



# Use remote audits to stay compliant during the COVID-19 pandemic

Access to your supplier's facilities may be limited or not permitted due to the restrictions of the Covid-19 pandemic. So, how can you assure yourself of the quality standards in operation to continue the supply of medicinal products whilst meeting regulatory requirements and protecting the patient?

## HOW CAN NNE HELP

NNE has developed a four-step approach for remote and virtual GMP/GDP auditing to help you overcome travel restrictions, closed borders, access restrictions to supplier sites

and meet cGMP needs in clinical trial supply or routine commercial operations.

This risk-based approach helps provide acceptable cGMP compliance documentation for the continued use of existing suppliers, CMOs/CDMOs and for interim or conditional approval of new facilities during periods of uncertainty or governmental restrictions.

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

organizational units where travel or access is temporarily not possible.

Our approach can be applied to manufacturers of raw materials, GMP components, drug substances, drug products (API), medical devices, Cannabis, C&G 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/CDMOs.

### STEP 1 ASSESSMENT & PLANNING

Planning meeting to assess the operation and determine key topics and scheduling of the audit activities.

If new supplier or CMO/CDMO: Risk assessment of the operation 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

The 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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