Desk assessment and reliance approaches

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Facts

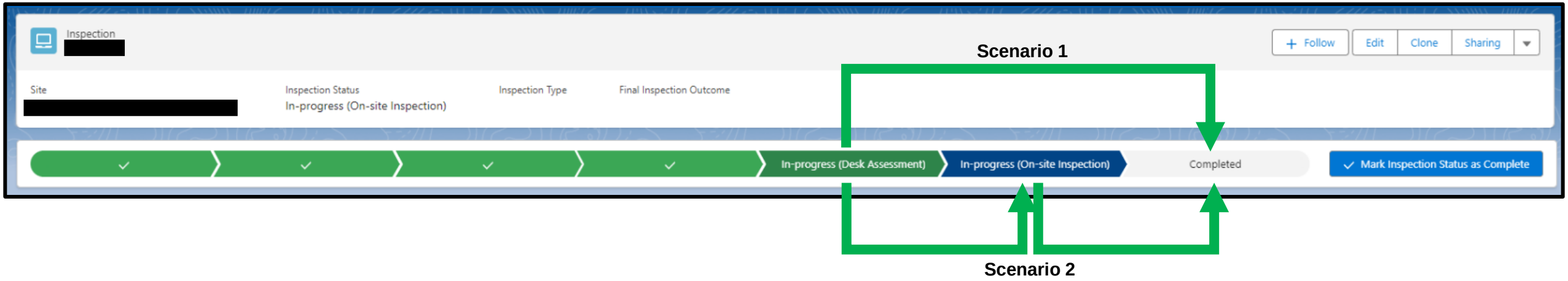
- On-site inspections are resource-intensive activities.
- Assessment of GxP compliance often lies on the critical path to regulatory decision-making.
- Hosting of multiple regulatory inspections is burdensome for the sites inspected.
- Applying the principles and enablers of GRP (including efficiency and QRM), it is wise to leverage available and reliable evidence of compliance and noncompliance with GxP
- There is no on-site inspection without good cause.

What is desk assessment ?!

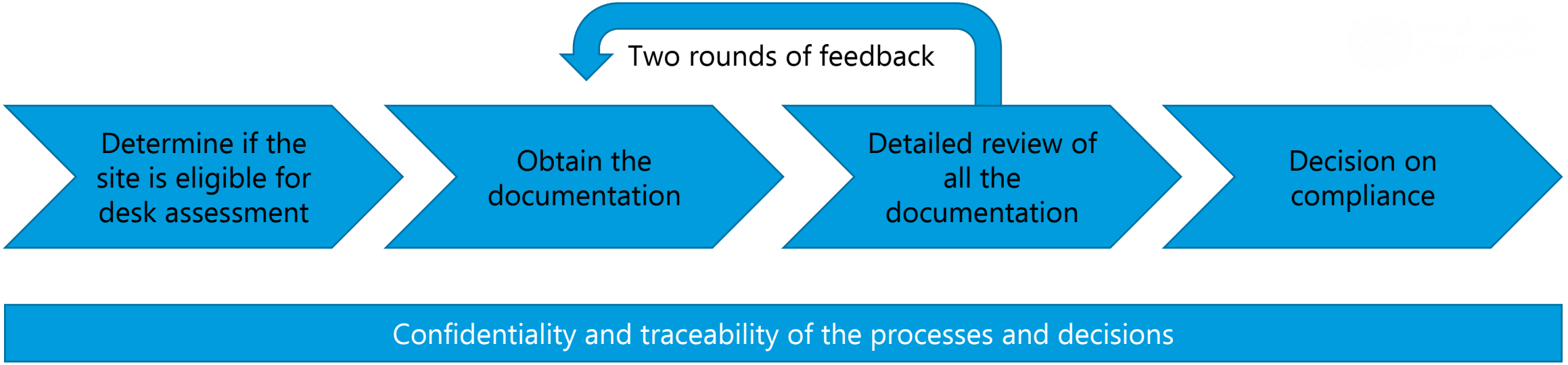
- The evaluation of documentary evidence by a competent regulatory authority recognized by the inspectorate, for compliance with the required good practices (GxP) in support of marketing authorization and other regulatory decisions. Desk assessment may be performed in support of a new marketing authorization, or for routine GxP inspection (including in the frame of specified product(s) life-cycle management as required).

