SCIEX

The Power of Precision

QUESTIONNAIRE RESPONSE

TABLE OF CONTENTS

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

Confidential - Company Proprietary

SCIEX
The Power of Precision

1.0 Introduction

The supplied documents and sample files in this package are for informational purposes only. Neither AB Sciex LLC, nor any of its affiliates, officers, directors, employees, contractors, or agents make any warranties, express, implied, or statutory in these documents and files. The information contained herein represents the current information and opinions on the topics discussed on the date of issue. The supplied information should not be interpreted in any way as a commitment of SCIEX. SCIEX cannot guarantee the continued accuracy of any information after the date of issue.

2.0 General Company Information

2.1. **Company name:** SCIEX
2.2. **Website:** https://sciex.com
2.3. **Locations:** SCIEX has offices and/or manufacturing plants in Concord, Canada, Mexico DF, Mexico, Framingham, USA, Redwood City, USA, Sao Paulo, Brazil, Nieuwerkerk aan den Ijssel, Netherlands, Chodovec, Czech Republic, Wien, Austria, Copenhagen, Denmark, Helsinki, Finland, Darmstadt, Germany, Budapest, Hungary, Milan, Italy, Wroclaw, Poland, Madrid, Spain, Brugg, Switzerland, Warrington, UK, Shanghai, China, Kowloon, Hong Kong, Haryana, India, Tokyo, Japan, Seoul, South Korea, Singapore, Moscow, Russia, Taipei City, Taiwan, Bangkok, Thailand, Victoria, Australia and Auckland, New Zealand.

    2.3.1. Headquarters: 500 Old Connecticut Path, Framingham, MA 01701 USA
    2.3.2. Manufacturing:
    2.3.2.1.   Singapore Manufacturing Site: Blk 33, #04-06 Marsiling Industrial Estate Road 3 Woodlands Central EST Singapore, 739256
    2.3.2.2.   Carlsbad Manufacturing Site: 2470 Faraday Ave., Carlsbad, CA 92010, USA
    2.3.3. Sales, Support, and Service: For specific contact information in the region of interest please visit the SCIEX website at https://sciex.com/about-us/contact-us
    2.3.4. Main Warehouse/Ship from Location: 921 W Bethel Rd Building 200, Suite 201, Coppell, TX 75019

2.4. **Business scope:** SCIEX designs, manufactures, markets, sells, services and supports liquid chromatography, capillary electrophoresis, mass spectrometer instruments, and associated software and consumables

    2.4.1. Products: https://sciex.com/products
    2.4.2. Background, history, and size: https://sciex.com/about-us/our-history

    SCIEX creates scientific instrumentation (such as mass spectrometers), software and services for the life science, clinical research, and industrial markets, empowering our customers with technologies that are used in drug discovery and manufacturing, food and environmental safety, and clinical research.

    SCIEX employs over 1,700 associates. The actual current number of associates in various job functions and turnover rate are considered proprietary information can only be disclosed under the control of a Confidential Disclosure Agreement.

    2.4.3. Operations: There is one shift, Monday-Friday, 8 AM - 5 PM. SCIEX is not unionized.
    2.4.4. Executive management: For a current overview of the SCIEX management team please visit https://sciex.com/about-us/executive-management
    2.4.5. Future business plans: Future business plans are considered business confidential
    2.4.6. Public relations: Please visit, https://sciex.com/about-us/press-releases, for up to date news and press releases
    2.4.7. Parent corporation: Complete corporate information can be found at https://www.danaher.com/ and http://investors.danaher.com/annual-report-and-proxy

3.0 Quality Management System

SCIEX

The Power of Precision

SCIEX has established, documented, implemented, and maintains the Quality Management System and continually improves its effectiveness in accordance with the ISO 9001, ISO13485, 98/79/EC In Vitro Diagnostic Directive requirements, FDA 21 CFR Part 820, Canadian Medical Device Regulations and Japan Ministerial Ordinance No. 169 (MHLW MO169).

3.1. Quality management system registration/certification

3.1.1. Does SCIEX have a defined quality system?

SCIEX has ONE Quality Management System (QMS). All of SCIEX regardless of site must adhere to the SCIEX QMS.

