# Conducting Remote GxP audits

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Jan 2021

# Presentation content

- Definition of audit types
- Regulatory Requirements
- Advantages and challenges
- Tools and Resources available
- Differences to onsite audits

# Definition of Audit Types

- **Onsite audit**: An audit that is performed at the physical location of the auditee.

- **Remote audit**: Remote audits refer to the use of information and communication technologies (ICT) to gather information, interview an auditee, etc., when “face-to-face” methods are not possible or desired in order to evaluate site Compliance level.
  - **Virtual audit**: An audit performed remotely utilizing a virtual environment. A virtual environment may be composed of digital and/or non-digital activities using technological assets (software, hardware, sensors, PLCs, automated devices, conferencing applications) subject to available technology and / or auditee agreement.
  - **Paper Audit**: An audit in which the auditee provides requested documentation to the auditor for independent review in order for the auditor to make an evaluation of the auditee’s compliance to industry regulations, regulatory requirements and company policies and procedures.

# Audit side

## Remote Audit

Receive as Auditee


Perform as Auditor

# Remote Audits- Strategy Alignment with Regulatory Agencies & Industry Standards


EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brussels, 10 April 2020
*(Revision 2 – 26 May 2020)*

NOTICE TO STAKEHOLDERS

QUESTIONS AND ANSWERS ON REGULATORY EXPECTATIONS FOR MEDICINAL PRODUCTS FOR HUMAN USE DURING THE COVID-19 PANDEMIC

Remote audits of the active substance manufacturer
Where on-site audits are not possible, the QP can rely on paper-based audits and also take into consideration the results of inspections from EEA authorities.
Remote audits should provide confidence that the active substance is fit-for-purpose and will not negatively affect the safety and efficacy of the medicinal product. The QP is expected to justify the controls in place on a scientific basis and record a risk assessment on a product specific basis


U.S. FOOD & DRUG ADMINISTRATION

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Manufacturing, Supply Chain, and Drug Inspections | COVID-19

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Due to the COVID-19 pandemic, FDA announced in March 2020 that it was temporarily postponing all domestic and foreign routine surveillance facility inspections.
With respect to pre-approval inspections,4 FDA intends to continue using other tools and approaches, including requesting existing inspection reports from other trusted foreign regulatory partners through mutual recognition.
FDA prepares for resumption of domestic inspections with new risk assessment system" issued on July 10, 2020. FDA is using its COVID-19 Advisory Rating system to determine… on a case-by-case basis, to conduct only "mission-critical" inspections.


ISO International Organization for Standardization
Web: www.iso.org

IAF International Accreditation Forum
Web : www.iaf.nu

Edition 1
Date: 2020-04-16

ISO 9001 Auditing Practices Group
Guidance on:
REMOTE AUDITS

There are a variety of reasons that an auditor may not be present due to safety constraints, pandemics or travel restrictions. The voluntary or mandatory confinement due to the current COVID19 pandemic, commissioning of windmill assembly of scaffold, explosive testing and other scenarios are all examples where auditing remotely is beneficial.

# Audit method As Per Risk Ranking

Remote audits can be performed per a risk based approach, when an onsite audit is not possible or in combination with onsite auditing
Remote audits are performed according to the overall auditing method and principles of onsite audits

**High Risk**:

- Perform on site audit (where possible)
- Where onsite audit is not possible perform virtual audit

**Medium Risk**:

- Perform virtual audit

**Low Risk**:

- Perform paper audit.

