QUICK REFERENCE GUIDE

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

VIRTUAL AUDITING FOR GXP COMPLIANCE

COVID-19 represents an unprecedented challenge for life science companies seeking to **maintain the continuity of pharmaceutical operations** and product supply. The essential containment measures being implemented globally require a **dynamic, pragmatic and risk-based** response to quality oversight and third-party audit.

Even before **COVID-19**, PharmaLex had developed and implemented a stepwise and risk-based methodology to deliver **virtual audits**. This approach enables you to maintain oversight of your Supply Chains and ensure the continuity of your clinical and commercial operations.

HOW CAN PHARMALEX HELP?

There is still quite a bit of uncertainty. We do not know how long we will be impacted by the social distancing or how long it will be before auditors will be allowed on-site.

With 33 offices in 21 countries, PharmaLex is uniquely placed to support your global audit requirements.

CONTACT PHARMALEX

If you would like to learn more about our virtual audit services, our team are available to answer your questions.

Contact us on contact@pharmalex.com

For more information, visit: **www.pharmalex.com**

OUR PROCESS

1 RISK ASSESSMENT

PharmaLex can conduct / support a risk assessment to:

- Determine the criticality of the audit, and whether a deferral is acceptable
- Where the audit is essential, determine the feasibility of a virtual audit
- Identify the risks associated with a remote audit and mitigating actions

2 AUDIT PREPARATION

- Agree an agenda for the virtual audit
- Identify key information for review by the auditor, in PharmaLex or your data room
- Prepare and issue an audit questionnaire for completion by the auditee

3 VIRTUAL QMS DEMONSTRATION

- Review of key Quality Management System document, such as Site Master File (SMF), Quality Manual, Standard Operating Procedures (SOPs), Quality Agreements, Validation reports, Risk Assessments

4 VIRTUAL AUDIT

- Video conferencing with key site personnel and Subject Matter Experts (SMEs)
- If required, a virtual tour of areas of the facility can be conducted

5 REPORTING & CAPA

- PharmaLex will prepare a comprehensive written report that details the areas covered during the audit, observations classified by risk and recommended remediation actions for each observation
- PharmaLex can support the implentation or oversight of Audit CAPAs. If required, PharmaLex can support a focussed on-site assessment once local restrictions have been lifted and site access is granted

! DON'T FORGET

Deferral or delay of qualification audits may prevent the on-boarding of critical third parties. This can have a detrimental impact on the continuity of your clinical or commercial operations, and ultimately the supply of medicines to patients.

DID YOU KNOW...

The effective implementation of Risk Management Principles, and Risk Assessments, can enable you to continue your operations during COVID-19 related restrictions.

! DON'T FORGET

Once COVID-19 restrictions are eased suppliers won't just be looking to catch up on your audit requirements but everyone else's too! Be prepared for inaccessibility due to auditee capacity beyond the immediate COVID-19 restrictions. Your QA teams will also experience increased workloads and QA capacity may be an issue.

DID YOU KNOW...

With over 250 Quality and Compliance technical experts, and an Audit team of 100+, PharmaLex can manage your audit program and enhance your QA team's capacity

ABOUT PHARMALEX

25+ YEARS
OF INDUSTRY EXPERIENCE

OVER 50%
OF OUR PROJECTS ARE GLOBAL

100% COVERAGE
OF ALL PRODUCT CATEGORIES INCLUDING MEDICINAL PRODUCTS, MEDICAL DEVICES, CONSUMER HEALTH AND VETERINARY

40+
HEALTH AUTHORITY MEETINGS PER YEAR WITH EMA/FDA/PMDA

95%
OF OUR PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE WITHOUT MAJOR FINDINGS