3.1.2. Is it registered to any standard? What is the scope of coverage? How long has SCIEX been registered?

The SCIEX QMS is compliant to both ISO 13485:2016 and ISO 9001:2015 in addition to any regulations that we are required to adhere to. These are described in the Quality Manual.

SCIEX is ISO 9001:2015 (Certificate Number FM 31547) registered since 1995. The scope of registration is: "The design, manufacture, service, support, sales and marketing of capillary electrophoresis, liquid chromatography, mass-spectrometer instruments along with associated software and consumables."
https://sciex.com/Documents/company/ISO9001.pdf

SCIEX has had ISO 9001 certification since May 25, 1995.

SCIEX is ISO 13485:2016 (Certificate Number FM 559520) registered since 2012. The scope of registration is: "The design, manufacture, service, support, sales and marketing of capillary electrophoresis, liquid chromatography, mass-spectrometer instruments along with associated software and consumables."
https://sciex.com/Documents/company/ISO-13485-certificate.pdf

SCIEX has had ISO 13485 certification since Feb 13, 2012.

3.1.3. Why are all sites not listed on the ISO certificates?

The sites that appear on our ISO certificates are sites that have activities that are directly impacted by the ISO requirements; for example, Concord – Design Control, Singapore – Manufacturing. This does not mean that sites that are not listed are not covered by our ISO certificates.

All of SCIEX is required to adhere to the SCIEX QMS. All of SCIEX is certified to both ISO 9001:2015 and ISO 13485:2016.

3.2. Quality Organization

3.2.1. Does SCIEX have a quality unit independent from manufacturing and development? Yes, SCIEX has a Regulatory Affairs and Quality Assurance Department that works independently from manufacturing and development. SCIEX maintains a quality management system (complies with ISO 9001, ISO 13485 standards and satisfies 21 CFR Part 820 regulations).

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

Confidential - Company Proprietary

SCIEX

The Power of Precision

3.2.2. How many quality personnel (QA/QC) do you have? ~35 associates, SCIEX as a whole employs over 1700 associates

4.0 Document Management/Control

4.1. Documentation: SCIEX maintains a registered quality management system. SCIEX has documented the following:
- **4.1.1.** Quality manual
- **4.1.2.** Control of documents
- **4.1.3.** Control of records
- **4.1.4.** Quality policy
- **4.1.5.** Quality planning
- **4.1.6.** Responsibility, authority and communication
- **4.1.7.** Management review
- **4.1.8.** Resource management and training
- **4.1.9.** Infrastructure
- **4.1.10.** Work environment
- **4.1.11.** Planning of product realization
- **4.1.12.** Customer-related processes
- **4.1.13.** Design and development planning
- **4.1.14.** Design and development inputs
- **4.1.15.** Design and development outputs
- **4.1.16.** Design and development review
- **4.1.17.** Design and development verification
- **4.1.18.** Design and development validation
- **4.1.19.** Design transfer
- **4.1.20.** Design history file
- **4.1.21.** Control of design and development changes
- **4.1.22.** Purchasing/verification of purchased product
- **4.1.23.** Production and service provision (Installation and servicing)
- **4.1.24.** Control of monitoring and measuring devices
- **4.1.25.** Complaint files
- **4.1.26.** Monitoring and measurement (Internal audit, processes, product)
- **4.1.27.** Control of nonconforming product
- **4.1.28.** Analysis of data/statistical techniques
- **4.1.29.** Improvement/CAPA

Procedures are in place for document control, control of engineering changes (hardware, software, and design documentation) and control of end-user manuals and customer-facing documents. Only approved and effective documents are available at point-of-use. SCIEX has a documented policy regarding the retention of quality records that conforms to regulatory requirements. Requirements are defined for the identification, collection, indexing, filing, storage, maintenance, retrieval, and disposition of quality records.

4.2. Document control process: The document control process at SCIEX manages and controls documents for all SCIEX locations that provide written instruction for each quality management system process.

4.3. Management review processes: SCIEX Leadership regularly reviews the status, adequacy, continuing suitability, and effectiveness of the Quality Management System in satisfying the requirements and regulations.

