TMF WEEK 2022

by montrium

Become a Better Storyteller and Implement a TMF Maturity and Process Model

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Agenda

- The meaning of process
- Elements of a process
- Maturity Level: assess and evaluate
- Three dimensions of inspection readiness
- Montrium eTMF Services

WHAT IS A PROCESS?

- Final goal
- Book the flights
- Book the hotel
- Prepare your bags
- Check the passport
- and....
- Take the flight!

WHAT IS A PROCESS?

A set of activities and/or tasks to get a specific result

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Is the Trial Master File a process?

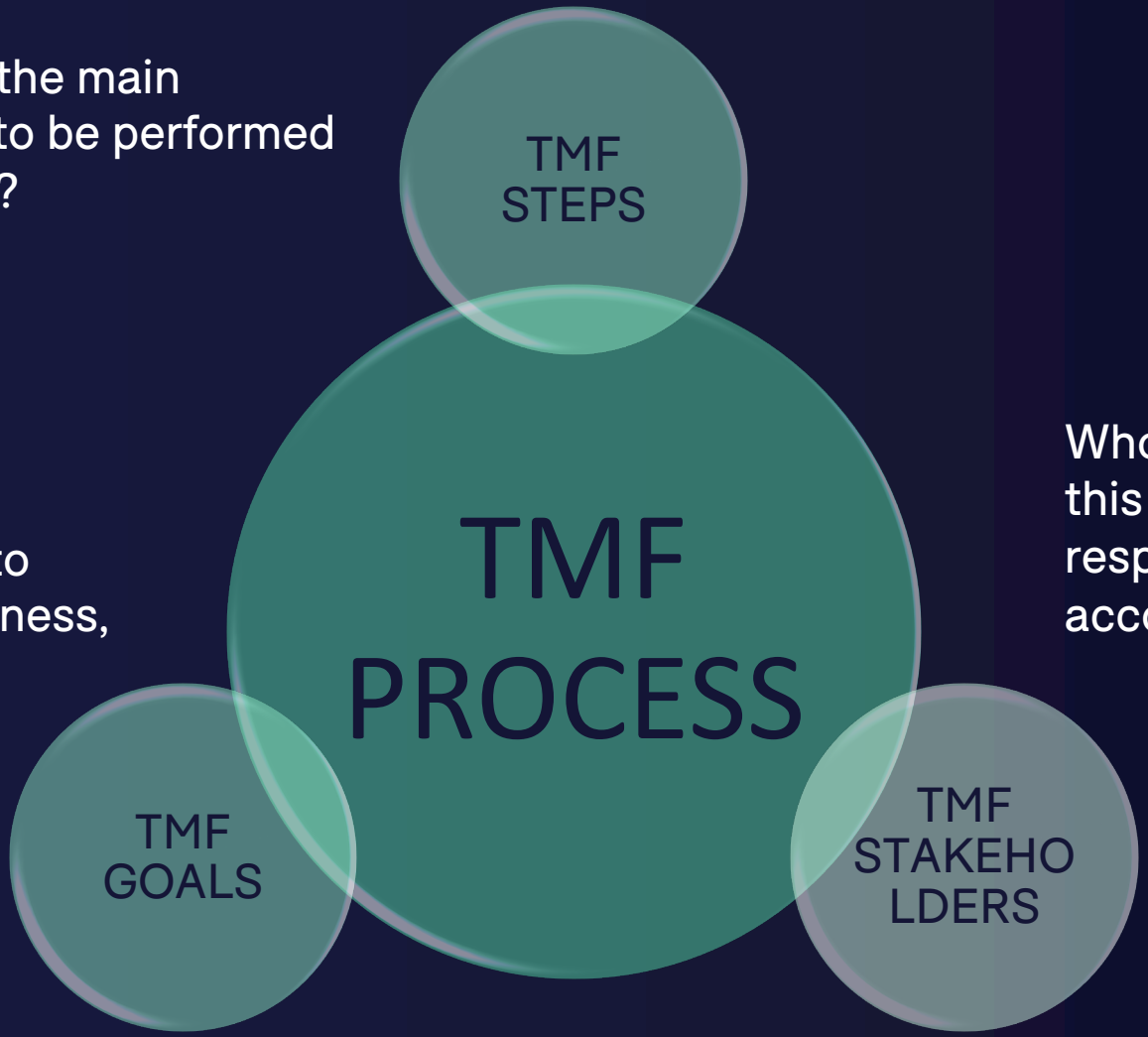
a) Yes
b) No
c) I don’t know

TMF is ....

