SELF-DECLARATION OF COMPLIANCE WITH WHO GOOD CLINICAL LABORATORY PRACTICE PRINCIPLES

Company:	Lexogen GmbH
Registered address:	Campus Vienna Biocenter 5, 1030 Vienna, Austria
Applicable laboratory site:	Campus Vienna Biocenter 5, 1030 Vienna, Austria
Effective date:	12. August 2026

Lexogen GmbH hereby declares that designated next-generation sequencing service activities supporting clinical research are performed under a documented quality management system compliant with the principles of:

World Health Organization, Good Clinical Laboratory Practice (GCLP), 2009, Diagnostics Evaluation Series No. 3.

For projects formally designated as GCLP projects, Lexogen applies documented controls intended to ensure:

- ✓ qualified and competent personnel;
- ✓ controlled procedures and records;
- ✓ appropriate qualification and maintenance of equipment;
- ✓ validation, qualification or verification of applicable analytical workflows;
- ✓ sample identification, traceability and chain of custody;
- ✓ predefined project requirements and acceptance criteria;
- ✓ technical review and authorization of results;
- ✓ data integrity, confidentiality and secure data management;
- ✓ management of deviations, investigations and corrective actions;
- ✓ appropriate Quality Management oversight; and
- ✓ retention of records sufficient to support auditability and reconstruction of the work performed.

This declaration applies only to activities:

1. performed at the laboratory site identified above;
2. expressly designated as GCLP activities in the applicable contract, statement of work, study plan, quality agreement or equivalent project documentation;
3. performed within the approved scope of the applicable Lexogen NGS service workflow; and
4. conducted using approved procedures, qualified systems and authorized personnel.

Depending on the agreed project scope, covered activities may include sample receipt and reconciliation, sample quality control, nucleic-acid processing, NGS library preparation, library quality control, sequencing, approved bioinformatic processing, technical review, reporting, data transfer and archiving.

This declaration does not extend to activities outside the approved workflow scope, unsupported sample types or configurations, experimental or non-qualified methods, clinical interpretation, diagnosis, treatment selection or patient-management decisions.

Project-specific requirements, responsibilities, acceptance criteria, deliverables and retention periods are defined in the applicable contractual and controlled project documentation. Where agreed customer or sponsor requirements are more stringent, those requirements apply.

This document is a **self-declaration by Lexogen GmbH**. It does not constitute accreditation, certification, inspection, authorization or endorsement by the World Health Organization or by any independent accreditation or regulatory body.

Lexogen GmbH confirms that the accuracy and continued applicability of this declaration are subject to periodic review and to review following material changes to the relevant quality system, laboratory site or approved workflow scope.

12. August 2026, Vienna, Austria

Stephane Barges
CEO

Irmlind Gabler
Head of Quality Management

OPERATES UNDER GCLP GOOD CLINICAL LABORATORY PRACTICE

Lexogen GmbH | Campus Vienna Biocenter 5, 1030 Vienna, Austria | Telephone: +43 (0) 1 345 1212 | info@lexogen.com | www.lexogen.com
Lexogen, Inc. | 51 Autumn Pond Park, Greenland, NH 03840, US | Telephone: +1-603-431-4300