5.0 Human Resources

5.1. Resource provision and training: SCIEX has provided the necessary resources to maintain the effectiveness of the quality management system and meet regulatory and customer requirements. All associates meet the minimum requirements for the job function and are qualified to perform their role and responsibility. Responsibilities and resumes at time-of-hire are filed with the Human Resources Department.

Confidential - Company Proprietary

SCIEX

The Power of Precision

5.1.1. Associates are assessed by their managers for training needs and appropriate training is performed. Training programs are provided at SCIEX on a continuous basis by utilizing in-house experts and outside professionals. Field Service Engineers are certified and are re-certified every 2 years. Training records are maintained.

5.1.2. Consultants and subcontractors are managed as a supplier for SCIEX and training requirements will be outlined in contractual agreements.

5.2. **Security:** SCIEX has a Facilities department and maintains procedures to address the physical security of our buildings and their content. Access to all buildings is controlled. Access to main server rooms and sensitive Research Design and Manufacturing areas are controlled to authorized personnel only. Visitors must sign-in and be issued a visitor's badge and escorted while on-site.

6.0 Purchasing – Supplier Management

SCIEX maintains procedures to evaluate suppliers. There is a supplier qualification process and a qualified supplier will be placed onto an approved list. Suppliers are then evaluated at planned intervals based on quality, delivery, and other applicable criteria. Only approved parts from approved suppliers are purchased and included in manufactured product(s). Supplier records are maintained according to applicable laws and regulations.

7.0 Design and Development Process

7.1. SCIEX product design and development process has the following stages for both hardware and software development projects:

7.1.1. Concept

7.1.2. Planning

7.1.3. Design

7.1.4. Prototype

7.1.5. Pilot

7.1.6. Launch

7.2. SCIEX maintains procedures for these product life cycle process activities and defines associated deliverables for each activity. The required roles and responsibilities for a cross-functional team are defined in these procedures. Reviews are held at the end of each stage which involves a thorough assessment of the required deliverables and confirmation that the project may proceed to the next stage. A design history file is established and maintained for required design projects.

7.3. As noted, software development projects follow the same design and development process. SCIEX maintains procedures for defining software requirements, source code reviews, software testing, error reporting, software revision tracking, and software release. Software designs and source code are reviewed by qualified software personnel to ensure adherence to programming standards. SCIEX practices Agile software development for source code reviews and software testing. Designs and code are reviewed constantly as part of the pair programming and refactoring practices. With the Agile practices of Test Driven Development (software testing), high-level requirements are refined in story test creation to create an executable functional specification that tests for the requirement under development. Customers reporting software errors are directed to the software development group for cause investigation and corrective action.

8.0 Operations

SCIEX maintains procedures for the production of our products. These procedures ensure that our products conform to their specifications. Materials used in manufacturing of our products are inspected, identified, and stored in designated locations. The quality of the product is ensured throughout the product realization process from incoming, in-process, and final product testing according to established specifications and test procedures. All identified test equipment used during manufacturing are calibrated and traceable to NIST where applicable. Calibration, inspection, and test

Confidential - Company Proprietary

SCIEX

The Power of Precision

records are retained. SCIEX maintains procedures for identification and traceability throughout product realization. SCIEX maintains procedures for shipping products. This includes product visual inspections, appropriate packaging to ensure product quality is preserved, kitting, and labeling. Shipping records are retained.

9.0 Installation and Service

SCIEX maintains procedures for the installation and service of our products. If applicable, trained personnel install our products at the customer site. Customer training for the use of SCIEX products are available at https://sciex.com/support/training. Maintenance and service of our products are performed by trained Field Service Engineers at the customer site. SCIEX will tune the instruments until the optimal operating environment is obtained, and results are documented. Customers with instruments that are found out-of-calibration should contact SCIEX. SCIEX provides technical support and field sales and service calls. For a complete listing of contact information, please refer to, https://sciex.com/about-us/contact-us.

10.0 Nonconforming Product

SCIEX maintains procedures for the control of nonconforming products. Processes are in place to detect nonconformities in materials and to authorize actions required for appropriate disposition of the nonconforming materials at all stages of a product. Nonconforming materials and products are identified, segregated, and dispositioned by authorized personnel.

