PHARMACEUTICAL REMOTE AUDIT PROCESS

When access to your supplier's facilities is limited or even not permitted, how can you assure yourself of the quality standards in operation to provide continuity of supply of medicinal products, whilst meeting regulatory requirements and protecting the patient?

Using our network of international GMP experts, e-rooms and videoconferencing, NSF have developed a four-step approach to allow for remote and virtual GMP auditing which helps you to unlock supply chains and meet cGMP needs in clinical trial supply or routine commercial operations. This hybrid risk-based approach will help provide interim or conditional approval of facilities during periods of uncertainty or governmental restrictions.

Our approach can be applied to manufacturers of raw materials, GMP components, drug substances and drug products, key services including packaging, QC laboratories, warehousing, distribution and pharmacovigilance, along with outsourced activities such as technical support, engineering contractors and QC release/stability testing.

Process Step	Methodology	Example Key Areas
Step 1. **Risk Assessment**	Risk assessment of the operation to determine if a remote audit is feasible and justifiable to enable interim approval of your supplier, CMO or partner.	> Site activities > Regulatory oversight > Licences/registrations > Inspection history > Recalls > Product/material assessment
Step 2. **Remote Review of PQS**	Remote review of the pharma quality system by expert evaluation of the supplier's key policies and procedures vs. internationally recognized quality and cGMP expectations.	> Site master file > Management oversight > Management review > Product review > Quality risk management > Investigation processes > Supplier management > Contamination control
Step 3. **Remote Audit**	Remote review and video conferencing session with subject matter experts to evaluate the evidence of implementation of the key policies and procedures in place.	> Virtual facility tour > PQR reports > Investigation reports > Batch records > Quality agreements > Audit schedule adherence > Contamination control strategy

Reporting

After steps 2 and 3, the NSF expert will prepare a detailed written report of findings and recommendations with an aim of allowing interim approval where justified and warranted.

CAPA Review

Where observations have been raised, the NSF expert will review the responses, CAPA plans and effectiveness checks to ensure they are appropriate.

Step 4. **On-Site Assessment**	Delivery of an on-site audit, to complete the formal GMP assessment. This can be an abbreviated review, given the comprehensive nature of steps 2 and 3.	> Physical observation of the facility to ensure appropriate, design, maintenance, hygiene and compliance to GMP > Site culture > Follow-up on evidence and CAPA plan implementation

RISK-BASED ASSESSMENT

Background Information	Information Required
Site Location	> Physical address of the site providing the service
Key Contact	> Name and contact details

Site Assessment	Information Required
Regulatory Oversight	> Is the facility subject to local authority oversight? > Has the facility been inspected by competent authorities or a certification organisation e.g. EMA, USFDA, ANVISA, etc.?
Licences/Registrations	> Obtain copies of latest official documents and verify scope
Inspection History	> Date of last inspections and outcomes
Recalls	> Has the site had any significant recalls or restrictions placed on it?
Company Profile	> Is the operation part of a larger organisation? > Does the facility operate to a common company PQS? > Is there evidence of corporate oversight e.g. audits of facility by a central team?
Site Activities	> What activities will the site be performing e.g. total manufacture, partial manufacture, packaging only, testing, stability?
Size of Location	> Number of employees at site
Cross-Contamination Risk	> What other products/materials are manufacture at the site?

Product Assessment	Information Required
Nature of Product/Material – Dose Forms	> ATMP/biologic/aseptic/sterile > Liquid/cream/ointment > Solid oral dose > Packaging only > Process critical material e.g. excipient, active, process aid
Stage of Development for Product	> R&D > Early phase development (phase 1/2 clinical trials) > Phase 3 clinical trials > Commercial supply

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