On-site and virtual audits for pharma

With many audits postponed in 2020, the time has come to tackle the backlog. On-site audits are restarting again, but for regions that are difficult to reach, virtual audits are a suitable and efficient option. They ensure quality standards in operation, meet regulatory requirements and continue the safe supply of medicinal products to the patient.

HOW CAN NNE HELP?

NNE has developed a four-step risk based approach for remote and virtual GMP/GDP auditing that meets cGMP needs in clinical trial supply or routine commercial operations. This provides acceptable cGMP compliance documentation for the continued use of existing suppliers, CMOs/CDMOs and for interim or conditional approval of new facilities. In addition, they are suitable for internal audits or self-inspections at remote internal organizational units.

WHICH PRODUCTION SETUPS?

Remote audits are suitable for various production setups, including:

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

Virtual audits can also be used for key outsourced activities, such as technical services, engineering contractors, QC release/stability testing and CMOs or CDMOs.

REMOTE AUDIT

1. ASSESSMENT & PLANNING

Risk assessment of operations to determine if a remote audit is feasible and justifiable.

Planning meeting to assess operations and determine scope, discuss key topics, schedule audit activities, decide on necessary documentation to prepare for the audit, and agree on and issue audit plan.

2. REMOTE PQS REVIEW

Remote review of the pharmaceutical quality system.

This is done through an expert evaluation of the internal manufacturing site or supplier's key policies and procedures vs. internationally recognized quality and cGMP expectations.

3. REMOTE AUDIT

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

4. REPORTING & CAPA REVIEW

Finally, for both on-site and remote audits, our NNE auditor will prepare a written report of findings and recommendations.

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

ON-SITE AUDIT

1. PLANNING

Planning meeting to determine scope and key topics, schedule audit activities, decide on necessary documentation to prepare for the audit, and agree on and issue audit plan.

2. PREPARATION

Review of relevant documentation and preparation of audit material.

3. PERFORMING AUDIT

Perform on-site audit according to agreed audit plan.

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