eTMF
BOOTCAMP
FROM TMF NOVICE TO EXPERT

Presented by

Dawn Niccum
Sr. Director of QA & Compliance
InSeption Group

Date

31 Mar 2021

Improving the Quality of your TMF through Metrics & Technology

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Housekeeping

- This session will be recorded and made available to all registrants
- All recordings will be available on demand via a link sent following each event
- The Certificate of Attendance will be provided within 7 days of each session
- Registrants must attend at least 1 eTMF Bootcamp session to receive the certificate

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Other Bootcamp Sessions

eTMF BOOTCAMP FROM TMF NOVICE TO EXPERT

Session 4

Jamie O'Keefe,
Vice President, Business
& Technology Consulting,
Just In Time GCP

Oliver Pearce,
Commercialization
Director, Montrium

How to Select & Implement an eTMF System in 90 Days.

April 14th @ 10am EST
(7am PST / 4pm CET)

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Session 5

Janine Penman,
Managing Director,
JPScientific

Oliver Pearce,
Commercialization
Director, Montrium

Bringing TMF Management In-House in 2021: The Year of the Sponsor eTMF

May 6th @ 10am EST
(7am PST / 4pm CET)

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Session 6

Stephanie Viscomi,
Associate Director,
TMF Operations, Alexion

Paul Fenton,
President & CEO,
Montrium

How to Manage a Multi-Vendor eTMF Ecosystem Effectively.

May 25th @ 10am EST
(7am PST / 4pm CET)

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Montrium is a leader in content management solutions for emerging life science organizations. We specialize in helping small and medium sized organization optimize and evolve their processes through the Connect platform

OUR HISTORY

2005
Established

50+
Experienced Employees

11000
Life Science Users

Montreal, CA
Headquartered in

OUR STORY

Life Science Exclusive
Extensive Industry Experience

Focus on Emerging Orgs
Leader for Small-Medium Companies

250+ Tech Implementations
An experienced partner

Global Customer Base
In over 30+ countries

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Your speaker today

Dawn Niccum

Sr. Director of QA & Compliance

dniccum@inseptiongroup.com

Dawn Niccum has over 25 years experience in the Pharmaceutical industry. She is currently the Sr. Director, Quality Assurance and Compliance for the inSeption Group. She is an expert in development and implementation of clinical trial systems. She has presented at numerous conferences on the clinical quality systems, trial master file, risk management, and inspection readiness. Dawn holds a masters degree in Regulatory Affairs from Purdue University, has certifications in clinical research, GCP quality assurance, and Project Management, and is a registered nurse.

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G R O U P

SERVICES

Clinical Operations

Site Management and Clinical Monitoring

Medical Writing

Quality Control

Quality Assurance

Electronic Trial Master File

Regulatory Operations

Data Management and Biostatistics

Contracts and Legal

Pharmacovigilance

OUR DIFFERENCE

It is our ability to provide an environment where the best and the brightest people can flourish, that is key to our success and that of the sponsors who trust us with their work.

Recognition:

Inc. 5000: Top 5,000 fastest growing companies in America (2nd consecutive year)

Philly 100: Top 100 fastest growing companies in Philadelphia Region

Lehigh Valley Business Association: Top 64 fastest growing companies in Lehigh Valley (2nd consecutive year)

97%
Client Retention Rate

<4%
Employee Attrition Rate

85%
Growth Rate

Session Objectives

1
Describe how to drive continuous improvement in your eTMF through metrics

2
Develop Key Quality Indicators to identify issues early

3
Explain the role of metrics in optimizing the quality of your eTMF

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Continuous Improvement

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POLL

What comes to mind when you hear "continuous improvement"?