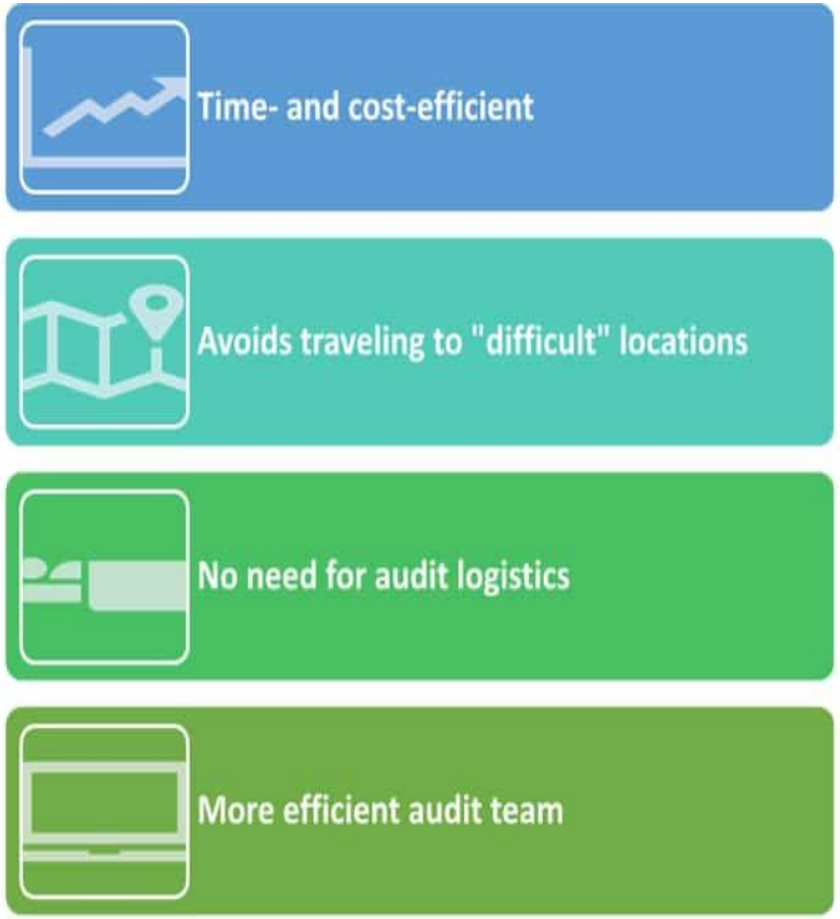
# Remote Inspection – Challenges

- Access to the required documentation depending on the level of electronic tools vs paper-based evidence.
- Timeliness of receiving information, which is harder to enforce when operate remotely
- There could be a lack of credibility of audit information received remotely
- Lack of face-to-face interactions make it harder to build a communication, present, explain and understand
- Calls are likely to need scheduling, removing the ability for ad hoc ‘at desk’ requests
- Reports and work papers may take longer to get reviewed than they would in a normal business environment
- Time differences may make it difficult to schedule sessions
- Language barriers make it harder to translate in real time, and can be greater over the phone than face-to-face
- Staff may be less engaged where operate remotely. Teams are more efficient and focused when co-located

# Remote Inspection – Challenges (continued)

- Translations to English – a lot of docs to be translated
- Late work hours (handling of requests that should be addressed by the next day in the end of the inspection day)
- Explanations in writing – response should be very clear and accurate
- Very tight time limitation for responses
- People availability during COVID-19
- A lot of documentation upon requests are to be reviewed by limited number of employees before sending
- Scanning of documents – on site availability of personnel to scan documents (like Batch records, Validation raw data, etc.)

# Remote Inspection - Advantages




Benefits of remote auditing

- Most data is accessible from anywhere, such as a cloud portal, mails, etc. In addition, interviews and even observations can be conducted through popular platforms like Skype, Teams or Zoom, which are regularly used by many of the companies already.
- Avoiding traveling to “difficult” locations ( an isolated area, or strict permits are needed to get in – even visas sometimes are required ). With a remote audit, you avoid these difficulties.
- Logistics related to auditing are not needed anymore. When conducting remote audits, usually organizations are relieved from logistics related to booking conference rooms and cleaning after the audit team leaves, as well as worrying about audit team accommodation, interruptions to employees’ regular workflow, and other related inconveniences
- Working from their home / office environment, the audit team will feel more comfortable, using all the necessary tools, such as high-speed internet, monitors, printers, etc. The productivity will be substantially increased in an e-audit needing fewer hours to complete a certain task.

# Remote Inspection – Main steps


(*) on-site additional audit may be needed according to accreditation rules

# Differences to onsite audits

**Virtual Audit Planning**:

- Agree with auditee prior to virtual audit:
  - The type of information and communication technologies for use during the audit
    - Robust, secure and effective
  - The availability of SMEs during the virtual audit
  - How to share and exchange documents
    - For documents available on paper only – ask in advance for specific documents to be ready available as scanned files which can be presented by screen sharing during the audit
- Request in advance of the audit, the documentation for review during the virtual audit
- Local requirements shall adhere to the right of privacy and shall be followed