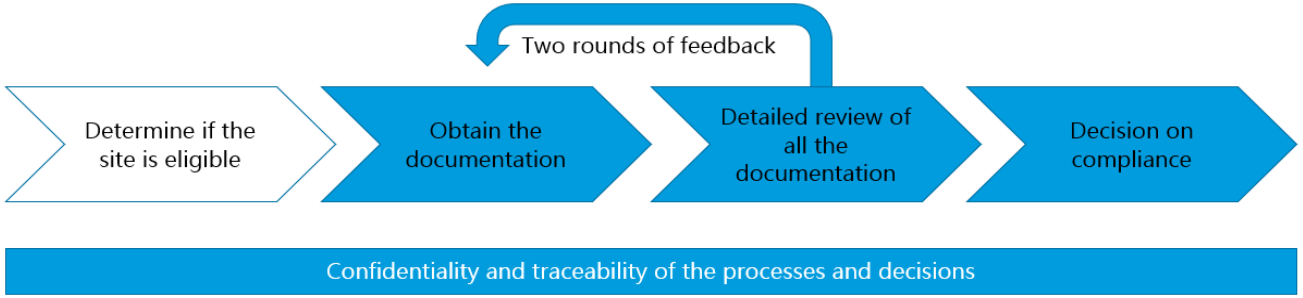
When is desk assessment considered ?!

- Desk assessment is considered as an integral part of the GxP inspection cycle, always prior to decision for onsite inspection



How to perform a desk assessment?

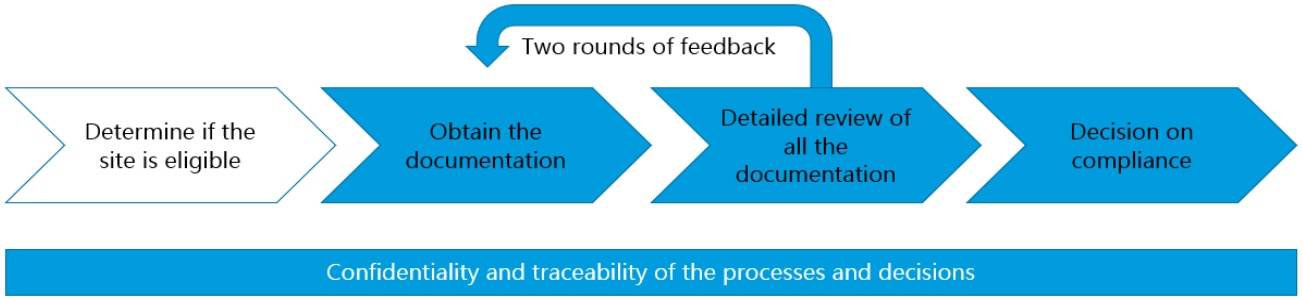




Identify eligible sites

- **Screen for**
  - Date of inspection (3-year limit)*
  - Availability and level of detail included in reports (contact authority or manufacturer)
  - Relevance of product inspected (specific, same family)
  - Relevance of information (full or by blocks)
  - Intelligence on the site (same QMS applied throughout or different QMS depending on the product line?)

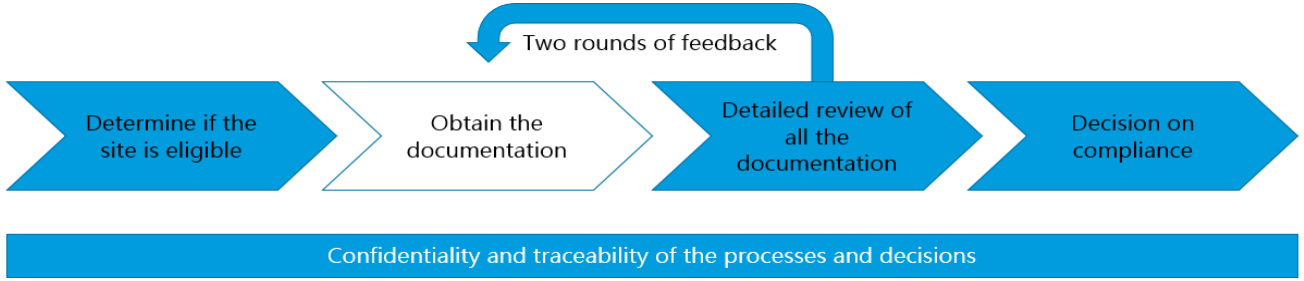
* May be increased to 4 or 5 years in the context of regulatory flexibility and depending on product/site risk



