NAEM Webinar

Virtual Audits: Planning is Key

30 July 2020

Doreen Parrish, Head Corporate EHS Audit/ Wade Miller, Lead Auditor

cEHS Audit

Takeda

Better Health, Brighter Future

Introducing Takeda's VirMote Audits

Takeda's VirMote Audit

- The cEHS Audit team's new Brand for Takeda

- **VirMote** Auditing - Combining technology of virtual computing experience and the collaborate tools of a remote work environment, VirMote auditing is one way we will be moving forward in this new world of working.

- Covid-19 provided the impetus for the audit program to adjust to limit physical interactions with site personnel.

Virtual:
Almost or nearly as described, but not completely or according to strict definition COMPUTING DEFINITION not physically existing as such but made by software to appear to do so

+

Remote:
Situated far from or away and having very little connection with or relationship to.

=

VirMote:
Situated away from, and not physically present, but seemingly to exist and be as described

Developing a new word to help transform Virtual or Remote Audit Concepts into Reality

Planning and Execution

Planning and Execution: VirMote Audits

Main take away after "testing" VirMote audit in Japan: executed too fast and too soon.

- Now through September, it's all planning. We're not "auditing to audit."

- Without planning, this could be only a temporary patch – a lost opportunity.

- However, continuous improvement and iterative process were part of Takeda's audit program to begin with. We are never going back. We are going to continue to use these tools.

- Perhaps we are now doing EHS audit the way we should have been doing it all along (or as we did in the past).

Takeda's Objectives for VirMote Audits

INTRODUCING... cEHS T'DA Audit Program

Transforming Takeda Culture through EHS Leadership & Turning Audit on its Head

A T

U

D I D

I U

T A

Transform Audit into Learning

Continuously Improving / Innovation

with

U & I

Develop Competence & Drive Performance

Connected / Mutual Accountability

People & Performance

Assure Compliance

EHS / Quality / Ethics & Compliance

T'DA!

The T'DA audit program was established to provide organizational learning, developing EHS leaders, drive performance, ensuring compliance and facilitate alignment of EHS goals and objectives across Takeda

Takeda's Objectives and Expectations for VirMote Audits

VirMote Audit Objectives:

1. Results should be similar whether it is a VirMote audit or a site visit audit

2. VirMote auditing introduces tools and refines the EHS audit program including the onsite audits

3. Alignment with T'DA Audit Objectives Managing Expectations

4. VirMote audit approach communicated to Leadership

5. Partnership with Quality and sites to identify synergies

6. Communicating that we will re-prioritize audits based on business needs and not just keep auditing to audit
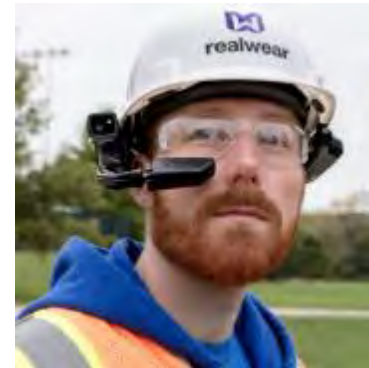
Technology Tools

Tools and Information Exchange

- MS TEAMs will be primary information exchange platform between audit team and site
  - Pre-audit documentation
  - Document Requests
  - Interviews
  - Schedule
  - Notes and Learnings
  - Presentations
  - Reports

Virtual Tools being reviewed on site-by-site basis.