# Tools and Resources (Information and Communication Technologies)

## Screen sharing platforms

MS Teams

Global Meet

Skype for Business

GoToAssist

## Communication devices

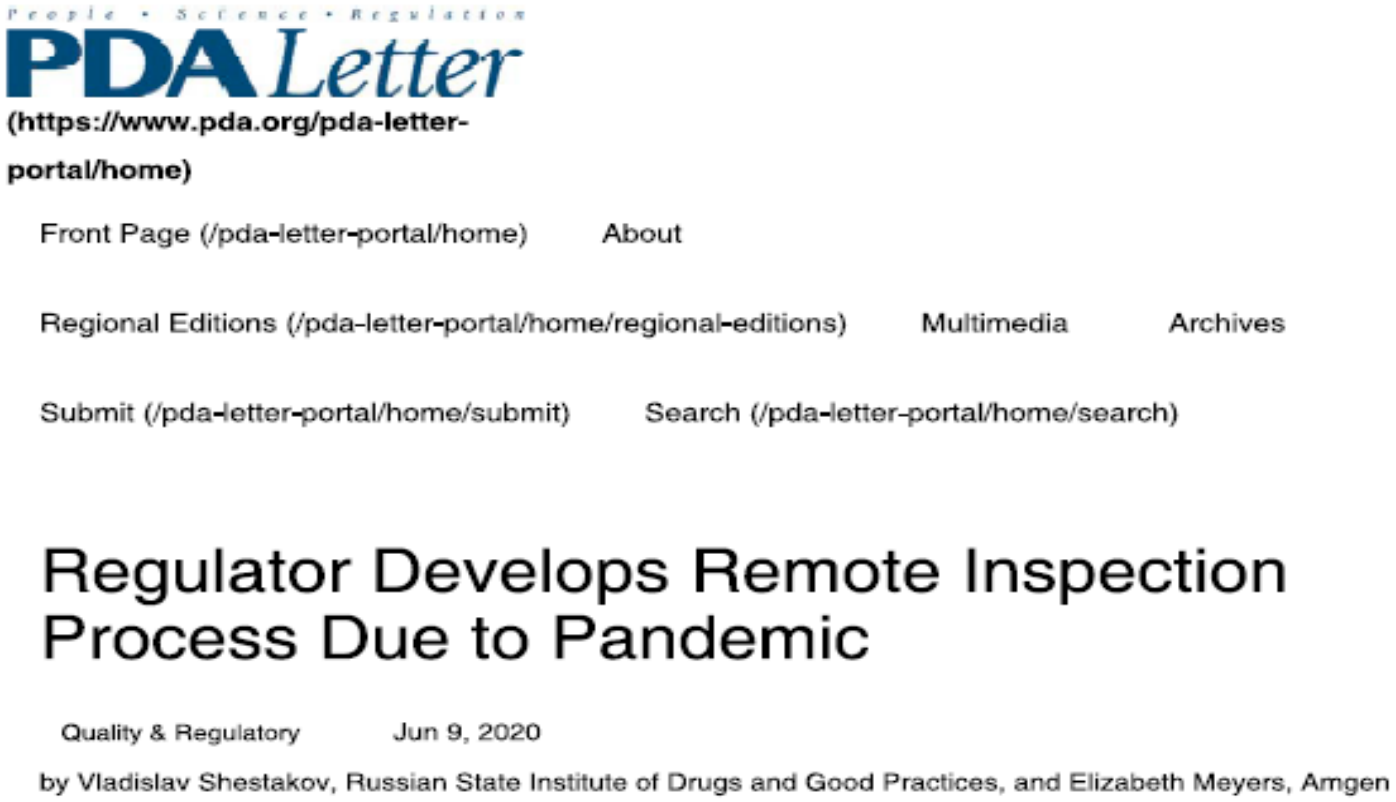
PC

Smartphone

Video cameras

Teleconferences

# Remote Audit preparation – example of RU MOIT Inspection



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## Regulator Develops Remote Inspection Process Due to Pandemic

Quality & Regulatory Jun 9, 2020

by Vladislav Shestakov, Russian State Institute of Drugs and Good Practices, and Elizabeth Meyers, Amgen

https://www.pda.org/pda-letter-portal/home/full-article/regulator-develops-remote-inspection-process-due-to-pandemic