a) Extra Work

b) Quality Assurance Responsibility
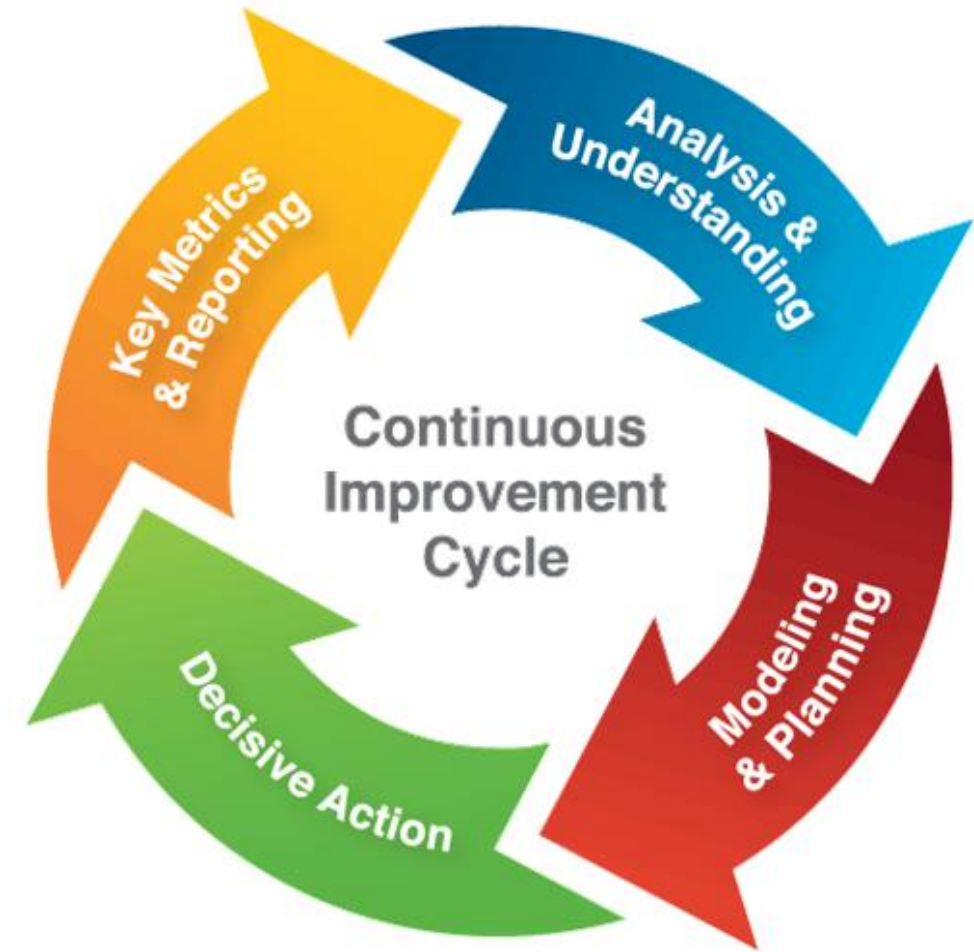
c) Component of Inspection Readiness

d) Other

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Continuous Improvement

Definition: Process of upgrading your organization's products, processes, systems, and services

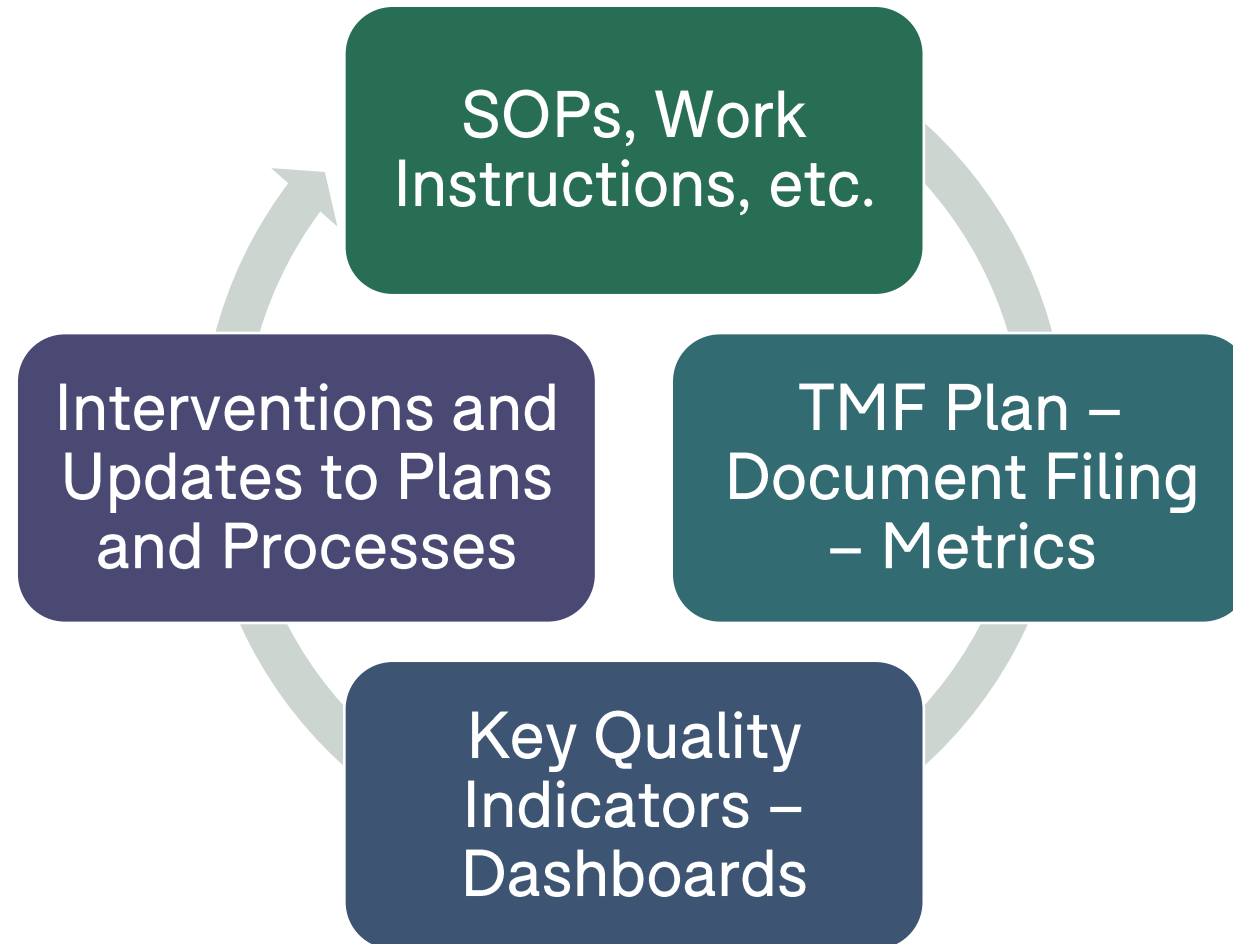Result: High quality products and services

