Stay compliant with virtual audits

Virtual audits are done remotely using augmented reality. They are an efficient way to ensure quality standards in operation, meet regulatory requirements and continue the supply of medicinal products to the patient.

HOW CAN NNE HELP?

NNE has developed a four-step approach for remote and virtual GMP/GDP auditing that meets cGMP needs in clinical trial supply or routine commercial operations.

This risk-based approach provides acceptable cGMP compliance documentation for the continued use of existing suppliers, CMOs/CDMOs and for interim or conditional approval of new facilities.

The approach can also be used for internal audits or self-inspections at remote internal organizational units.

IS IT RIGHT FOR YOUR ORGANIZATION?

Remote audits are suitable for various production setups, including:

- Raw materials
- GMP components
- Drug substances
- Drug products (API)
- Medical devices
- Cannabis
- Cell and gene therapy
- Packaging facilities
- Warehousing and distribution

It can also be applied to key outsourced activities such as technical services, engineering contractors, QC release/stability testing and CMOs or CDMOs.

STEP 1
ASSESSMENT & PLANNING

Planning meeting to assess operations and determine key topics and the schedule for audit activities.

If new supplier or CMO/CDMO: Risk assessment of operations to determine if a remote audit is feasible and justifiable to enable approval of your new supplier, CMO/CDMO or partner.

Key area examples

- Site activities
- Regulatory oversight
- Licences/registrations
- Inspection/audit history
- Recalls
- Product/material assessment
- Complaint history

STEP 2
REMOTE PQS REVIEW

Remote review of the pharmaceutical quality system by expert evaluation of the internal manufacturing site or supplier's key policies and procedures vs. internationally recognized quality and cGMP expectations.

Key area examples

- Site master file
- Management oversight
- Management review
- Product review
- Quality risk management
- Investigation processes
- Supplier management
- Contamination control
- Trend analysis
- Key quality processes
- Quality manual

STEP 3
REMOTE AUDIT

Remote review and video conferencing sessions with subject matter experts to evaluate the evidence of implementation of the key policies and procedures in place.

Key area examples

- Minutes of management review
- PQR reports
- Investigation reports
- Quality agreements
- Audit schedule adherence
- Contamination control strategy
- Manufacturing records
- Training records

STEP 4
REPORTING & CAPA REVIEW

Our NNE auditor will prepare a written report of findings and recommendations with the aim of allowing for approval for use where justified.

Where observations have been raised, the NNE auditor will review the responses, CAPA plans and e.g. effectiveness checks to ensure they are appropriate.

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