Quality Information – Nelson Labs NV

Company Information	
Company Name	Nelson Labs NV, a Sotera Health Company Private corporation. Established in 1991.
Legal Form	Public limited company
Parent Company	Sotera Health
Company Address	Romeinsestraat 12 3001 Leuven – Belgium
Website	www.nelsonlabs.com
Telephone	+32 16 40 04 84
Fax	+32 16 40 13 04
Business Information	
Business Classification	Nelson Labs NV is a contract laboratory for Extractables & Leachables (E&L) studies, compendial testing, release testing and impurity testing on medicinal products, biocompatibility testing and offers also microbiology testing services.
Federal Tax ID	BTW BE 0442.395.719
Dun & Bradstreet Number	766951479
Facilities	
Total Square Footage	4700 m²
Lab Space	2100 m²
Operating Hours	09h00 - 17h00
Number of employees	± 190
Quality Staff	13
Equal Opportunity	Nelson Labs NV is an equal opportunity employer.
Critical Contacts	
Management	Kurt Peeters (Managing Director) KPeeters1@nelsonlabs.com
Operations	Lise Vanderkelen (Director Lab Operations / Head of Quality Control) LVanderkelen@nelsonlabs.com
Quality	Rudi Segers (Quality Assurance Manager) RSegers@nelsonlabs.com
Sales	Johan Jaubin (Head Sales and Business Development) JJaubin@nelsonlabs.com
Additional Contacts	
Service Center	LeuvenCustomerService@nelsonlabs.com
Audit Scheduling	QAInbox_Europe@nelsonlabs.com
Proprietary Information	
References	Nelson Labs NV policies and procedures ensure the protection of our clients' names, and confidential and proprietary information, thus no references are able to be provided.
Sales/Financial Information	Nelson Labs NV is part of Sotera Health. Financial information is publicly available: • Sotera Health Company (Nasdaq SHC): see https://investors.soterahealth.com/ • Nelson Labs NV: see https://consult.cbso.nbb.be/consult-enterprise/0442395719, use company number (0442.395.719) to access the Annual Accounts
Manufacturer Statement	Nelson Labs NV is not a manufacturer, but a contract testing laboratory. Therefore, information regarding manufacturing processes is not applicable.
Payment Information	
Check Remittance / Billing Address	Accounts Receivable Romeinse Straat 12 3001 Leuven – Belgium
Wire Transfers	IBAN BE13 5490 0105 9839
Accreditation/Certifications/Registrations *	
ISO Accreditation	ISO 17025
ISO Registrar / Certificate Number	363-TEST (BELAC)
FDA FEI Identifier	3005742674
Last FDA Audit	September 2017
EU GMP	GMDP 1844 Human and Veterinary medicinal products (FAHMP)
GLP compliance	OECD Directive 2004/9/EC, T02 (Sciensano)
* Please note: Up-to-date certifications are available on the website https://www.nelsonlabs.com/quality/ Please go to the bottom of the page: "Nelson Labs Europe Certifications"	

Nelson Labs NV has procedures/processes including (but not limited to) the following:	
Quality Manual/Policy and Site Master File	*MAN0010 – Quality Manual / Site Master File*. The Nelson Labs NV Quality Manual / Site Master File provides the employees, auditors, and customers of Nelson Labs NV with a description of the Quality Management System and Quality Policy.
Change Control and Change Notification	*MAN0018 - Change Policy, SOP0413 – Development, Change Control, Periodic Review and Archiving of a Standard Operating Procedure* and *SOP0387 – Operational Change Control for Lab- and IT Systems.* Nelson Labs NV allows the Sponsor the choice to initiate a Study with or without a sponsor approved protocol. All changes as per protocol are communicated to the Sponsor. Additionally, all changes made through our change control process (changes of test methods, use and maintenance of GxP critical equipment, business changes) are assessed for the potential impact to you as a customer. The customer is always notified in case potential impact cannot be excluded.
Document Control	*SOP0413 – Development, Change Control, Periodic Review and Archiving of a Standard Operating Procedure*. Nelson Labs NV establishes and maintains procedures to control all documents required by regulations, standards, normative documents, test and calibration methods. Documents are controlled by revision number electronically through MasterControl, our document management software. Documents are reviewed, updated and approved as necessary.
Calibration and Maintenance	*SOP0383 – General Procedures Including Use and Maintenance for Laboratory Systems, SOP0386 – System validation* and *MAN0012 – Validation Policy*. The calibration and maintenance of equipment is primarily performed by experienced system owners or qualified suppliers of maintenance and/or calibration activities. Using documented procedures and Nelson Labs NV approved protocols, they work to prevent inaccuracy and deficiencies in data through the use of NIST traceable reference standards, laboratory working standards and standards for calibration activities.
Complaints	*SOP0428 – Dealing with Complaints*. Describes the practices for customer complaint resolutions.
Customer Feedback	*SOP0450 – Customer Survey*. Details the periodic customer survey process.
Control of Non-conforming Samples and lab inventory	*SOP0200 – Study Logging Procedures, Sample Receipt, Storage and Contamination Control Practices Using LOMS System* and *SOP0377 – Management of Inventories (Chemicals and Consumables) at Nelson Labs.* Samples and lab inventory which do not conform procedural criteria are quarantined.
Corrective Action / Preventative Action	*SOP0427 – Corrective / Preventive Action Procedures*. A Corrective Action/Preventive Action (CAPA) procedure is in place to address potentially recurring quality problems. The procedure includes verifying and validating corrective and preventive action, implementing and recording changes in applicable procedures, ensuring that the appropriate people are aware and involved in the preventive actions, and effectiveness verification. All CAPA action plans are reviewed and approved by responsible management. All actions are tracked to completion.
Quality Events and Deviations	*SOP0426 – Quality Events (Including Retest)*. This procedure details how to address quality events (e.g. deviations, system criteria fails, atypical or out of trend results). This procedure requires that all quality events are documented, assessed for impact, where appropriate investigated and actions defined and properly reviewed and authorized before the release of data to the Sponsor. If potential impact of a quality event on the test or data cannot be excluded, the Sponsor is to be notified.
Out of Specification (OOS) Results	*SOP0429 – Out-of-Specification Procedure*. An OOS is a result that falls outside the specification established by a compendial method, or as required by the Sponsor. According to the OOS procedure, an OOS must be documented, root cause identified through a failure investigation, its impact to data assessed and the validity of any results substantiated. If, after internal investigation, no clearly defined error can be identified, the Sponsor is to be notified.
Training	*SOP0419 – Personnel and Training*. Nelson Labs NV includes an extensive, documented training program for all employees based on a plan-do-check-act cycle. The completion of initial training needs is not the end of the training. New or revised procedures, QA audit findings, quality events, strategic corporate initiatives, critical incidents, ongoing needs, sponsor complaints… can induce short-term training needs. Provision of these trainings should be coordinated by Management and QA. Employees receive annual GMP and GLP training, whenever appropriate. Additionally, annual proficiency analyses are performed and a retraining program is implemented.
Traceability	*SOP0417 – Development, review, reconciliation and archiving of forms and raw data.* Process controls are in place to ensure traceability and to prevent contamination. Samples are uniquely identifiable. Associated items used in testing are traceable to the batch record, lot number, or part number. Laboratory records are kept in lab and logbooks, Raw Data Sheets (RDS) or Raw Data Packages (RDP).