Quality is a journey, not a destination.

Principles

- Ongoing cycle of positive change

- Kaizen: small step-by-step incremental improvement strategy

- W. Edward Deming's "Plan>Do>Check>Act" cycle

- Cornerstone of a Quality Management System

Continuous Improvement in TMF

Key Quality Indicators

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POLL

Which metric is most important?

a) Completeness

b) Timeliness

c) Quality

d) All are equally important

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Meaningful Metrics

- Accurate Completeness
  - Event Driven
  - Clustering Placeholders
- Timeliness
  - Document creation in relationship to filing
  - TMF as an active Study Management tool
- Quality
  - Focus shift from individual documents to overall logic of TMF
  - Risk Based approach

Key Quality Indicators

- Completeness of TMF
  - Does it tell the story of the clinical trial?
  - Key Document Review e.g., protocols, ICFs, RA/EC approvals, startup packages
- Time of approval in TMF in relation to document date
  - Define what document date means
- Quality
  - Number of documents meeting quality at first submission
  - Number of misfiles
  - Number of queries
  - Query aging

Set Tolerance Limits

- Tolerance Limit
  - Level, point, or value associated with a metric that will trigger an action.
- Based on knowledge of TMF Quality
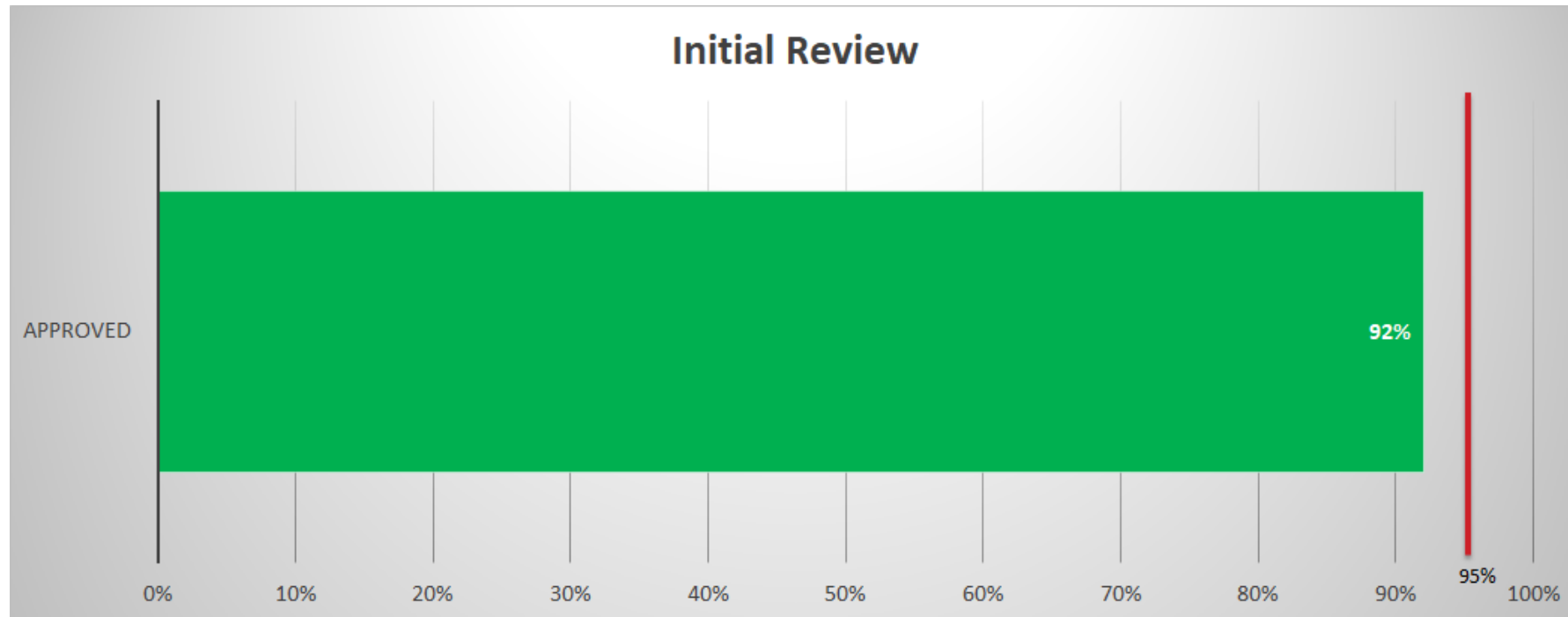- Set reasonable limits, don't expect perfection