11.0 Complaint Handling

SCIEX maintains procedures for customer complaint handling. Complaints (oral or written) can be logged through any SCIEX customer-facing functions: field service, field application support, application technical (phone) support, technical assistance centers, customer training, sales, and customer care/resources. The complaints will be received and reviewed. If a complaint required investigation, domain experts will be assigned to determine and record the root cause of the complaint issue.

12.0 Monitoring and Measurement

12.1. Internal audits: SCIEX maintains procedures for internal quality audits to assure compliance with the quality management system and determine its effectiveness
12.2. Corrective and preventive action: SCIEX maintains procedures for corrective and preventive actions (CAPA). The following are analyzed to identify quality problem trends:
   12.2.1. Processes
   12.2.2. Work operations
   12.2.3. Concessions
   12.2.4. Quality audit reports
   12.2.5. Quality records
   12.2.6. Service records
   12.2.7. Customer complaints
   12.2.8. Returned product

SCIEX evaluates these metrics to continuously improve the effectiveness of the quality management system and products and services delivered to customers

Has SCIEX been inspected by a regulatory body?

When was SCIEX inspected by a regulatory body? Yes, SCIEX hosted a routine FDA Regulatory Inspection in Q2 of 2019 and Q1 2016 and a Health Canada Regulatory Inspection in July 2018.

Confidential - Company Proprietary

SCIEX
The Power of Precision

13.0 Information Technology (IT)

13.1. **Disaster recovery:** SCIEX has an IT disaster recovery plan that is tested annually. SCIEX also has a general crisis management plan, as well as site-specific business continuity plans and emergency response plans.

13.2. **Backup and recovery:** SCIEX has an IT backup and restore procedure that is tested monthly

13.3. **Information security policy:** SCIEX has a comprehensive information security policy

14.0 Environmental Health & Safety (EHS)

14.1. **EHS Policy:** Danaher EHS Policy applies to all SCIEX operations. A copy of the current policy document can be obtained by contacting ehs@sciex.com.

14.2. **EHS Certification:** SCIEX Singapore holds OHS certification and operates an Occupational Health and Safety Management System which complies with the requirements of BS OHSAS 18001: 2007 for the following scope: The manufacture, service, and support of capillary electrophoresis, liquid chromatography and mass spectrometers and associated software, consumables and accessories.

SCIEX Singapore holds EMS certification and operates an Environmental Management System which complies with the requirements of ISO 14001: 2015 for the following scope: The manufacture, service, and support of capillary electrophoresis, liquid chromatography and mass spectrometers and associated software, consumables and accessories.

14.3. **Regulatory Inspections**: SCIEX maintains operating permits for hazardous materials, hazardous waste, biosafety, controlled substances, laser devices, and radiation protection at our various facilities. As a condition of these operating permits, we are subject to periodic agency inspection. Contact EHS via email at EHS@sciex.com for recent government inspections and related enforcement action information.

14.4. **Injury and Illness Injury Records and Worker's Compensation Insurance:** SCIEX tracks injury and illness metrics following the guidelines established under the Injury and Illness Prevention Program, EHS-007. Associates are required to report injuries and near-misses to their supervisor immediately. All injury reports are investigated to determine root cause, and corrective actions are tracked to closure to prevent reoccurrence. Injury accident and significant near-miss event information are communicated to associates when they occur as part of our ongoing training process.

    14.4.1. Occupational Health and Safety Administration recordable injuries are reported on an annual basis as required. Copies of OSHA logs can be obtained by contacting ehs@sciex.com. Versions of OSHA Logs which do not contain employee confidential information are available and can be shared with a customer upon request.

    14.4.2. SCIEX maintains Worker's Compensation Insurance under Danaher. Insurance is managed by Marsh. Current Worker's Compensation Certificates and Experience Modification Rates (EMR) are available through Marsh at Danaher.certrequest@marsh.com.

14.5. **Risk Assessment:** SCIEX maintains risk assessment documentation in compliance with US, European, and Australian occupational health and safety regulations for field service.

