



# GLP MONITORING AUTHORITY

## NORBROOK LABORATORIES LIMITED INSPECTION REPORT

Inspection & Organisation Information	
Inspection Number	Insp GLP 2000/12919-0023
Type and Purpose of Inspection	Statutory GLP Compliance monitoring inspection
Organisation Inspected	Norbrook Laboratories Limited
Organisation Address	105 Armagh Road Newry County Down Northern Ireland BT35 6PU
Organisation Type	Contract Research Organisation (CRO)
Dates of Inspection	23-24 July 2025
Lead Inspector	[REDACTED]
Accompanying Inspector	[REDACTED]
Date of Closing Meeting	24 July 2025
Inspection Report Date	14 October 2025

## Inspection Deficiencies

### 1.0 Critical Deficiencies

None.

### 2.0 Major Deficiencies

#### 2.1 Study Management and Conduct

2.1.1 There were concerns with the control and oversight of studies [REDACTED] and [REDACTED] with respect to the analytical conduct, management and reporting of the studies. These included:

- Studies [REDACTED] and [REDACTED] carrying out dissolution and spectrophotometric analysis of the test item ([REDACTED]) did not adhere to facility procedures regarding reproducibility of the working standard. These studies used a single absorbance reading of the standard which was not in line with SOP [REDACTED] (version [REDACTED] issued 1st August 2022), which required reproducibility of the standard against a blank. The failure to adhere to the procedure's requirements, and the impact upon the validity of the results had not been impact assessed in either study.
- Study [REDACTED] generated two separate results (absorbance of [REDACTED] on 08 January 2024 and [REDACTED] on 10 January 2024). However, [REDACTED] (which gave a failing result) was disregarded and [REDACTED] (which was within expected range) was accepted, with no documented justification.
- The final reports for studies [REDACTED] and [REDACTED] were not transparent in that:
  - Study [REDACTED] did not disclose the failure to adhere to SOP [REDACTED] requirements regarding reproducibility of the working standard, nor had this been impact assessed in the final report.
  - Study [REDACTED] was conducted as a repeat of [REDACTED] however lacked transparency by not indicating this constituted repeat work nor referencing the previous study. In addition, the failure to adhere to SOP [REDACTED] requirements regarding reproducibility of the working standard had also not been disclosed nor impact assessed in the final report.

### 3.0 Other Deficiencies

#### 3.1 Archiving

3.1.1 Electronic archiving procedures were not consistently in line with the requirements of OECD Advisory Document 15 (Establishment and Control of Archives that Operate in Compliance with the Principles of GLP, June 2007), as evidenced by the following individual examples:

- Electronic raw data from the [REDACTED] temperature monitoring system were confirmed by the facility as not subject to formal archiving since its implementation in August 2023. It was acknowledged that these data were however subject to regular back up per the facility's disaster recovery procedures and were available on demand for inspection. OECD 15 states:  
*"Data should be archived securely, under the control of the unique archivist, including, where relevant, an appropriate electronic repository whether this is on the original system or elsewhere, subject to suitable controls or in a stand-alone electronic archive [...]. The*

*Principles of GLP for archiving must be applied consistently to electronic and nonelectronic data. It is therefore important that electronic data are stored with the same levels of access control and indexing as non-electronic data”.*

- Archiving timelines of electronic study data from the following systems were not in line with requirements of OECD 15, which required the Study Director to fulfil this responsibility “during or immediately after completion (including termination) of a study” and in a “timely manner”:
  - [REDACTED] electronic “project” raw data were stated as only archived annually by the facility (via the [REDACTED] rather than after finalisation of each GLP study. The facility also confirmed that [REDACTED] “project” data from 2022 and 2023 were delayed archiving until April 2025. At the time of the inspection however, only four GLP studies’ [REDACTED] data remained to be archived from finalisation dates in April, May and June 2025.
  - [REDACTED] and [REDACTED] analysers’ electronic study data were stated as downloaded onto an external hard drive by system administrators but only transferred to the GLP archivist when full, which had not yet occurred. It was acknowledged that:
    - The hard drive was only accessible to administrators in a locked cabinet, though it was not password protected.
    - These electronic data were also uploaded to the facility’s network drive in a folder with controlled access, however this did not constitute formal archiving under the archivist’s control.

### 3.2 Computer Systems Validation

- 3.2.1 A requirement for the [REDACTED] environmental monitoring system’s electronic data to be archived during its life cycle as per GLP requirements was not considered under the user requirements specification (URS) of the computerised system’s validation.

### 3.3 Data Integrity Controls

- 3.3.1 Electronic “project” raw data generated in the [REDACTED] computerised system was stated as only locked annually by the facility as a batch of projects (for example 2023, 2024 etc...) rather than following finalisation of each GLP study. As such, a risk was identified that finalised study data could remain unlocked for up to several months in the system prior to eventual locking and subsequent archiving.
- It was acknowledged that the facility’s periodic review procedures included system audit trail review, however this involved only a sampling of studies on an annual basis and may not identify if any data had been altered or deleted without detection in the delay between finalisation and locking.

### 3.4 Laboratory Facilities and Equipment

- 3.4.1 A calibration sticker on [REDACTED] (Serial Number: [REDACTED] had not been updated when annual time verification had been completed on 26 February 2025 and stated that calibration was due February 2025. As such this would not allow analysts to identify if equipment had been calibrated as required prior to use.

