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Seven steps to make your logistics compliance GDP inspection ready

In the changing regulatory environment, are your logistics processes ready for a GDP inspection?



Written by the Pharma Logistics Editorial Team

Maintaining a high standard of GDP logistics compliance is a difficult task. By following these seven steps outlined on the following pages, you can:

- understand the standard expected of you,
- document how you are meeting and maintaining these standards,
- be prepared to answer questions from inspectors, and,
- take a snapshot view of your performance.



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1. Understand the expected standard of GDP compliance

Standards can vary globally and in some cases can be contradictory. The aim should be to comply with all **regulations** set by the countries on your logistics route. If this is not possible, ensure that your reasoning is documented and that you are meeting globally established standards.

Be aware of changes to regulations and stay up to date with investigations and enforcements. This will also give insight to upcoming areas of focus for regulators.

2. Set and follow a Standard Operating Procedure (SOP)

SOPs allow for the continuous improvement of standards of service and also provide evidence of your commitment towards protecting patients. Failure to write SOPs will signal to regulators that your company is not serious about effective compliance.

However, writing SOPs and then failing to follow them will show regulators a wilful disregard of standards.

Review and update SOPs regularly and maintain a master file of previous versions.

3. Document your entire process

If you don't document it, you have no evidence that you have actually done it.

Clean, clear and organised documentation can ensure that you are investigation ready. Ensuring that documents are updated and reviewed at regular intervals also evidences the development of your GDP compliance policy.

If you are keeping your documentation in order, you should be better equipped to deal with any issues of non-compliance and pin-point gaps in the process.

4. Review and manage your CAPA log

Preventive and corrective actions both have an important role in the effective running of quality systems. To be inspector ready, ensure that your CAPA log is being reviewed and addressed regularly.

Corrective actions should be dealt with in a timely manner, with the incident fully recorded and evidence of how the issue was addressed.

Preventive action should be a key focus to ensure that potential problems or non-conformance are understood and that a plan is being developed. An inspector will respond positively to proactive measures to address any future instances of non-compliance.

5. Review calibration and preventive maintenance programme

Preventive maintenance programmes are essential to prove equipment is working to the correct standard and is being monitored or repaired when necessary. Calibration must also be completed and monitored to eliminate any discrepancies between different equipment's data recording.

All records of maintenance and calibration should be up to date and ready for review.

6. Bring in fresh eyes or expertise to review your GDP process

Fresh eyes can point out gaps in your processes or high risk areas. Requesting review from different levels of stakeholders can also ensure compliance objectives are understandable and clear.

Experts can give specific guidance on areas of concerns or can offer specialized advice, for example, in preparing employees for interactions with inspectors.

7. Complete ‘snapshot’ GDP audits

Ensuring that you are carrying out snapshot **audits** of your GDP will allow you to stay on top of this complex issue.

Select one area to focus on and review your process and documentation. Ask if it is being followed and if it is effective.

Or create a theoretical incident of non-compliance. Using the process you have, are you able to understand, address and manage the incident?

Conclusion

Every company may face instances of unpredicted non-compliance. Having a fully formed process for GDP compliance can ensure that if an incident happens you are able to mitigate and manage the impact. You will also be able to evidence your actions to an inspector and maintain acceptable compliance standards.

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