- ❑ How do you collect the pieces of the story?
- ❑ How do you ensure the quality and consistency?
- ❑ How can you ensure compliance?
- ❑ How do you guarantee the completeness?
- ❑ How do you ensure inspection readiness?
- ❑ How do you document the quality check?

TMF PROCESS

What are the main activities to be performed and when?



What do you want to achieve? Completeness, quality, timeliness, compliance?

Who is going to perform this activity? Who is responsible and who is accountable?

TMF PROCESS

START FROM THE END (GOALS AND OBJECTIVES)

PLAN AND MAP YOUR ACTIVITIES

SET ACTIONS AND ASSIGN STAKEHOLDERS

TEST THE PROCESS

IMPLEMENT THE PROCESS

MONITOR THE RESULTS

REPEAT AND/OR IMPROVE IT

INSPECTION READINESS

COMPLETENESS

QUALITY

How do you ensure TMF inspection readiness?

a) By regularly monitoring my TMF
b) By using metrics and KPIs
c) By developing a robust process
d) All the above
e) I don’t know

- How to achieve my goal?
- What are the activities?
- What are the tools?

- Who is going to do what?

TMF PROCESS

Perform the activity according to the process identified
ACT
Don’t forget to check your process regularly
MONITOR
Improve thanks to lessons learned and gained experiences
IMPROVE

The process is a dynamic aspect of your TMF management

REGULATORY REQUIREMENTS

ORGANIZATIONAL CHANGES

IMPROVEMENT

Do you know the maturity level of your TMF process?

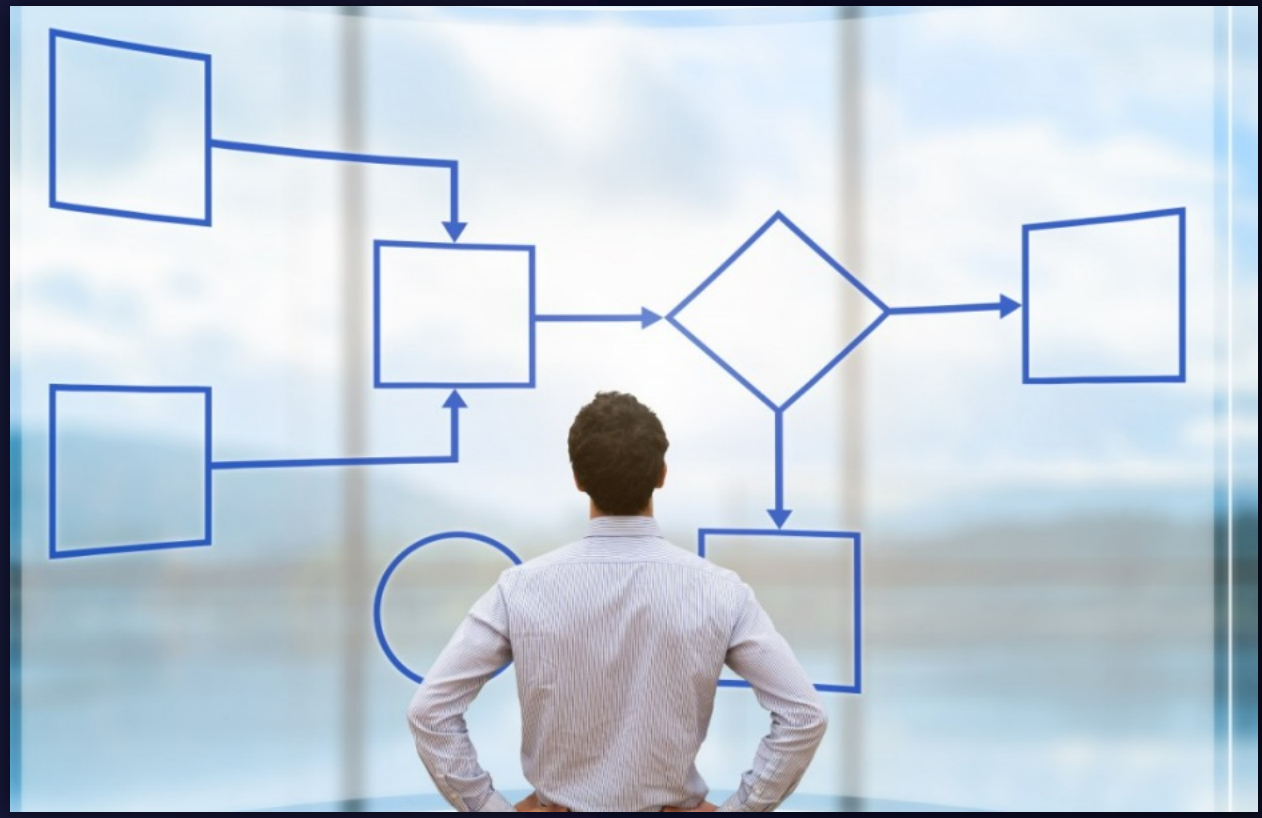
a) Yes
b) No
c) I don’t know what that is

