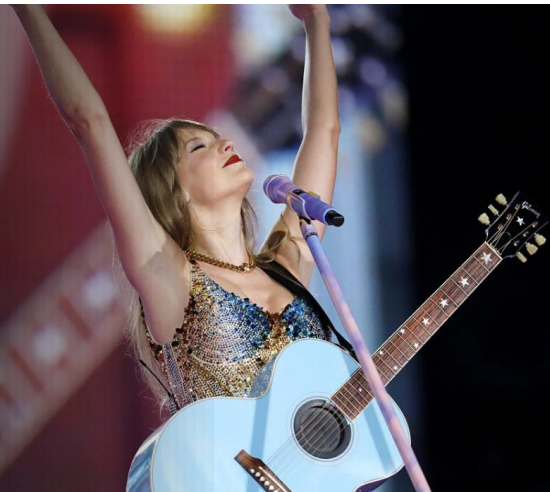


TMF Culture A New TMF Era

Seth Pearl and Jared Brooslin | October 13, 2025



Meet the Speakers

Seth Pearl

Title: Director, Business Development

Organization: Cencora (formerly Phlexglobal)

15+ years of Life Sciences experience helping clients achieve TMF Success. Focused on building industry leading TMF programs, with emphasis on Culture, Quality and Compliance.



Jared Brooslin

Title: Senior Manager, Trial Master File

Organization: Intellia Therapeutics

10+ years in the TMF Sphere of Influence working with small to large size CROs & Sponsors. Jared is well known for his niche in building TMF departments and training stakeholders on the importance of foundational knowledge and culture of the Trial Master File. Follow him @TMFGenius on X





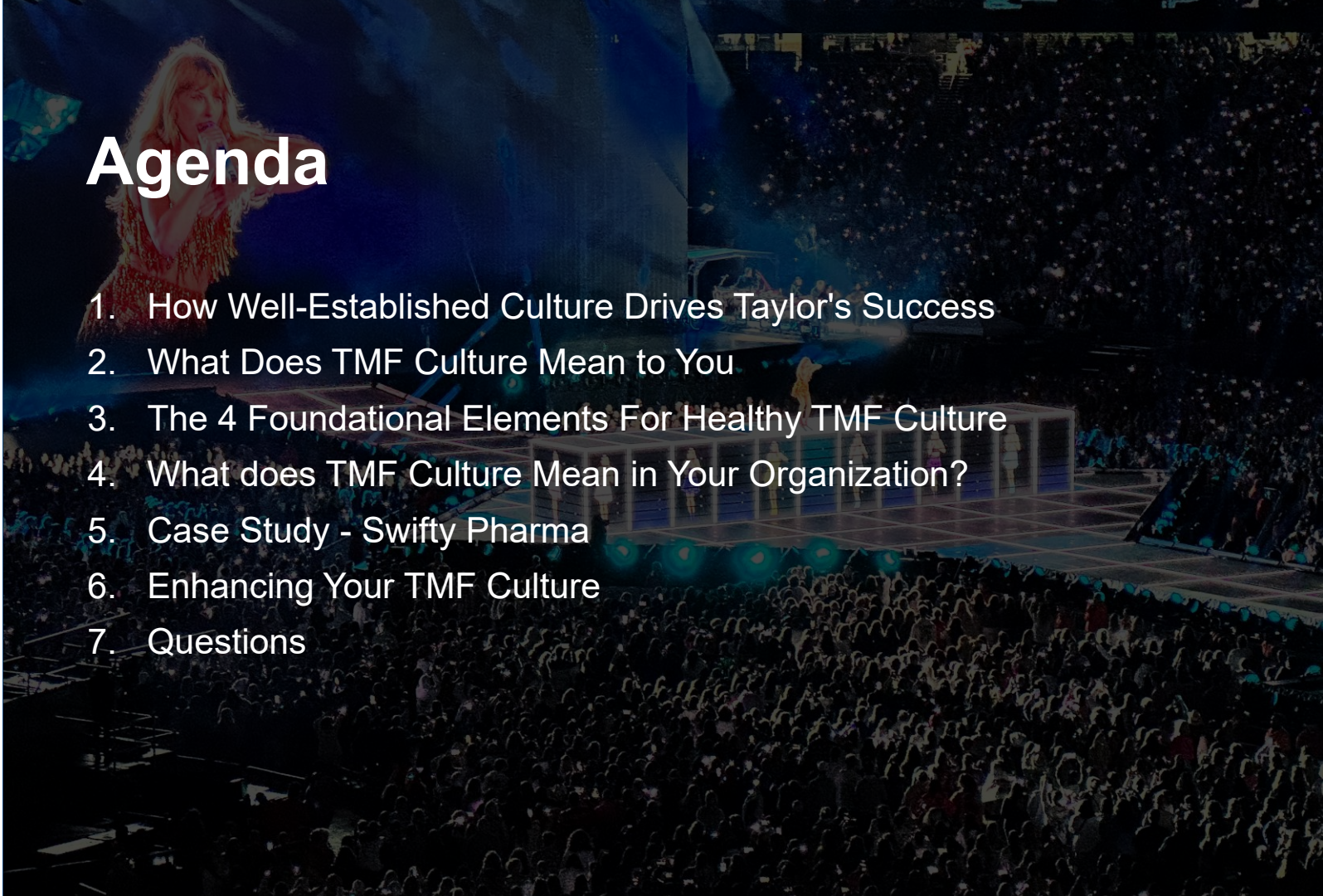
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The views and opinions expressed in this presentation are those of Seth and Jared and do not necessarily reflect the official policy or position of their employer, nor CDISC..