## List of Quality Documents to be Reviewed During Inspection

| № | Requested document |
|---|---|
| | **Pharmaceutical quality system documentation** |
| 1 | Copy of manufacturing site license |
| 2 | Copy of site GMP certificate (issued by local Authority) |
| 3 | CA/PA for observations from the previous inspection |
| 4 | Description of the product XXX production flow – name, address and manufacturing stages for each involved site. Information about quality agreements between involved sites and agreements status. |
| 5 | Analysis of Pharmaceutical quality system functionality by management for effectiveness evaluation (last report) – Quality Management Review report |
| 6 | Annual Product Review Product XXX for 2019 and procedure for quality review creation (sections: review of finish drug product quality, review of complaints, review of deviations, review of changes). Procedure for APR creation. |
| 7 | Procedure for product release. List of persons who performs product release. |
| 8 | Procedure for change control management and list of major changes for the Product XXX for 2019/2020 |
| 9 | Procedure for deviation management and list of deviations for the Product XXX for 2019/2020 |
| 10 | Self-inspection procedure. List of persons who perform self-inspection. Information about self-inspections for the production facility (rooms) used in Product XXX manufacturing process with status of self-inspections (dates, conclusions, responsible auditors) |
| 11 | Procedure for complaints management. List of complaints for 2019/2020 for Product XXX (if applicable) |
| 12 | Procedure for recalls management. List of recalls for 2019/2020 for Product XXX for (if applicable) |
| 13 | List of approved suppliers of materials for Product XXX |
| 14 | Job description for key personnel: Head of manufacturing, Head of Quality Control |
| 15 | Detailed layout of XXX manufacturing facility with indication of rooms grades, personnel & material flows, equipment location, indication of manufacturing line used for manufacturing of Product XXX |
| 16 | Detailed layout of QC laboratories used for Product XXX testing |
| 17 | Detailed diagrams of HVAC system for facility where Product XXX is produced |
| 18 | Detailed layout of warehouses involved in Product XXX manufacturing |
| 19 | Procedure for handling of intermediate and finished products on warehouse (receiving, storage) |
| 20 | Copy of Master Batch Record for Product XXX packaging (batch number is up to manufacturing site'sdecision) |
| 21 | In-process controls of Product XXX manufacturing process (procedure that defines performing of In-process controls) |
| 22 | Storage conditions for Product XXX (procedure that defines storage conditions) |
| 23 | List of planned validation and qualification activities for 2020 (related to equipment and production rooms used for Product XXX manufacturing |
| 24 | Report and protocol of qualification of production rooms used for Product XXX manufacturing |
| 25 | Report and protocol of manufacturing line qualification used for Product XXX manufacturing |
| 26 | Specification for FDP Product XXX manufacturing |
| 27 | Specification for LDP (before packaging) Product XXX manufacturing |
| 28 | Stability study report for Product XXX including data along all product shelf life. Procedure for products stability study. |
| 29 | Plan for Product XXX stability study |
| 30 | Analytical methods validation (or methods transfer report) for Product XXX *(methods will be selected after specification receiving)* |
| 31 | Procedure for OOS management. List of OOS for 2019/2020 for Product XXX |