Evaluation and assessment to identify:

- Gaps
- Priority
- Future state

Gaps:

- What is not covered with the actual process?
- What are the missing steps?



Priority:

Risk-based approach to better allocate resources and time

Future state:

- Best practice
- Industry benchmark
- Final goal

What are the other dimensions (in addition to the process) that are fundamental to TMF management?

a) People and Technology
b) People and Business
c) Technology and Study Design
d) Technology and Regulations
e) I don’t know

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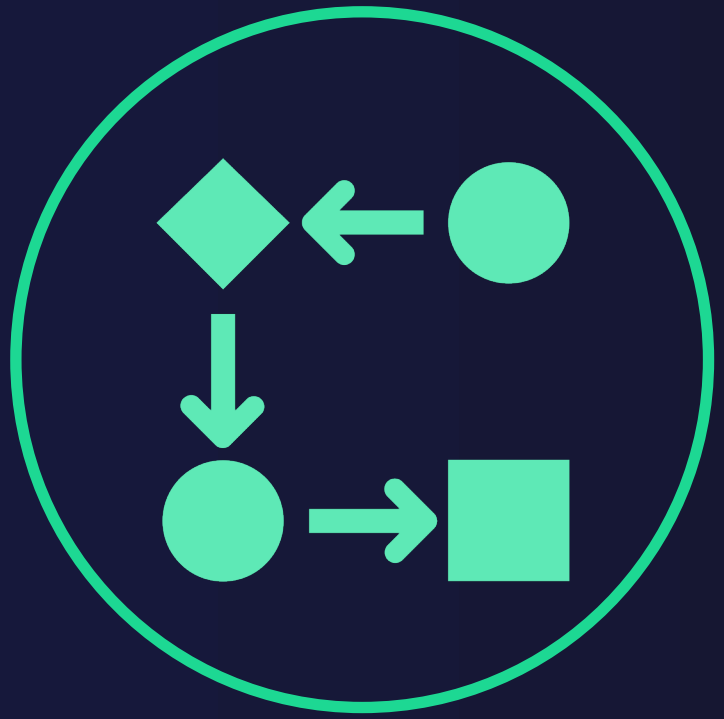
People
and
technology
for a robust process

