a CRA type role to a specialized position in the life science industry. With the rapid growth and necessity for TMF professionals, an increasing number of new hires or department transfers are coming into the field in need of essential instruction to quickly improve their proficiency and more productivity. It is important that all TMF professionals understand foundational concepts and requirements for the management of and the content of a TMF. TMFs are not merely a repositories, they are living sources of content and documentation that when done right, can be an asset for Quality and clinical trial oversight.

This course will cover TMF fundamentals and defining characteristics of paper-based TMFs and eTMF systems. It will illuminate regulations and guidances that prescribe or will prescribe TMF management. The course will outline the essential elements of a TMF and introduce TMF Reference Model — the standard blueprint for the content and organization of the TMF, including nomenclature and structure. Participants will look at processes for management including expectations for Quality checks for maintaining an inspection-ready TMF. Participants will learn who the stakeholders of the TMF are and what process supports should be in place to ensure fidelity of the TMF management processes.

Upon completion of this course, participants will know or be able to

- Cite current laws, guidances and regulations governing TMF management
- Define and list the essential elements that constitute a TMF
- Outline the unique challenges of the TMF that add to the complexity of its management by various study team representatives
- Explore strategies for relating the requirements for management of the to various TMF stakeholders of the study team representatives
- Identify compelling benefits and the review the challenges of an eTMF system to stakeholder of disparate functions
- Understand the interdependence of various components of a TMF Management Plan
- Monitor TMFs for completeness and compliance
- Anticipate pitfalls and proactively begin to troubleshoot issues
- Address common challenges of the TMF professional
- Learn about the Framework for the Destruction of Paper and TMF Exchange Mechanism

*9:00-5:00

REMEDIATION STRATEGIES: Best Practices to Achieve Inspection Readiness and GCP Compliance

Instructors

Lead: Donna Dorozinsky, *President,* **JUST IN TIME GCP**

Emily Roberts-Thomson, *VP, Clinical Operations,* **ACERTA**

Something is bound to go awry -if it hasn't already. Even with sound strategic planning, due diligence, and care during execution there are simply too many factors to account for and too many unforeseen developments. The challenges that you face call for a responsive process. You need to put in place a remediation strategy to manage this process if you want to make Inspection Readiness and Quality a reality.

This course is a pragmatic examination of fundamental influencers of Inspection Readiness and Quality. TMF leaders must synthesize an understanding of company culture, electronic systems, staffing, operations, international regulatory expectations, CRO partners, and so forth into a comprehensive TMF strategy. Participants will be challenged to devise systems to think critically and act strategically to improve efficiency. Instructors will share tools, methods, best practices and strategies.

This course will present approaches and strategies for improvement and remediation through a balance of reflection, networking, peer-to-peer learning and instruction. Participants will return to work prepared, equipped, and informed to lead partners and internal allies to think meaningfully about quality.

Upon completion of this course, participants will know or be able to

- Conduct gap assessments and implement process improvements that provide justification for resource allocation
- Use metrics to develop KPIs with the intent to identify most relevant risk factors through quality reviews
- Have a Quality Management System that is supported by processes
- Build and manage cohesive cross-functional teams to drive remediation
- Create a technology road map based on company needs
- Improve interoperability and speed and explore automation for extracting artifacts, emails and data
- Implement remediation strategies that bolster processes and ensure inspection readiness
- Manage migrations as a strategy for remediation
- Direct remediation timelines and resourcing

**Courses include continental breakfast at 8AM, two networking breaks, and lunch.*