- Sites already have some technologies
- Leverage existing infrastructure
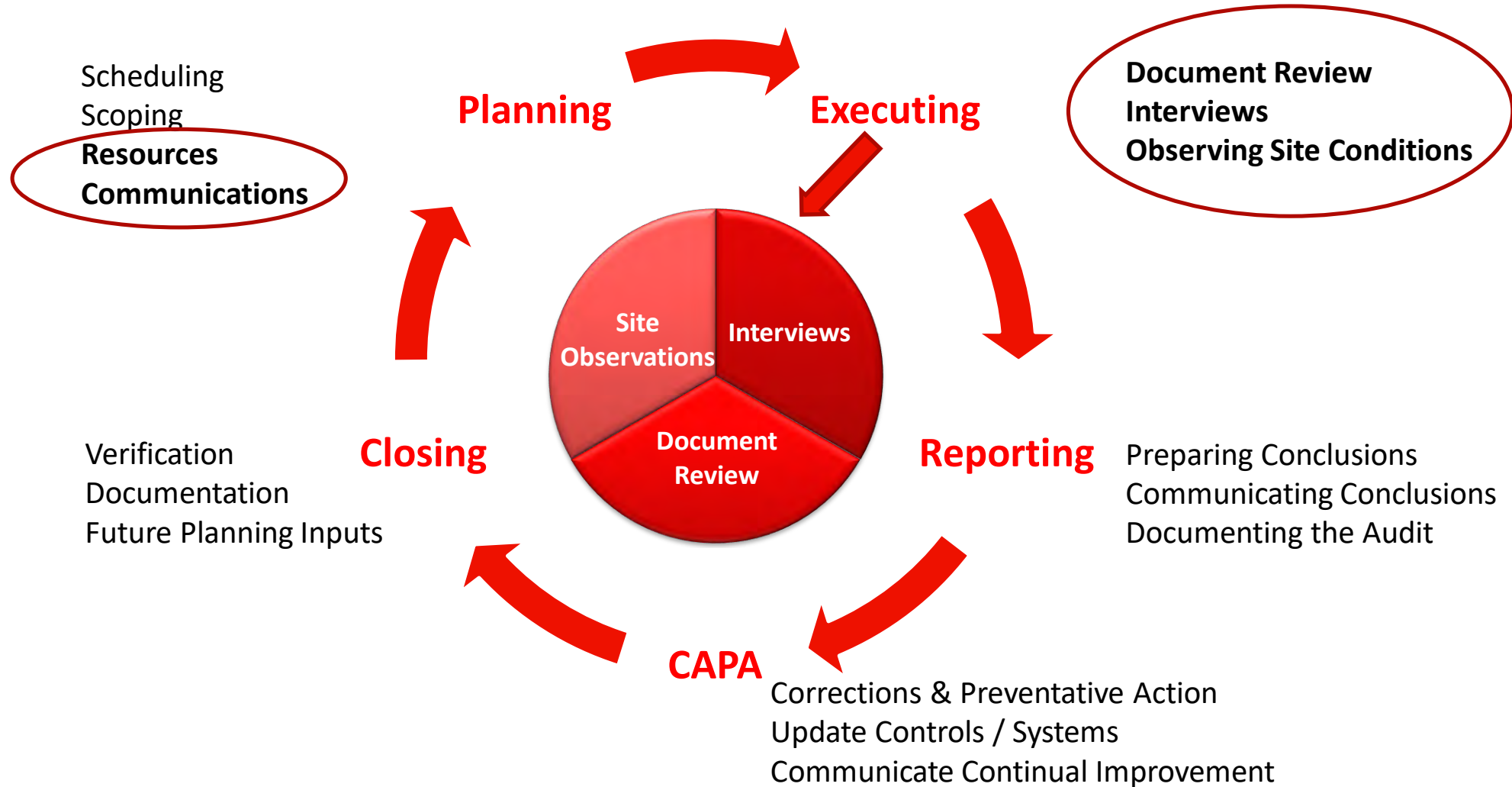- MOC for new technologies

Sites are leading technology; we are still learning
Applications are powerful, but we need to know how to use

Gap Analysis

Scheduling
Scoping
Resources
Communications

Planning

Executing

Document Review
Interviews
Observing Site Conditions

Site Observations

Interviews

Document Review

Verification
Documentation
Future Planning Inputs

Closing

Reporting

Preparing Conclusions
Communicating Conclusions
Documenting the Audit

CAPA

Corrections & Preventative Action
Update Controls / Systems
Communicate Continual Improvement

The **what** we do is not changing, it is only the **how**...

Notable Impacts to Audit Process to Address in Audit Procedure

VirMote Considerations Include:	Auditors	Sites
Additional detail in the planning to allow generation of audit information ahead of audit execution		X
Additional planning and execution time	X	X
Technology training (e.g. MS TEAMS, SharePoint/GoogleDocs/Other File Sharing, onsite technology and infrastructure)	X	X
IT resource availability		X
Constraint of auditor availability due to longer duration and higher planning engagement	X	
Increased communication channels (software and hardware technology)	X	X
Additional scheduled team meetings	X	X
Dedication to the audit, particularly during execution phase	X	X

Additional time and resource demands on the planning and execution portions of the audit

Roles and Responsibilities

T'DA Learnings – Key Roles in VirMote Audits

- Much higher level of interaction in planning at all levels

- Not as much opportunity for less experienced Guest Auditors (less team collaboration, coaching and advisement)

- Site and audit team must dedicate time to the audit (no multi-tasking)

- Lead Auditor needs to have multiple communication systems (multiple computers/channels of communication)

Need to manage expectations for how audit information is communicated

Pre-Audit and Audit Procedures

T'DA Learnings – Considerations for VirMote Audits

- Sites must provide detailed process information, including virtual tours before audit – Recorded tours in advance....

- Documentation and process information (including virtual tours) must be available > 1 week prior to interviews.

- Increased Audit Duration (up to 2.5 Xs longer), but similar actual audit time

- Time zone is a significant planning consideration

Need to manage expectations for how audit information is communicated

Facility Selection for Virtual Audits

SWOT Analysis

Takeda Experience - SWOT

Strengths

T'DA audit program already aligned to incorporate VirMote

Local as possible, Global as needed – Tech at Sites

Quality Requirements created urgency in adopting technology and adapting audit programs

Weaknesses

Timing – COVID lockdown at end of FY after planning

Audit Lead new to the organization

Internal auditor pool not as deep when managing for higher EHS Audit Competence

Opportunities

Alignment with Global Quality organization

Technology is powerful, but we still need to know how to use

Leverage site expertise for continual improvement

Threats

Takeda-Shire Integration (Already a lot of changes across the organization)

Resource constraints for the FY 2020 audit plan

Still have unknowns

Thank You!

Doreen Parrish, CPEA, CHMM

Head of EHS Audit

Corporate Environment, Health and Safety

Takeda Pharmaceutical Company Limited

Mobile +41 79 961 0376

doreen.parrish@takeda.com

Wade Miller, CPEA, CHMM, PMP

EHS Audit Lead

Corporate Environment, Health and Safety

Takeda Pharmaceutical Company Limited

Mobile +1 339 927 3800

wade.miller@takeda.com