Nelson Labs™
A Sotera Health company

Quality Information – Nelson Labs NV

Company Information	
Company Name	Nelson Labs NV, a Sotera Health Company Private corporation. Established in 1991.
Parent Company	Sotera Health
Company Address	Romeinse Straat 12 3001 Leuven – Belgium
Website	www.nelsonlabs.com
Telephone	+32 16 40 04 84
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	4200 m²
Lab Space	2100 m²
Operating Hours	9h00 - 17h00
Number of employees	130
Quality Staff	10
Equal Opportunity	Nelson Labs NV is an equal opportunity employer.
Critical Contacts	
Management	Eric Meyers (VP of EMEAA Operations) EMeyers@nelsonlabs.com Jos Bollen (Managing Director) JBollen@nelsonlabs.com
Operations (Chemistry)	Frank De Smedt (Director Lab Operations) FDesmedt@nelsonlabs.com
Operations (Microbiology, Pharma)	Lise Vanderkelen (Head of Quality Control) LVanderkelen@nelsonlabs.com
Quality	Bart Boerjan (Quality Assurance Manager) BBoerjan@nelsonlabs.com
Service Center	Johan Jaubin (Head Sales and Business Development) JJaubin@nelsonlabs.com
Additional Contacts	
Service Center	InfoEurope@nelsonlabs.com
Audit Scheduling	BBoerjan@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 sales and financial information is proprietary, thus no sales or financial information is able to be provided.
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
Overnight Address	Not applicable
Wire Transfers	IBAN BE13 5490 0105 9839
ACH Transactions	Not applicable

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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, Veterinary and Investigational medicinal products (FAHMP)
GLP compliance	OECD Directive 2004/9/EC, T02 (Sciensano)

Please note: Up-to-date certifications are available on the website.
www.nelsonlabs.com/Quality

go to

Nelson Labs Europe Certifications

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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	*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) 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 control software. Documents are reviewed, updated and approved as necessary.
Calibration and Maintenance	*SOP0277 – Equipment Use and Maintenance* 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 *SOP0384 – Notification and Inspection Procedures of Material and Equipment Receipt - Lab Inventory.* 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 root cause analysis, 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.
Deviations	*SOP0426 – Non-Conformances / Deviations (Including Retest).* This procedure details how to address technical and non-technical deviations, atypical and out of trend results. This procedure requires that all deviations be documented, assessed for impact, where appropriate investigated, and properly reviewed and authorized before the release of data to the Sponsor. If potential impact of a deviation 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, non-conformances, 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. All 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).

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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.	
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 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*. Datapacks, 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 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.	
Approved by	Bart Boerjan, Quality Assurance Manager	Signature: BB Date: 01 APR 2020