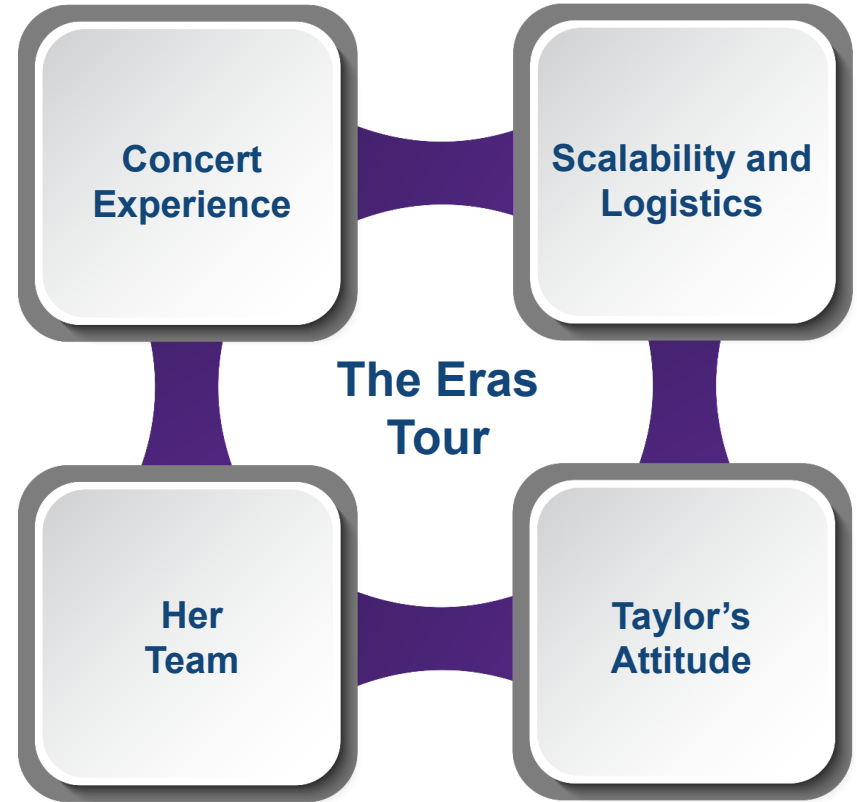




Agenda

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1. How Well-Established Culture Drives Taylor's Success
 2. What Does TMF Culture Mean to You
 3. The 4 Foundational Elements For Healthy TMF Culture
 4. What does TMF Culture Mean in Your Organization?
 5. Case Study - Swifty Pharma
 6. Enhancing Your TMF Culture
 7. Questions

How well-
established
culture drives
Taylor's success



The Concert Experience

Breathtaking sets, beautiful costumes, and great choreography

A well-managed TMF Functions with everybody fulfilling their role. When it's showtime and Inspection readiness activities are about to start, it's your duty to put on the show.

The Inspectors didn't show up for a garage band performance, they have expectations.

Investment in stage, lighting, and sound driving a memorable fan experience.

Having the right people, process, and technology in place are key for the TMF to work effectively. Many of us are faced with limited budget and capacity, it is essential to do the best with what we have for bring the best experience to the users.





Scalability and logistics of her concerts

Global Tours are built to Scale with Logistics Seamlessly Planned

There needs to be solid investment into the planning and execution of the TMF. A well rounded TMF culture will be able to respond based on the business need. If during the study, there is a need for additional internal resources or vendor support, a plan should already be in place.

149 Concerts, 5 Continents, 2 Years

Build a repeatable process and be agile to deal with unseen TMF challenges that come your way. Use the time between inspections to regroup and learn from your successes and challenges.