### 3.5 Organisation, Personnel, Delegation & Responsibilities

3.5.1 Errors or omissions were identified on the facility's master schedule as follows:

- Study [REDACTED] was not listed on the master schedule.
- Study [REDACTED] was listed as a characterisation study however was identified upon inspection as being a dissolution study.

### 3.6 Reporting

3.6.1 QA statements for studies reviewed did not include dates audits were reported for Final/Draft Protocols or Protocol Amendments to either the SD or Test Facility Management (TFM), instead listing 'N/A' under the date reported section. This implied that QA did not report audit findings for this critical study phase to SD and TFM when in fact this was the case.

### 3.7 Standard Operating Procedures

3.7.1 Standard Operating Procedures governing the administration of [REDACTED] and [REDACTED] analysers ([REDACTED] effective 18 April 2025 and [REDACTED] effective 02 October 2023, respectively) did not address how electronic data would be formally archived nor how frequently, only describing back-up procedures.

3.7.2 SOPs [REDACTED] effective 29 August 2022) and [REDACTED], effective 13 November 2023) did not specify the timeline in which [REDACTED] electronic data should be formally archived following study finalisation, despite the facility stating this took place on an annual basis (refer to finding 3.1.1).

### 3.8 Study Management and Conduct

3.8.1 Inconsistencies in GLP compliance statements were identified in phase reports for statistical analysis conducted at Test Site [REDACTED]. The Principal Investigator (PI)'s GLP compliance statements were at odds with the contents of the Study Director (SD)'s GLP compliance statements in final reports. The examples identified were:

- Studies [REDACTED] The PI's phase report GLP compliance statement stated, "*conducted in compliance with the principles of good laboratory practice as defined in the 'United Kingdom Good Laboratory Practice Regulations Statutory Instrument 1999 No.3106' and the OECD Principles of Good Laboratory Practice*", but the SD's GLP compliance statement stated that the statistical analysis phase was conducted "*in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, Issued January 1998) ENV/MC/CHEM (98) 17 which are in accordance and implement the requirements of Directive 2004/9/EC and 2004/10/EC*".

Phase reports for these studies stated that statistical analysis was conducted in compliance with UK GLP regulations, however, this test site was located in [REDACTED] Ireland and was therefore subject to the Irish National Accreditation Board (INAB) and European Directives GLP regulations, as confirmed by the Test Site's GLP statement of compliance issued by INAB dated [REDACTED]

- Study [REDACTED] The PI's phase report GLP compliance statement stated, "*conducted in compliance with the principles of good laboratory practice as defined in the 'OECD Principles of Good Laboratory Practice (revised 1997, Issued January 1998) ENV/MC/CHEM (98) 107'*" but did not specify which national legislation. However, the SD's

GLP compliance statement stated that the statistical analysis phase was conducted "in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM (98) 17 which are in accordance and implement the requirements of Directive 2004/9/EC and 2004/10/EC".

OECD advisory document 13 (The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, February 2002) states: "*The extent of compliance with the GLP Principles should be indicated with specific reference to the OECD Principles of GLP and Regulations with which compliance is being claimed. This claim of compliance will cover all phases of the study and should be consistent with the information presented in the Principal Investigator claims.*"

There was no evidence the SD had identified or impact assessed these inconsistencies, which were also not identified throughout reporting, quality control or Quality Assurance (QA) processes at both the Test Site and Test Facility.

### 3.9 Training

3.9.1 Training records did not consistently demonstrate maintenance of a complete record of the qualifications, training, experience, and job description for each professional and technical individual, required per the Principles of GLP, as evidenced by:

- [REDACTED] had completed [REDACTED] training in November 2023 and had an associated competency statement signed by [REDACTED]. However, [REDACTED] job description and CV had not been updated to include any [REDACTED] responsibilities, their job title remained as [REDACTED] and they were still present as such on the facility organogram dated [REDACTED].
- Training records for [REDACTED] did not evidence any review of applicable OECD Advisory Documents to their roles. It was stated by the facility during interview that this was not routinely recorded as standard practice for GLP staff.

### Report Author and Reviewer

#### Report Author:

[REDACTED]  
[REDACTED]  
UK GLP Monitoring Authority & MHRA

#### Report Reviewer:

[REDACTED]  
[REDACTED]  
UK GLP Monitoring Authority & MHRA

**Appendix I – Deficiency Definitions****Deficiency Definitions (GLP)****Critical:**

- a) Where evidence exists that significant departure(s) from the Principles of GLP has occurred resulting in:
  - i) the test facility, or a part thereof, or a study is not in compliance with the Principles of GLP and/or
  - ii) the study data are unreliable and/or
  - iii) a combination of several “Major” findings (defined in (c)) across the basic GLP quality systems, indicating a systemic quality assurance failure, and/or
- b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (c))

**Major:**

- c) A non-critical finding where evidence exists that a significant departure from the Principles of GLP has occurred:
  - i) that may not have developed into a critical issue, but if not addressed immediately may lead to a facility, system or study being out of compliance, and/or
  - ii) where evidence exists of a failure of one of the basic GLP quality system elements, and/or
  - iii) a combination of several “other” findings, none of which on their own may be major, but which may together represent a major finding

**Other:**

- d) Where evidence exists that a departure from the Principles of GLP has occurred, and/or established guidelines and/or procedural requirements but it is neither Critical nor Major