# Remote Audit preparation – example of requests organizing

Regulatory Compliance Department

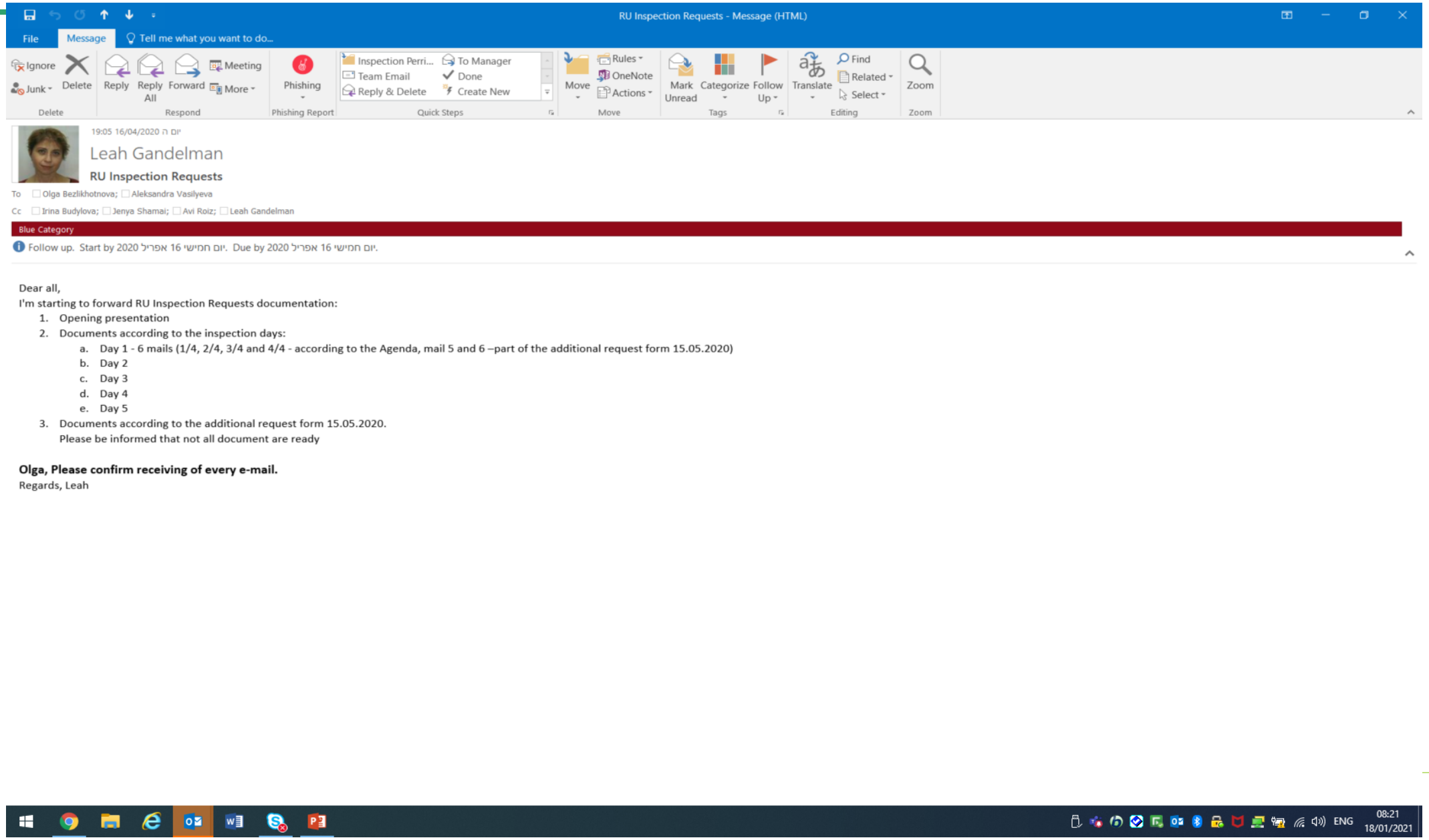
**GRA Audit Requests**

**Please be noted that:**

1. **The time period was changed to 01/01/2019 until now – All for both OSD + Sterile.**
2. **All documents are valid for 7 days. If you would like to have an updated copy during the audit, the document will be provided upon request.**

| No. | Request | Attachments and Comments |
|---|---|---|
| 1 | List of all major changes since previous GRA – present (facility, personnel, processes, etc.) | Attachment 01 - CC List 01.01.2019-30.10.2020 |
| 2 | List of licensed products delivered to different markets | Attachment 02 - List of Products and Markets |
| 3 | List of products delivered to customers | Attachment 03 - LIS00407 - External customer Requirements |
| 4 | List of deviations, non-conformances (previous GRA – present) | Attachment 04a - List of Deviations – OSD<br>Attachment 04b - List of Deviations - Sterile |
| 5 | List of NTMs (previous GRA – present) | Attachment 05 - KFS Notification to Management |
| 6 | List of complaints (previous GRA – present) | Attachment 06a - List of complaints - OSD<br>Attachment 06b - List of complaints - Sterile |
| 7 | List of recalls (previous GRA – present) | Attachment 07 - List of Recalls |
| 8 | List of Field Alert Reports | Attachment 08 - List of Field Alert reports |
| 9 | List of OOS / OOT investigations (previous GRA – present) | Attachment 09 - LIR-TW 01.01.2019-01.11.2020 |
| 10 | List of CAPAs since last GRA | Attachment 10 - KS Open CAPA 01.01.19 - 29.10.20 - Excel Export |
| 11 | Updated Site Master File incl. attachments | Attachment 11 – Site Master File Ed. 35 |
| 12 | Index of site SOPs | Attachment 12 - Index of Site SOPs |