Hard Work Brought Financial Success; \$1.4 Billion Gross Revenue

Achieving a successful TMF is hard work, but having a healthy TMF culture allows that to happen. In doing so, you bring about opportunities for recognition and professional growth.

The Swift Agency (The Team)

Taylor's Tour is Successful because her Team is Supportive

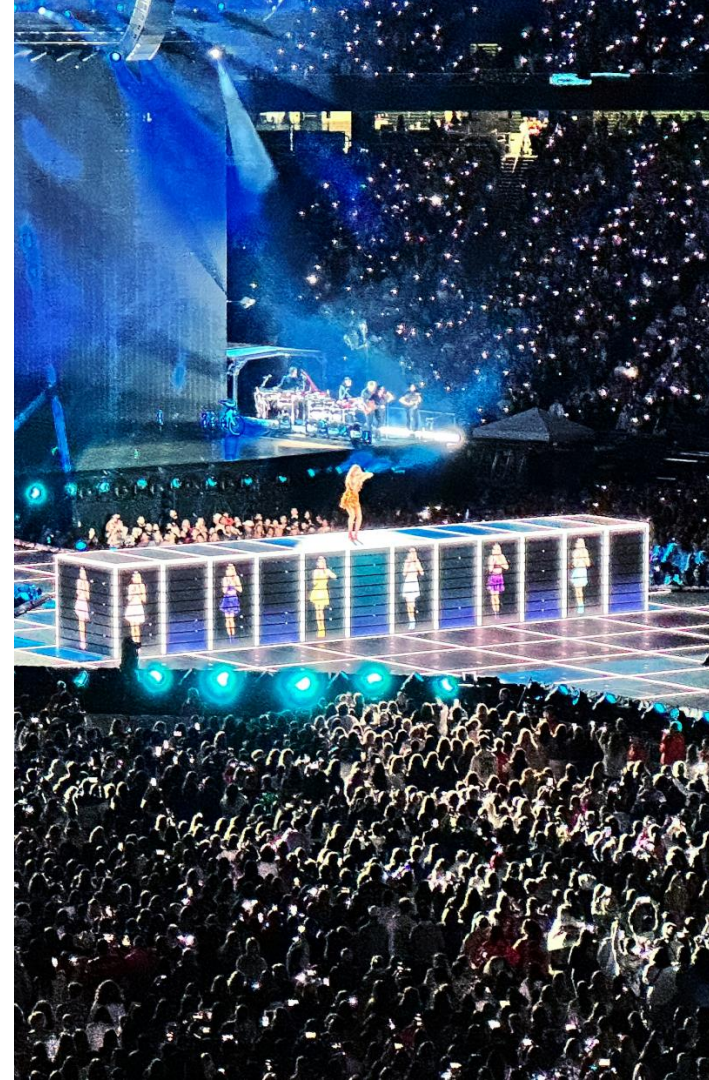
A TMF department needs the support of each TMF Stakeholder over the duration of the clinical trial. Each stakeholder brings their own expert knowledge that feeds into the overall success of the TMF.

Taylor's PR team creates Billions of Positive Impressions for her Fans

Advocates for the TMF need to promote the message of its importance within the clinical operations space. Develop a narrative that provides an unshakable culture of expectations, trust, and understanding.

Taylor's Team is Dedicated to Deliver Excellence Night after Night

There needs to be a consistent approach toward trial success to ensure the medicine makes it way into the hands of the patients. Whatever obstacles you face, the TMF Stakeholders need to be dedicated to always work to rise above those challenges.





Taylor being Taylor

It was not just a Concert, but a journey through her Evolution as an Artist

The TMF is more than being inspection ready. It encapsulates the ups and downs of the clinical study. The TMF tells the whole story of the sweat, tears, and joy in bringing a drug to the market.

Taylor's ability to tell a story through her music allows her fans to make that personal connection to understand where she came from and where she is going

How you tell the story of the TMF is as important as the TMF itself.

The continuous success of her concert is dependent on connection Taylor makes with ticketholders/fans through all the decisions made along her journey

Having a top-notch TMF program takes a village, but it needs you to lead. A lot will depend on the details you implement, both big and small, in creating a thriving TMF program. How well stakeholders connect with your TMF Program will determine its success. In the end, ask yourself...do you want to be the reason why the drug did not get approved?

What Does TMF Culture Mean To You?

"Culture is the foundation of TMF. Without it, success has boundaries."



