

IMPLEMENTING REMOTE GLP INSPECTIONS, A BUMPY ROAD

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GLP Inspections During COVID-19

March
2020

Summer
2020

Autumn
2020

Spring
2021



GLP Inspections During COVID-19

- March 2020:** Became clear that Belgium was heading towards lockdown.
Procedure for remote inspections drafted.
All onsite inspections suspended and switched to remote approach.
Guidance to industry issued.
- Summer 2020:** Further development of remote approaches and preparation for return to site inspections using hybrid approach.
- Autumn 2020:** Plans to return to site suspended due to pandemic and remote approach maintained
- Spring 2021:** Return to site inspections using hybrid approach.

Belgium & COVID-19

- National lockdown initiated on 18 March 2020
- Home working was obligated (unless essential economic activity)
- Limited displacements were allowed (only essential)
- Live meetings were not allowed
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March 2020

- Legal requirement in Belgium for time between two inspections is 3 years
- There are no legal backdoors in our legislation to provide an administrative prolongation of the certificate (in comparison to other QMS)
- Postpone as much inspections as possible to the max of 3 years after last inspection and hope the situation gets better
- Remote inspections were initiated as some facilities could no longer be postponed
- No internal policy was available, start developing a strategy for remote inspections

Remote Inspection Development

1. Accept the brutal facts: an onsite inspection cannot be replicated
 2. Identify where risks are to data and study compliance
 3. Assess what can be inspected and accept what cannot
 4. Create strategy and develop inspection tools
 5. Implement remote inspections
- Initial approach was at very least provide oversight of Quality Management System based on the assumption of a return to site within a year. Other inspection tools were investigated in case return was not possible, and inspections were adapted as 2020 progressed.

Remote Inspection Development

- First approach:
 - Contact facility to discuss how this can be handled
 - Find out what documents are electronically available, what has to be scanned, what has to be provided via screen sharing
 - Document request via email (SOP's, training records, QA files, study files ...)
 - Use of Webex (Zoom, MS teams, ..) for meetings and interviews
 - Use of basic file sharing system where available
 - Remote inspection was organised as a regular inspection, but everything online, including facility tour (phone camera)

Remote GLP inspection

Conclusions:

Inspection process is very similar to an onsite inspection, however, there are disadvantages:

- Being online during the whole inspection is very tiring and demanding for both parties and not very efficient
- Facility tour is not easy
- Study file was provided as one large pdf (4000-5000 pages), very hard to audit.
- Waiting for evidence to be uploaded, emailed

→ Improve the process for the next inspection

Remote GLP inspection process (up until now)

- Contact the facility upfront to discuss the process
- Every remote inspection is well prepared with a risk assessment (which is documented in the inspection report).
- Based on the risk assessment, in most cases facility tour is skipped
- Risk assessment includes review of 3 latest inspection reports, updates on the floor plans
- Online opening meeting
- Audit all requested documents, questions/remarks/ requests for additional information is shared at the end of the day, answers have to be provided the next day
- Facility is requested to be online on our before lunch and one our before the end of the day in case of urgent matters
- Days of study audit, facility is requested to be available at any time, certainly when raw data can only be shown via screen sharing (show and tell)
- Last day includes, actual discussion of all findings and open points not resolved during the inspection days and closing meeting.

Remote GLP inspection process (up until now)

- For facilities with large studies, inspection is limited to the general QMA without study audits, with a focus on data integrity processes, QA process (QC process if available).
- Unfortunately, these facilities are reaching the legal deadline of 3 years.
- Follow up inspection including study audits will be scheduled as soon as possible.
- Exceptionally, a expiry date is included on the certificate for dose facilities

Remote GLP inspection – future plans

- Belgian GLP CMA is part of Sciensano, Belgian institute for public health.
- Sciensano has several labs accredited for ISO 17025 and ISO 15189
- Investigating what scientific software Sciensano has in house and compare that with softwares at GLP facilities (e.g, HPLC software, LCMS software, ELISA software, ...)
- Investigate possibility for facilities to share data to the inspection team to allow remote review within the software
- Secure platform is available to share large data files in an encrypted manner

Things to consider

- Depending on what documents are already available, requested documents should be asked 2-3 weeks in advance to allow the facility to scan everything
- Facility should have a process to ensure the scans are verified copies of the original (process is also verified during inspections)
- Facility knows upfront what studies will be audited → has there been a clean up before it was sent?
- Very little interaction, what do we miss?
- In case inspection is done with several inspectors, good planning is critical to identify who will be online when and who of the facility needs to be available and when.
- Availability of virtual breakout rooms (to conduct parallel inspection sessions)
- IT support staff should be readily available on both sides
- Finding a good balance on when people have to be available

Things to consider

A remote virtual inspection

- is solely **opted for by the competent authority** (is not the wish of the inspectee);
- is **voluntary** and should be decided case-by-case;
- is carried out by **mutual agreement** between the CMA and the test facility management;
- is **not a general replacement** (on-site inspections will continue to remain the preferred way of inspection).
- is carried out for **safety reasons or other constraints obstructing** an on-site inspection.
- might be **limited to a crisis** like the COVID19 pandemic

What now?

- In Belgium it is again allowed to perform inspections, taking into account the visitors policy of the facility.
- To limit the inspection time on site (and limit the number of inspectors), we will continue auditing several documents up front (SOP's, QA planning, training files ...)
- Further development for Hybrid Remote/onsite inspection approach
- Risk assessments will be still be done before every inspection regarding a facility visit, personnel to interview, ...

Remote inspections and certification/annual overview

- For receiving authorities, only the outcome is important:
 - When the outcome of the remote inspection is similar to onsite inspection, this is not indicated on the Annual overview of Belgium
 - When a follow up inspection is required, this is added in the remarks.
- Remote inspection is not indicated on the certificate, but is discussed in the final inspection report, indicating whether a follow up meeting is needed.

Summary

- Accepted that cannot replicate a full onsite inspection
- Initial position taken that some oversight better than none at all
- Approach now uses Webex (or other) and screen sharing with remote review of data where relevant
- Procedure under development to continue Hybrid Remote/Onsite approach once travel restrictions are lifted

Contact

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