    14.5.1. SCIEX also conducts Job Hazard Analysis reviews on field service functions and instrument service procedures.

    14.5.2. Contact EHS via email at EHS@sciex.com for current methods statements, risk assessment, and Job Hazard Analysis documentation.

14.6. **Associate Training Records:** Field Service associates are provided with health and safety training during onboarding and at regularly scheduled intervals. Training is provided in the form of work instructions, online safety awareness courses, and Job Hazard Analysis documentation. Refer to QP-300 Training Program – Associates, Contingent, and Visitors.

    14.6.1. Associate training records are available upon customer request by contacting ehs@sciex.com.

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

SCIEX

The Power of Precision

14.7. EHS Programs: EHS compliance programs have been established in compliance with government regulations and environmental safety and health management best practices. Documents are stored in the Master Control system.

15.0 Corporate Social Responsibility

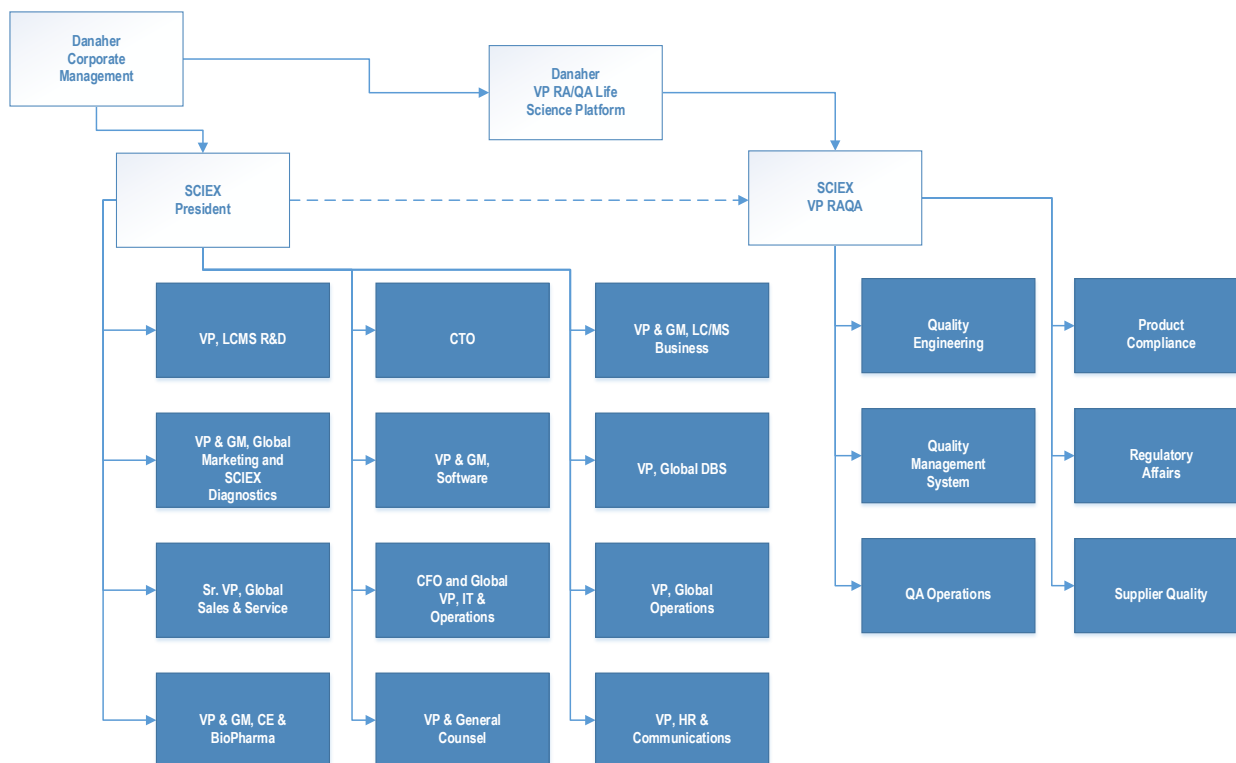Questions related to conflict minerals, child labor, sustainability, etc. are found on the DHR website, http://investors.danaher.com/corporate-governance.

