

Quality Questionnaire Response

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Contents

Contents

1. Introduction	3
2. General Company Information	4
3. Quality Management System	5
4. Document Management/Control	7
5. Human Resources	7
6. Purchasing – Supplier Management	8
7. Design and Development Process	8
8. Operations	10
9. Installation and Service	10
10. Nonconforming Product	10
11. Complaint Handling and Post-Market Surveillance	11
12. Monitoring and Measurement	11
13. Information Technology (IT)	12
14. Environmental Health & Safety (EHS)	12
15. Corporate Social Responsibility	13
16. High-Level Quality Procedures per QMS Process	14
17. Functional Organizational Chart	15
18. Additional Questions / Help	15
19. DOCUMENT REVISION HISTORY	16

1. Introduction

Purpose

- 1.1.** This Quality Questionnaire is intended to provide a high-level overview of the SCIEX Quality Management System, regulatory alignment, and quality governance practices and is provided 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. General Company Information

2.1. Company name: SCIEX

2.2. Website: <https://sciex.com>

2.3. Locations: Global Presence: SCIEX is a global company with multiple locations worldwide. For specific information about SCIEX locations and country-specific contacts, please refer to our website at <https://sciex.com>.

2.3.1. Key Locations:

- **Headquarters:** 250 Forest Street, Marlborough, MA 01752, U.S.A.
- **Manufacturing:**
 - 2.3.1.1. Singapore Manufacturing Site:** Blk 33, #04-06 Marsiling Industrial Estate Road 3 Woodlands Central EST Singapore, 739256
 - 2.3.1.2. Carlsbad Manufacturing Site:** 2470 Faraday Ave., Carlsbad, CA 92010, USA
- **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>
- **Main Warehouse/Ship from Location:** 921 W Bethel Rd Building 200, Suite 201, Coppel, TX 75019

2.4. Business scope: SCIEX designs, manufactures, 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 and capillary electrophoresis instruments), software and services for pharmaceutical, 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 2,500 associates. The actual current number of associates in various job functions and turnover rate are considered proprietary information and 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. Quality Management System

SCIEX has established, documented, implemented, and maintains the Quality Management System and continually improves its effectiveness in accordance with ISO 9001, ISO 13485, EU IVDR (EU) 2017/746, FDA 21 CFR QMSR, Japan Ministerial Ordinance No. 169 (MHLW M0169), and other applicable regulatory requirements as required.

SCIEX evaluates global regulatory requirements relevant to its products and services to ensure alignment with applicable regulatory obligations.

The specific regulatory requirements are determined based on product classification, intended use, and market distribution.

Where applicable, SCIEX maintains technical documentation, post-market processes, and regulatory reporting controls consistent with regional regulatory expectations, including those in the European Union. Products designated for Research Use Only (RUO) are clearly labeled and managed in accordance with applicable regulatory requirements.

SCIEX integrates risk-based thinking throughout the QMS using the Plan-Do-Check-Act (PDCA) cycle wherever practical. This ensures that risk identification, evaluation, and mitigation are embedded into planning, execution, monitoring, and improvement activities. The risk level of each process informs audit frequency, training requirements, and resource allocation. This risk-based framework is applied globally and is tailored to SCIEX's product portfolio.

3. Quality Management System continued

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 May 25, 1995.

The scope of registration is: "The design, manufacture, distribution, service, support, and sales of capillary electrophoresis, liquid chromatography, mass-spectrometer instruments and their associated software and consumables."

SCIEX is ISO 13485:2016 [Certificate Number FM 559520] registered since Feb 13, 2012.

The scope of registration is: "The design, manufacture, distribution and service of liquid chromatography and mass-spectrometer instruments and their associated software and consumables."

Additional certification details are available at: <https://sciex.com/legal-pages/legal-information>

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

ISO certificates list sites that perform activities directly assessed against ISO requirements (for example, Design Control or Manufacturing). Sites not listed are still covered under the certification, as **all SCIEX sites operate under and are required to adhere to the same global SCIEX Quality Management System**, which is certified to 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.

3.2.2. How many quality personnel [QA/QC] do you have?

About ~80 associates. The actual current number of associates in various job functions and turnover rate are considered proprietary information.

3.3. 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.

4. Document Management/Control

4.1. **Documentation:** SCIEX maintains a registered quality management system.

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.

Refer to Section 16 for more information on the QMS processes.

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.

5. 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.

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 as required. Training records are maintained.

