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

To Register, please call 201-871-0474 or **Click Here**

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.*

To Register, please call 201-871-0474 or Click Here

DAY TWO WEDNESDAY, MAY 15, 2019

*9:00-5:00

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

Instructors

Lead: Lisa Mulcahy, *Owner and Principal Consultant,* **MULCAHY CONSULTING**
Alex Markiel, *Director, Clinical Operations, Head of Clinical Document Control*, **PHARMACYCLICS**

The electronic repository that holds TMF documentation -the eTMF system, is a critical tool that the pharmaceutical and device industry utilizes for the management of the content created in support of the clinical study. The eTMF system is more than just a repository of the evidence created of followed company processes, ICH-GCP, and laws. The system can also be a tool to facilitate the conduct of the study.

The selection, evaluation, and implementation of the eTMF system is a process that needs to be conducted with thoughtful intent since the management of the TMF is rooted in the process defined, the people who will execute and oversee, and the system to facilitate. Evaluation and comparison of eTMF systems, through the identification of desired functional and system requirements is vitally important so that a company selects the system that is best for them.

Once the system is chosen, establishing the processes and resources that are necessary to support the use of the system at the point of Go Live and thereafter, are paramount. Putting the right amount of infrastructure in place will help to ensure both regulatory compliance and optimal short and long-term benefits since without it there could be unnecessary process inefficiencies, user unhappiness, and resource and monetary costs. Change management is a key component to put effort into since the successful integration of the use of an eTMF system into the everyday work life is important to foster the modification in process.

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

- 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
- Organize an evaluation of eTMF systems based on company suitability, present and/or future TMF operating models in use or to be used in future, process impact, people impact, risks, costs, and long-term benefits
- Prioritize and communicate your company's needs and other factors that may influence your choice of eTMF system
- Evaluate the various TMF Management operating models' impacts on the process of utilizing an eTMF system to manage TMF documentation
- Create and implement comprehensive transition plans based your company's priorities
- Begin to prepare your company for TMF management process and system changes resulting from the implementation of an

*9:00-5:00

TMF ALLIANCES AND COLLABORATIVE PARTNERSHIPS: Improve Quality and Inspection Readiness

Instructors

Michelle Ingraham, *Manager, Information Governance and Compliance,* **PPD**
Melissa Umbehauer Chiasson, *Senior Manager, Process, Training and Compliance,* **TAKEDA**
Michele Weitz, *Senior Director GCP, Compliance Operations,* **CLOVIS ONCOLOGY**

As a TMF professional you rely on groups such as CROs, sites, and internal functional units to achieve compliance and GCP. Your charge of promulgating a universal understanding of definitions and getting them to adhere standardized processes is no small task especially when you consider the disparity among those groups.

You and your TMF management team must provide support and rigorous oversight of process and performance to ensure that Inspection Readiness and Quality are realized. This course will review the expectations of regulatory authorities for setting forth expectations in a TMF Management Plan for each clinical study. Participants will learn to streamline processes throughout the study life cycle to ensure they are inspection-ready from day one to archiving and beyond.

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

- Streamline processes to support work across-functional units to work with vendors
- Consider and surmount obstacles to CRO oversight and QC in third party-owned systems
- Build and manage cohesive cross-functional teams
- Establish processes and KPIs that account for a CRO's own assessment systems
- Tailor a TMF Management Plan with streamlined processes throughout the study life cycle
- Create a culture of quality through two-way communication
- Plan and execute governance that facilitates change management
- Improve interoperability and speed with AI for extracting artifacts, emails and data
- Know the essential requirements for machine-to-machine exchange of TMF content

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

TRIAL MASTER FILE INSTITUTE

Dear Colleague,

ExL Events is pleased to expand the TMF Series by bringing the TMF Institute to the West Coast. Guided by our industry research and compelled by persistent requests from our network of TMF professionals, we founded the TMF Institute to meet the needs of the industry.