# Remote Audit preparation – example of requests sending



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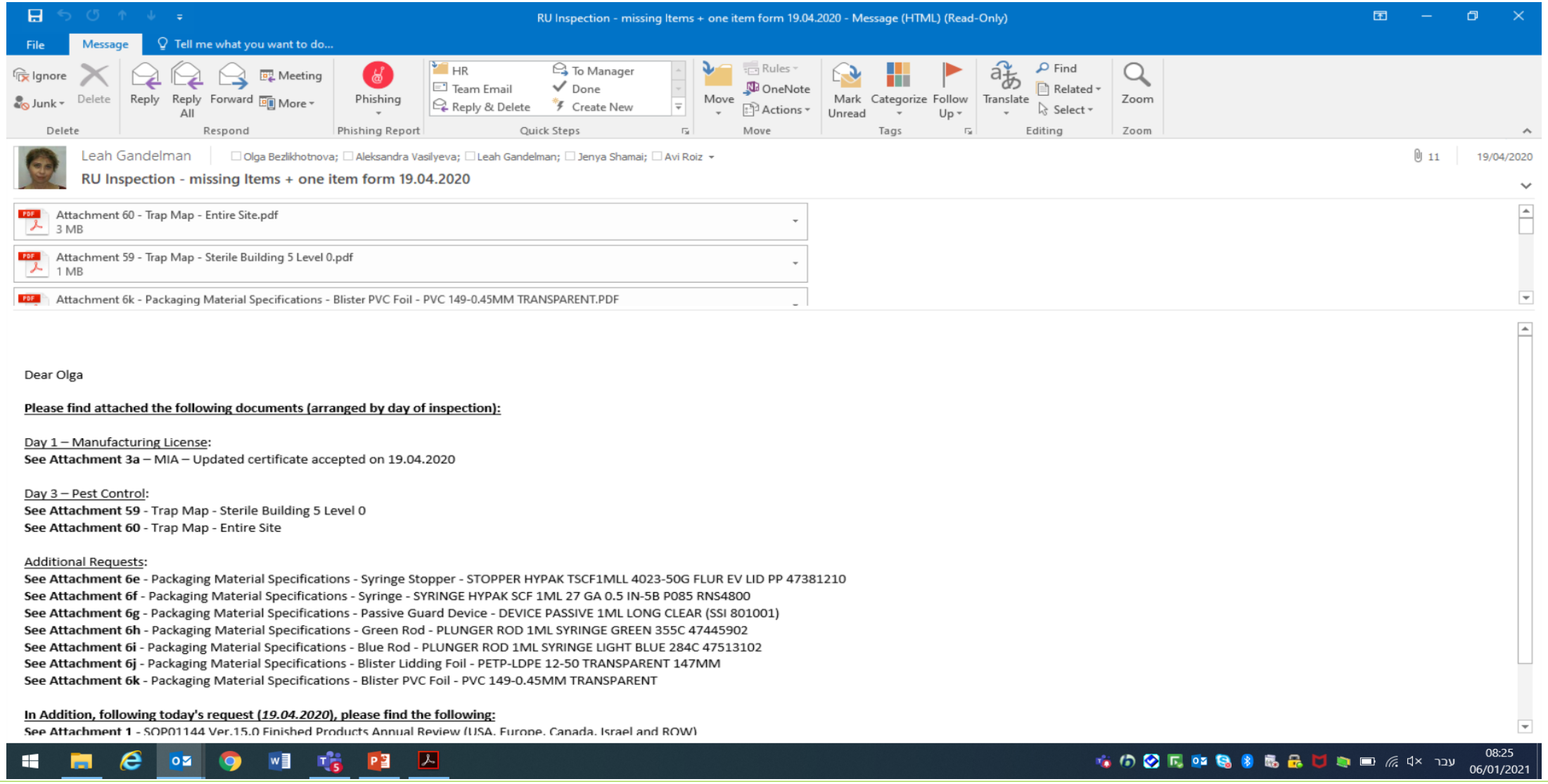

# Differences to onsite audits

**Presenting documents/facilities during the virtual audit**:

- Document review may be performed independent of participation of the auditee
- When screen sharing application is used during a virtual audit, all non-essential applications should be closed
- Interruptions may be required to read and analyze information that has been provided
- During interruptions/ breaks, ensure the sound is mute and image switched off to ensure privacy

- A virtual tour of a facility or specific portions of facilities should be requested (when possible)
- Recommended to prepare Facility Video tour

# Differences to on-site audits

**Virtual Audit Conclusion:**

The audit report should clearly

- State the extent of use of ICT
- The effectiveness of its use in achieving audit objectives
- Indicate those processes that could not be audited and should have been audited on-site

This information is important for the decision process and subsequent audits

# Remote Inspections


Thank you.