Training people



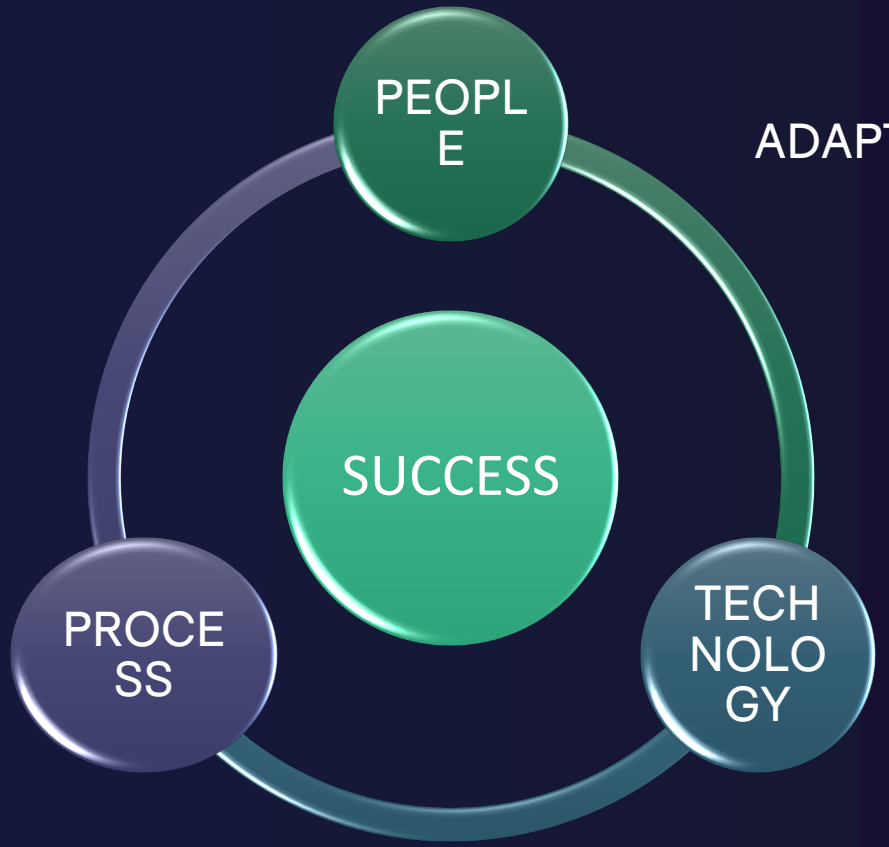
Technology to support

People,
process &
technology
for inspection readiness

Technology as a
supportive tool for the
process and people

Innovation and continuous improvement enabled through process excellence and high-performing organization culture

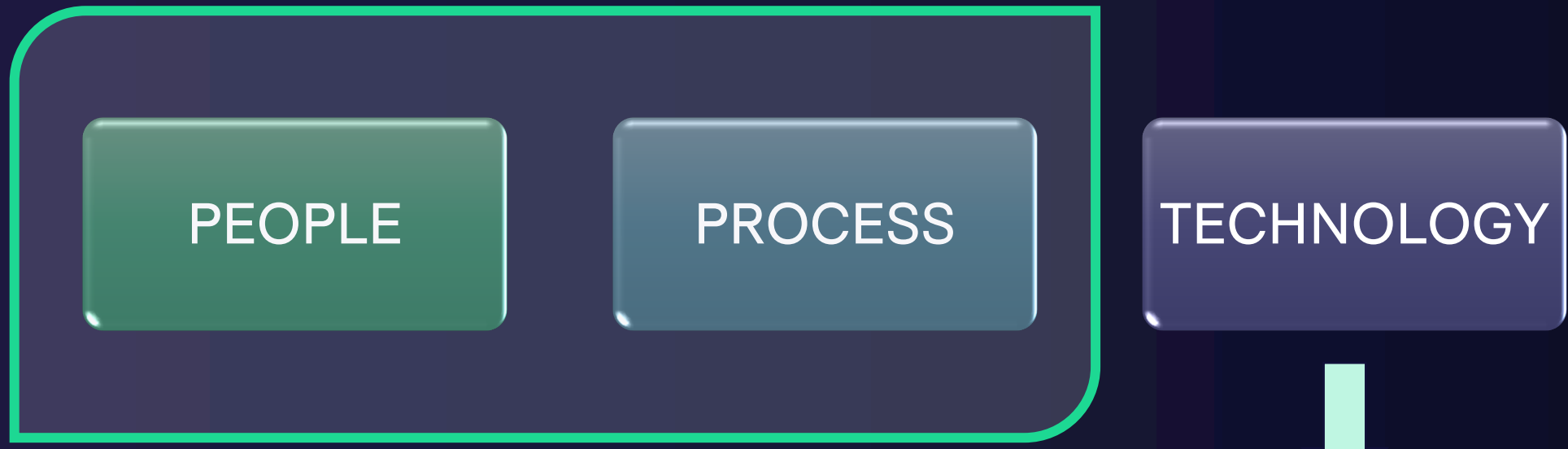
TMF management is comprised of these three dimensions working together for one common goal: inspection readiness