What happens when a tolerance limit is missed?

a) Investigation and Root Cause Analysis

b) Depends at what timepoint it hits

c) Increased review employed

d) Defined in the TMF Plan

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Threshold Setting

% of documents passing initial review > 95%

Initial Review

APPROVED — 92%

95%

Investigation and Root Cause Analysis

- Review the documents failing initial review – what do they have in common
  - Sender
  - Artifact
  - Country/Site
- Explore all aspects to determine error
  - Procedure
  - Process
  - Tools/Equipment
  - Training Material
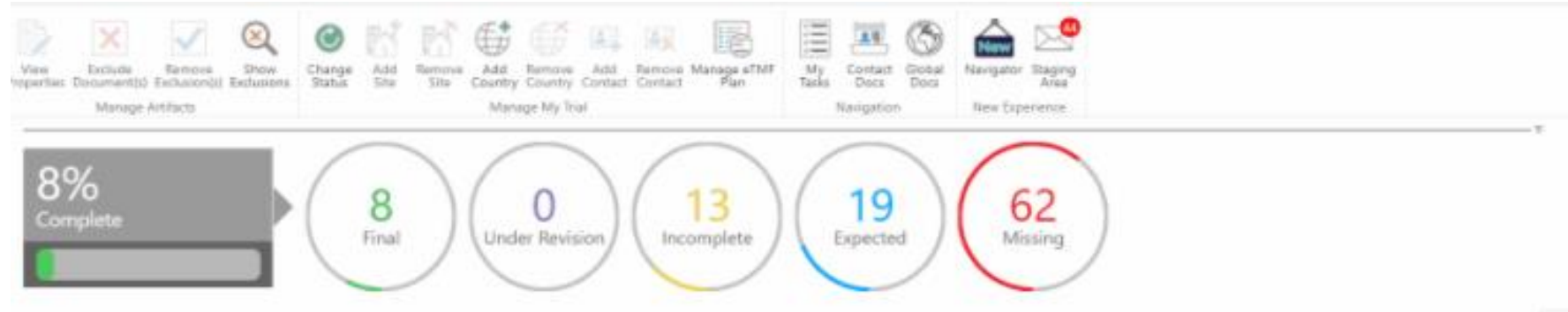
Target Solution to Issue

The Role of Metrics in Quality

Metrics and Continuous Improvement

- Identify issues early – early intervention, less issues overall
- Shows state of control
- Allows Continuous Improvement – during a study and in the overall process
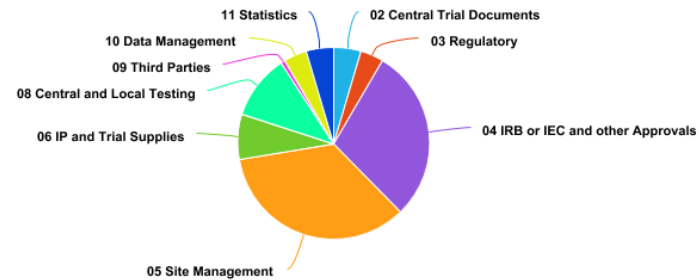- Continuous Improvement is the cornerstone of inspection readiness

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Dashboards

In conclusion

- TMF Quality goes beyond individual document quality
- Use eTMF tools to trigger action
- Continuous Improvement efforts show "state of control" as part of overall Quality Management System

Get in touch

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Thank You!

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