“Foundational 4” - Elements For Healthy TMF Culture

Intentions

- Establishing what "good/great" looks like within your organization.
- Having a vision and goals for the TMF department are key. Oftentimes this can be a multi-step maturity model/plan.
- Easy to follow TMF process documentation practices

Expectations

- What outcomes do you expect when you achieve "good/great" TMF?
- Establish a known standard within your organization
- Clearly defined roles and expectations.

Respect

- Transparent TMF stakeholder expectations for deliverables and inspection readiness
- Hierarchy of Issue Escalation
- Establishing accountability and a culture of quality.

Awareness

- Importance of TMF to trial success
- TMF Management is a study team responsibility
- What is going on around you?
 - Study timelines and conflicting study deliverables
 - Bandwidth of study team availability

What does TMF culture mean in your organization? Make it known

Understanding the gaps to 100% inspection readiness

- Is 100% inspection ready really needed?
- Is 90% (realistically) okay?
 - Think completeness in large Phase 3 Study (100K documents with 10K missing)

TMF stakeholder expectations

- Who is expected to file, what gets filed, and to where?
- Who is responsible for Quality Reviews?
- What determines TMF completeness?

Constant Communication

- Does TMF Group have a seat at the table. Larger meetings, standalone meeting. (Praise when things go well)
- Don't just call out TMF when things aren't going well.



Case Study: Swifty Pharma



Background

Mrs. Kelce is the TMF manager at Swifty Pharmaceuticals, which is currently running five phase-3 clinical trials on a new drug (TravJasix) that reverses the progression of CTE utilizing mRNA medicine. Mrs. Kelcey has been notified that the FDA will be coming for inspection in 2-months.

Challenge

Mrs. Kelce started at Swifty Pharmaceuticals 2 years ago and has been only person of the TMF Department during that time. Although each study's TMF is held in an internal system, Mrs. Kelce doesn't often attend study team meetings, because they typically never get to the TMF topics before time ends. On occasion, when time does allow, she notices that a high number of team members dropping off or a lack of engagement by the remaining team members.

As a department of one, Mrs. Kelce does not make time to speak with her TMF Vendor but must rely heavily on the outsourced TMF operations team they provide. The primary work of this TMF operations team is to issue queries on the filed documents. To her surprise, she doesn't understand why most of the documents receive a query when document owners need only to follow her 35-page TMF plan and the 20-tab TMF Index that she created. Furthermore, she relies on each study team to run their own KPIs as they see fit.

Lastly, while she continuously tells leadership that the TMF is and must be 100% inspection ready all the time, she constantly gets pushback from the functional leads that they are not responsible for doing the completeness reviews, nor do they feel that TMF is equally important to the clinical trial as their own deliverables.

Mrs. Kelce thinks she can handle the inspection on her own. She knows that there are some weak areas within the TMF, but 2-months should provide more than enough time prepare for the inspection.

As she tells her line-manager, "All everyone must do is simply follow the TMF plan and TMF map as I have written."

Case Study: Key Elements



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Lessons Learned: "Foundational 4" Elements for Healthy TMF Culture

Inspection Outcomes

Filing of Documents is Inconsistent

- TMF Plan was difficult to follow
 - Lack of constancy across the 5-studies
 - ALOCA++ not often observed in docs
 - RACI Matrix not obeyed

Expected Documents Were Not Easily Located

- TMF Map was not clear on filing locations
 - DM kept their docs on SharePoint
 - Absence of filing uniformity within artifacts
 - Standard naming conventions fell short

Quality of TMF is of Grave Concern

- Study team accountability is non-existent
 - Completeness reviews were missing
 - Most docs had queries open 30+ days
 - KPIs were inaccurate across studies

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Enhancing Your TMF Culture

Define

The behavior that you expect, Ownership and Accountability - Set and Manage Expectations Appropriately

- Your third parties (vendors) wants to please you
- Your internal team wants to successfully support inspection readiness
- Campaign for Executive Leadership buy in

Collaborate

Communication is Essential, if you are not getting the outcomes you expect, speak up

- Setup office-hours
- Prioritize TMF on Study Team meetings, or arrange a TMF focused meeting
- Prioritize relationships with your TMF vendor

Transparency

- Share your long-term TMF vision with stakeholders, to gain support
- Make your expectations for quality the standard known.
- Understand your capabilities and limitations within your TMF department

Engaging

- Mascots/Logos
- Events (Yearly, bi-yearly)
- Make TMF approachable

A wide-angle shot of a large-scale concert or festival. The stage is illuminated with bright, colorful spotlights, and a large crowd of people is visible in the foreground, mostly seen from behind. The text "Thank You" is overlaid in large white letters across the center of the image. On the far left, there is a vertical decorative border with a grid of colored dots in blue, red, and yellow.

Thank You