ADAPTIVE CULTURE

SYSTEM UPGRADE

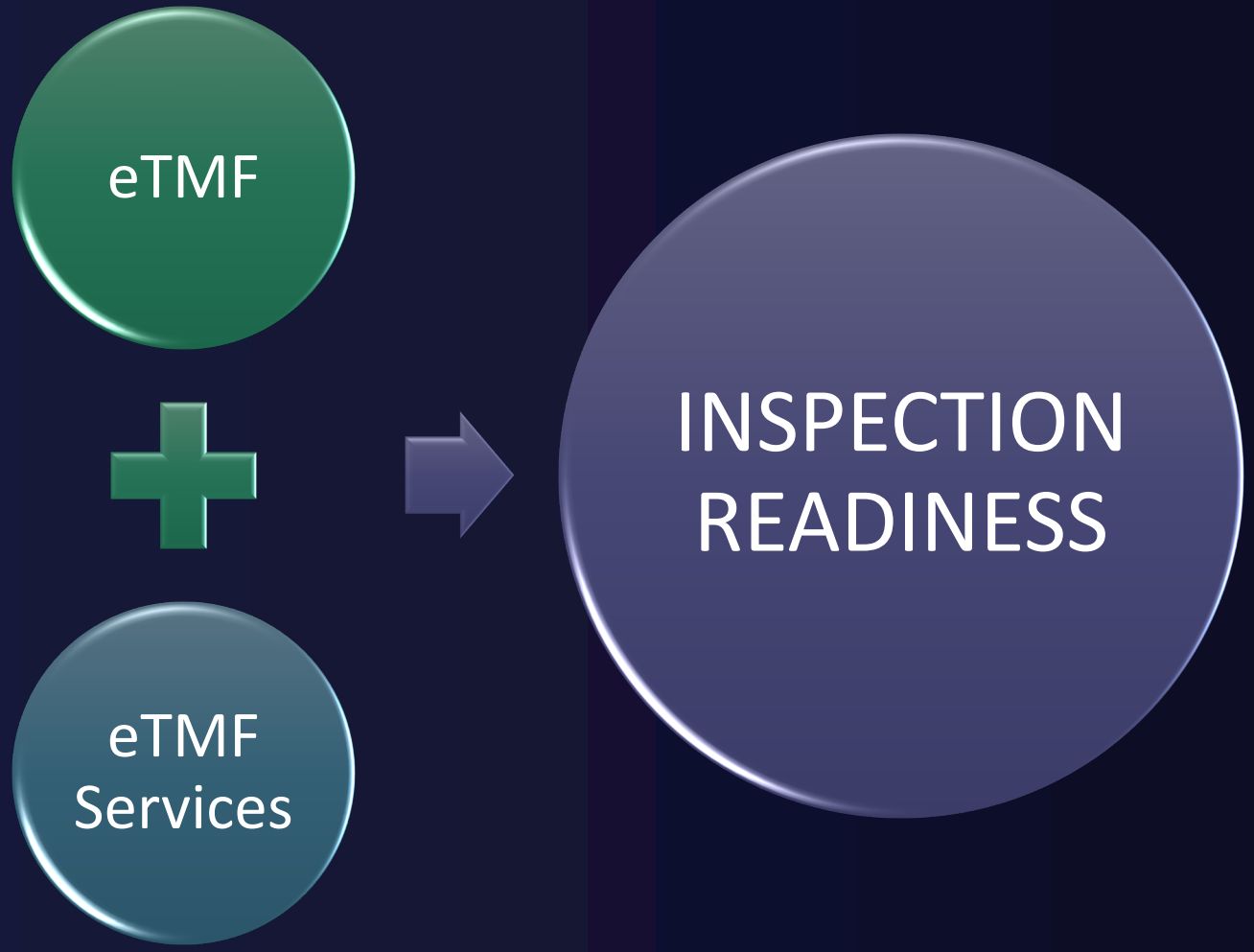
PROCESS IMPROVEMENT



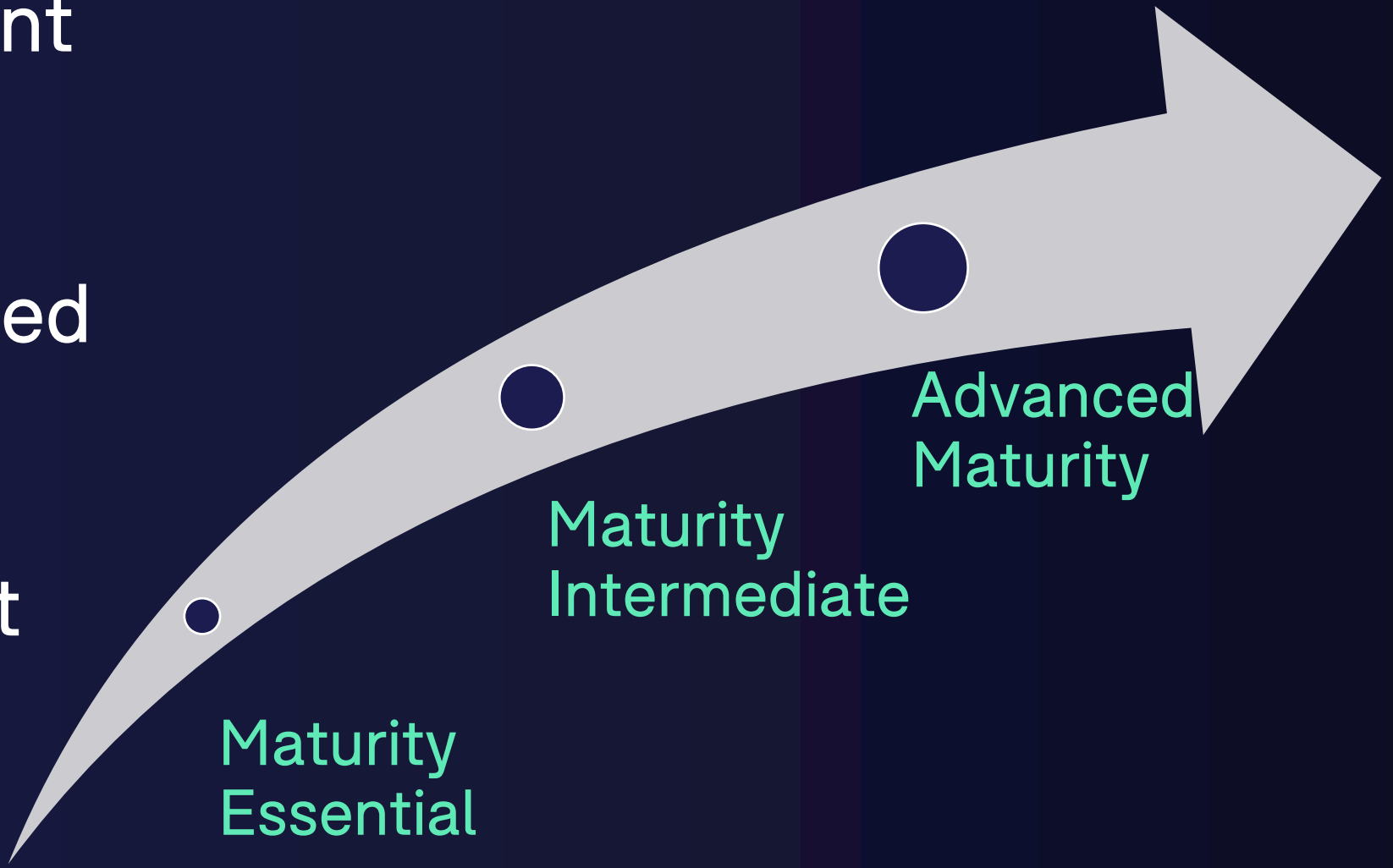
Montrium eTMF Connect

Montrium eTMF Services

An eTMF system supported by a strong TMF culture and knowledge, combined with the development of a robust process are the key factors in ensuring a successful inspection



Three different levels and packages of trainings based on your maturity starting point



TMF PROCESS

- ❑ TMF PRINCIPELS AND GCP
- ❑ DOCUMENT QUALITY CONTROL
- ❑ TMF INDEX & REFERENCE MODEL
- ❑ eTMF PLAN
- ❑ BENEFITS OF AN eTMF

- ❑ RISK-BASED APPROACH
- ❑ TMF METRICS AND KPIs
- ❑ TMF MERGER & ACQUISITION
- ❑ QUALITY BY DESIGN TO TMF
- ❑ INSPECTION READINESS
- ❑ TMF STORYBOARD
- ❑ BRING TMF MANAGEMENT IN-HOUSE
- ❑ TMF LONG RETENTION

- ❑ TMF QUALITY CONTROL
- ❑ TMF CURRENT REGULATION
- ❑ TMF PROCESSES
- ❑ TMF DATA INTEGRITY
- ❑ OVERSIGHT THROUGH eTMF

Approach to a successful TMF process

- Understand your maturity level
- Define your vision
- Re-design your process

eTMF Services to develop TMF process

Assessment

Health Check

Oversight

Quality

TMF PROCESS

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TMF process can be a challenging journey, but you are not alone. **Montrium's eTMF Services** can be your expert guide.