The growing need for professional growth among TMF leaders is demonstrated by an explosion of enrollment in the workshops and seminars part of our global TMF Summit Series. The San Francisco event expands upon the activities and peer-to-peer learning of the 35+ workshops and seminars that we have produced since we entered the TMF arena.

The Institute's purpose is to teach participants what they need to know and be able to do based on their particular purview or echelon. The cadre of instructors for each course is composed of experts with the experience and background to expand participants' knowledge base enhance their savvy at TMF leaders.

Through a meld of lectures, participatory learning, and peer-to-peer interaction, the Institute's courses are fashioned to train, equip, inform, and prepare participants to exceed expectations through professional growth and advancement.

We look forward to seeing you at the Institute.

Best regards,

Brian L. Anderson
TMF Series Producer

Scott Grossman
Managing Director, Conference Production

HYATT REGENCY SAN FRANCISCO AIRPORT

1333 Bayshore Highway
Burlingame, CA 94010

Designed for on-the-go guests, Hyatt Regency San Francisco Airport is a sleek hotel just five minutes from SFO. Feel at home in rooms and luxury suites with bay views and access San Francisco International Airport and downtown Burlingame with complimentary shuttle and trolley service. Take advantage of ample meeting space and chic dining options.

To make reservations, guests can call 650-347-1234 or 877-803-7534 and request the negotiated rate for **ExL's TMF Institute San Francisco**.

To make reservations online, go to https://bit.ly/2RlYADx.

The group rate is available until April 23, 2019. Please book your room early, as rooms available at this rate are limited.

*ExL Events is not a affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, bureaus or travel companies. ExL Events is a affiliated with event company Questex, LLC. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL's reserved guest room block using the details provided.

Become an Educational Underwriter

Would you like to learn about becoming an Educational Underwriter? Would you be interested in hosting an affiliated event? ExL will work closely with you to customize a package that suits all of your needs. Experts and thought leaders from Educational Underwriters may also apply to become an instructor. To learn more about these opportunities, please contact Dor Peled, Senior Business Development Manager, at dpeled@exlevents.com or 917-258-5159.

MEDIA PARTNERS

FiercePharma · Health Sciences Records & Archives Association · MEDtube · pharmaphorum · PharmaVOICE · pharmaLEADERS · PM360 · Technology Networks

HOW TO REGISTER

Phone 201-871-0474

Email register@pmaconference.com

Online Click Here

Mail PMA Conference Management
PO Box 2303
Falls Church VA 22042

Fax 253 663 7224

REGISTRATION FEES

EARLY BIRD PRICING	STANDARD PRICING	ONSITE PRICING
Register by April 5, 2019	*Register After April 5, 2019*	
Two Courses $1,795	Two Courses $1,895	Two Courses $2,095
One Course $1,195	One Course $1,295	One Course $1,395

GROUP DISCOUNT PROGRAM

*Offers may not be combined. Neither Early Bird rates nor One-Course registrations apply.
To find out more on how you can take advantage of group discounts, please call 201-871-0474.

SAVE 25% For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the programme (must register four). This is a savings of 25% per person.

SAVE 15% Can only send three? You can still save 15% off of every registration.

Terms and Conditions

By registering for an ExL Events' ("ExL") event, you agree to the following set of terms and conditions listed below:

Registration Fee

The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

Payment

Make checks payable to ExL Events and write 794619 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organisation and register simultaneously to realise group discount pricing options.

Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

Cancellation and Refund Policy

If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com.

Credit Vouchers

Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.

ExL Events is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

Substitution Charges

There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants.

ExL Events' liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, instructor or venue.

*The opinions of ExL Events' conference instructors do not necessarily reflect those of the companies they represent, nor ExL Events.

Please Note: Instructors are subject to change without notice. In the event of an instructor cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL's designated speakers and is designed for informational purposes for its attendees. It is **NOT INTENDED** for purposes of copywriting or redistribution to other outlets without the express written permission of ExL or ExL's designated instructors.. Neither ExL nor its content providers and/or instructors and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. **EXL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE**. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.