Identify eligible sites

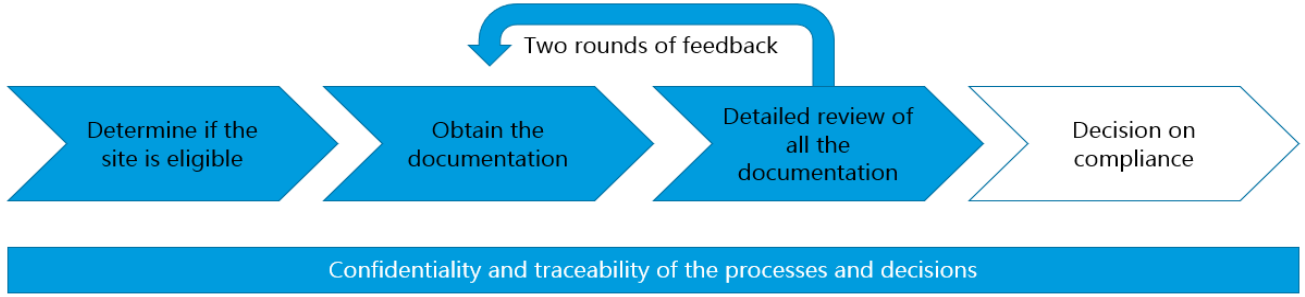
- …. in order to enable a verification of whether a desk assessment may be performed in lieu of an onsite inspection, please complete the following table by clearly indicating the areas in which the WHO product is manufactured and if these areas were covered by WLA/SRA inspections over the last three years.

Product Name	Manufacturing facility/rooms	Manufacturing equipment	Packaging line	Product dedicated (yes/no)	If shared, specify type of products	Covered by (WLA name and date of inspection)?
Product A	Eg. Workshop 7, line I, IIb	Roller compactor X, tableting line Y	Packing line A	Yes	General products only (non-beta lactam, non hormone, etc)	(Authority X, Oct 2-6 2023)



Obtain the documentation

- **Information from National Regulatory Authorities (or agencies such as UNICEF or MDSAP for IVDs)**
  - Current site compliance status, Inspection reports and GMP certificates
  - CAPAs and letters exchanged between authorities and the site
- **Reports from previous WHO prequalification inspections**
  - Publicly available for compliant sites (WHOPIRs)
- **Information from manufacturer**
  - Product quality reviews, Site master file, list of inspections & outcomes,
  - BMRs/BPRs, executed batch records, certificates of analyses, etc.
  - Lists of complaints, recalls, etc.



Decision on compliance

- **Based on number and severities of deficiencies**
  - Inspector proposes assessment outcome
  - Outcome final decision by Team Lead Inspection
- **Only two outcomes possible**
  - Compliant
  - On-site inspection required
- **Validity of compliance**
  - 3 years from the last day on-site
  - 2 years for high-risk products (e.g. sterile products)
  - 1 year if inspection report is insufficiently recent or if there is indication that another SRA may inspect it soon, if there is any reason to inspect onsite

Timeline of a desk assessment

30 DAYS

Two rounds of feedback

Determine if the site is eligible → Obtain the documentation → Detailed review of all the documentation → Decision on compliance

Confidentiality and traceability of the processes and decisions

30 DAYS | 90 DAYS | 7 DAYS

WHO PQT Inspections:

Reliance & importance of establishing effective & strategic Partners to increase regulatory efficiency

- Pharmaceutical Inspections Cooperation Scheme (PIC/S)
- EMA GMDP IWG – GMP related activities
- EMA GCP IWG – GCP and BE activities
- FDA EMA MHRA TGA HC ANVISA WHO WG – API sites
- International Group on Nitrosamines
- IAPG – Interagency Pharmacist Group (Partners and UN agencies)
- NRA's – individual (Confidentiality agreements)
- ICMRA – GMP Digitalization working group
- MDSAP – Sharing of audit findings by Notified bodies (for IVDs)
- WHO Listed authorities (WLA) and ML3/ML4 NRAs based on GBT

Traceability of processes and decisions

- **Processes guided by a set of SOPs and Templates**
- **Progress monitored in online database**
  - Time-stamped
  - Evidenced: documents, emails, meeting notes…
- **Three –level approval process**
  - Inspector in charge of planning
  - Inspector in charge of review
  - Team lead
- **Desk assessment and outcome letter sent to the manufacturer**
- **WHO Public Inspection Report published**


THANK YOU
World Health Organization