Data Integrity	*SOP0430 – Good Documentation Practice (GDP) and Signature Policy* and *MAN0014 – Data Integrity Policy*. These documents describe Nelson Labs NV's data integrity system and establish the company policy for managing the integrity of data according to the principles of ALCOA++, including e-records and e-signatures and requirements for computerized systems. Driving regulations for the QMS are 21CFR11, EU GMP Annex 11, OECD GLP 17 and principles from GAMP 5.	
Internal Audits	*SOP0421 – Internal Audit: Process and Facility Based Inspections*. Describes the documented internal audit program. Actions to correct deficiencies and prevent recurrence are documented, reviewed and approved before audit closure. *SOP0423 – Periodic review of (critical GxP) computerized systems* describes the documented periodic review program for GxP critical systems. Actions to correct deficiencies and/or prevent recurrence are documented, reviewed and approved before periodic review report closure.	
Management Responsibilities	*SOP0448 – Company organization table* and *SOP0449 – Management review procedures*. Nelson Labs NV Management has established a Quality Policy and Quality unit which acts independently within the organizational structure. Management reviews the effectiveness of the Nelson Labs NV Quality System on an annual basis according to ISO/IEC 17025:2017.	
Study Documentation	*SOP0392 – Archive procedures*. Data packages, which contain study information including raw data, are maintained. Nelson Labs NV's Quality Document retention period is 10 years for study related data. Data will never be destroyed without prior notification and approval of the Sponsor. Non-study related quality records are maintained until end of business.	
Supplier Management	*SOP0381 – Vendor and Subcontractor qualification and monitoring procedures*. All suppliers are qualified through our supplier management process. The quality capabilities of vendors/subcontractors are reviewed prior to placing any orders. Supplier performance is assessed on an ongoing basis through product quality tracking systems and evaluated on a yearly supplier evaluation.	
Test Data Review	*SOP0425 – Quality Assurance and Quality Control*. All raw test data undergoes, at a minimum, a full review by a reviewer (Data Review). Reporting by Study Director, (Associate) Scientific Project Manager or Scientific Expert is also assessed by a second person (Cross Review). Finally, a final project review is performed by a member of the Quality Assurance department.	
Validation	*SOP0204 – Method Validation*, *MAN0012 – Validation Policy* and *SOP0386 – System Validation*. Analytical test methods undergo validation to assess accuracy, precision, specificity, detection limit, quantitation limit, range and linearity (where applicable). Computerized systems undergo a lifecycle and are validated based on their system category (based on USP <1058> and GAMP 5) as described in SOP0386.	
Equipment	*MAN0012 – Validation Policy* and *SOP0386 – System Validation*. Each piece of equipment is uniquely identified. Before being put into use, a new piece of equipment undergoes a qualification (IQ, OQ and PQ) or calibration, where applicable. Qualification, validation and/or calibration efforts are based on the system category as described in SOP0386.	
Additional information	Additional information about the above and other topics can be found in our *MAN0010 – Quality Manual / Site Master File*, which can be consulted at https://www.nelsonlabs.com/audit-documents/ (please go to the bottom of the page, section "Leuven, Belgium").	
Approved by	Rudi Segers, Quality Assurance Manager	Signature: Signed by: Rudi Segers Signer Name: Rudi Segers Signing Reason: I approve this document Signing Time: 21 Oct 2024 | 10:50:44 AM CEST C9CDC429D9234A4EB3DFC39D4D3883A4