16.0 High-Level Quality Procedures per QMS Process

Table 1. QMS Process

QMS Process	Quality Procedure
Management of the Organization, Management Review	● QP-100 Quality Management System Manual ● QP-101 Management Review of Quality System
QMS Change Management and Quality Planning	● QP-202 QMS Change Management and Quality Planning
Human Resource	● QP-300 Training Program - Associates, Contingent and Visitors ● QP-308 Programs for Managing SCIEX Associates
Resource - Monitoring and Measuring	● QP-307 Measuring Equipment Mgt. ● WI-307-14 Global Service Measuring Equipment
Facilities Infrastructure Management	● QP-332 Infrastructure and Work Environment Management ● EHS-029 Management of Change ● WI-332-22 Electrostatic Discharge (ESD) Control
IT - Global	● QP-304 Non-Product Software Validation Procedure
Document Control	● QP-400 Document and Record Control
Design and Development	● QP-500 Product Development Lifecycle Process
Control of External Suppliers	● QP-600 Global Purchasing Controls & Supplier Management ● QP-602 Selection of Potential Suppliers ● QP-606 Feedback & Communication
Shipping, Identification and Traceability, Handling, Storage and Distribution	● QP-703 Distribution Center's Operation and Control
Production	● Drawings, assembly and test procedures

SCIEX
The Power of Precision

Confidential - Company Proprietary

QMS Process	Quality Procedure
Service	● QP-915 Installation and Service Overview
Sales and Marketing, Order Management	● QP-1010 Customer Ordering Process ● QP-1011 Creation and dissemination of Advertising Promotional Material
Application and Technical Support	● QP-1105 Working with the Customer
Audits	● QP-1203 Global Internal Audit Program
Complaints	● QP-1300 Complaint Handling Procedure
Customer Feedback	● QP-1301 Voice of the Customer
Post Market Surveillance	● QP-1302 Post Market Surveillance Process
Post Market Actions	● QP-1306 Field Actions, Corrections and Removals ● QP-1604 GSSO Process
CAPAs	● QP-1400 Corrective and Preventive Action Process
Analysis	● QP-1500 SCIEX Data Analysis Process ● QP-1501 Customer Defect Tracking & Resolution Process ● QP-1504 Statistical Tools for Data Analysis
Regulatory Requirements	● QP-1305 Medical Device Reporting ● QP-1603 External Documents and Standards Control ● QP-1610 Application and Maintenance of Licenses and Registrations
Clinical Affairs	● QP-1650 Product Evidence Strategy Planning

17.0 Functional Organizational Chart

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

Confidential - Company Proprietary

SCIEX
The Power of Precision

Org chart:

- Danaher Corporate Management
  - Danaher VP RA/QA Life Science Platform
    - SCIEX VP RAQA
      - Quality Engineering
      - Quality Management System
      - QA Operations
      - Product Compliance
      - Regulatory Affairs
      - Supplier Quality
  - SCIEX President
    - VP, LCMS R&D
    - VP & GM, Global Marketing and SCIEX Diagnostics
    - Sr. VP, Global Sales & Service
    - VP & GM, CE & BioPharma
    - CTO
    - VP & GM, Software
    - CFO and Global VP, IT & Operations
    - VP & General Counsel
    - VP & GM, LC/MS Business
    - VP, Global DBS
    - VP, Global Operations
    - VP, HR & Communications

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

Confidential - Company Proprietary

SCIEX
The Power of Precision

18.0   Additional Questions / Help

If upon complete review of this document additional information is needed, please forward your specific request(s) to the following regional email boxes:

Region	Email Box
North America	amer.custformrequest@sciex.com
EMEA	CustomerQuestionnaires.EMEA@sciex.com
India	sciexnow.india@sciex.com
Japan	jp_support@Sciex.com
China	Service.china@sciex.com
ANZ & ASEAN	sciexnow.asean@sciex.com
HK & TW & Korea	service.Taiwan@Sciex.com

Headquarters
500 Old Connecticut Path
Framingham, MA 01701 USA
https://sciex.com

SCIEX

The Power of Precision