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. Purchasing – Supplier Management

- 6.1. 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. 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. Transition
- 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 file is established and maintained for required design projects.
- 7.3. **Risk Management**
 - 7.3.1. SCIEX maintains a documented, lifecycle-based approach to product risk management that is integrated into design and development activities. Risks associated with product performance, safety, software, and usability are identified, evaluated, and controlled throughout the product lifecycle.
 - 7.3.2. Risk management activities are reviewed during design reviews and are maintained as part of the Design History File or equivalent product documentation, as applicable. Outputs from complaint handling, post-market surveillance, and corrective actions are evaluated for potential impact on product risk assessments.
- 7.4. **Software Development**
 - 7.4.1. **Overview**

This software development process defines a structured, lifecycle-based approach for developing, maintaining, and releasing software products in a regulated environment. It integrates planning, design, implementation, verification, security, configuration control, issue resolution, and release activities to ensure product quality, safety, compliance, and traceability.
 - 7.4.2. **Lifecycle and Planning**

Software development follows a phased lifecycle aligned with overall product development, from concept and planning through design, verification, release, and post market maintenance. Activities are scalable based on product risk and complexity. Each project establishes a development plan that defines scope, responsibilities, deliverables, tools, review points, and required records. Privacy, security, and risk management activities are planned early and maintained throughout the product life.

7. Design and Development Process continued

7.4.3. Design and Implementation

Software design proceeds from high level architecture to detailed design, with appropriate documentation and design reviews to ensure completeness, consistency, and alignment with requirements. Coding is performed according to defined standards, and source code is maintained under version control. Configuration management ensures that design outputs, source code, tools, third party components, and build environments are uniquely identified, traceable, and reproducible.

7.4.4. Code Review and Build Control

Code changes undergo structured reviews that may include both personal reviews and peer reviews. Reviews ensure compliance with requirements, design intent, and quality standards, and that defects are identified and resolved before acceptance. Software builds used for verification or release are created in controlled environments, uniquely identified, and archived or reproducible.

7.4.5. Verification and Quality Assurance

Verification confirms that software design outputs meet defined requirements. Verification activities are planned, risk based, and proportionate to change impact. Test cases, protocols, executions, and reports are documented and approved. Traceability is maintained between requirements, risk controls, and verification evidence. Verification results are assessed to determine readiness for subsequent lifecycle phases and release.

7.4.6. Privacy, Security, and Risk Management

Data privacy and cybersecurity are addressed across development and maintenance activities. Security risks are identified, assessed, and mitigated through planned technical and procedural controls. Ongoing monitoring, vulnerability management, incident response, and patch validation ensure continued product security after release. Responsibilities and escalation paths are clearly defined.

7.4.7. Issue Resolution and Maintenance

Reported issues are classified, investigated, and evaluated to determine root cause, impact, and required action. Approved fixes follow formal change control and lifecycle processes appropriate to their risk and urgency. Outcomes include planned releases, hotfixes, or patches, with clear communication to stakeholders and customers when applicable.

7.4.8. Release and Distribution

Software releases are prepared, verified, and approved through a controlled process that ensures production readiness. Release artifacts, documentation, and distribution mechanisms are verified before deployment to customers. Formal reviews confirm that regulatory, quality, and operational requirements are met prior to release.

7.4.9. Records and Continuous Compliance

All required plans, design artifacts, review records, verification evidence, release approvals, and change records are retained according to defined record keeping rules. The process supports audits, traceability, and continuous improvement throughout the software product's lifecycle.

8. Operations

- 8.1.** SCIEX maintains procedures for the production of our products. These procedures ensure that our products conform to their specifications. Materials used in manufacturing 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 records are maintained. 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. Installation and Service

- 9.1.** SCIEX maintains procedures for the installation and service of our products. As 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, field sales and service calls. For a complete listing of contact information, please refer to, <https://sciex.com/about-us/contact-us>.

10. Nonconforming Product

- 10.1.** 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. Complaint Handling and Post-Market Surveillance

11.1. SCIEX maintains procedures for customer complaint handling. Complaints 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 requires an investigation, domain experts will be assigned to determine and record the root cause of the complaint issue. Information from complaints, service activities, returned products, and customer feedback is reviewed and trended to identify potential quality or performance issues. Where appropriate, this information feeds into corrective and preventive action, risk management updates, and regulatory reporting or field actions, as applicable.

12. 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 appropriate metrics to continuously improve the effectiveness of the quality management system and products and services delivered to customers

12.3. 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 2019, which concluded with no FDA Form 483 observations issued, and a Health Canada Regulatory Inspection in July 2018.

13. Information Technology (IT)

SCIEX applies risk-based controls to computerized systems supporting quality and regulatory activities to ensure data is protected, accurate, and retrievable. Access to systems is controlled, backups are maintained, and data retention practices are defined in accordance with applicable requirements.

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 under the EHS process.

13.2. Backup and recovery: SCIEX has an IT backup and restore procedure that is tested bi-annually.

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

14. Environmental Health & Safety (EHS)

14.1. EHS Policy: The Danaher EHS Policy applies to all SCIEX operations. This document is posted publicly on the Danaher EHS & E-Sustainability Website: <https://www.danaher.com/about-danaher/sustainability>.

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.

14.2.1. 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 Records and Worker's Compensation Insurance: SCIEX tracks injury and illness metrics following the guidelines established under EHS defined processes. 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 AON Risk Services. Current Worker's Compensation Certificates and Experience Modification Rates (EMR) may be requested from SCIEX EHS.

14. Environmental Health & Safety (EHS)

continued

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.

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

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 controlled document system SmartSolve.

15. Corporate Social Responsibility

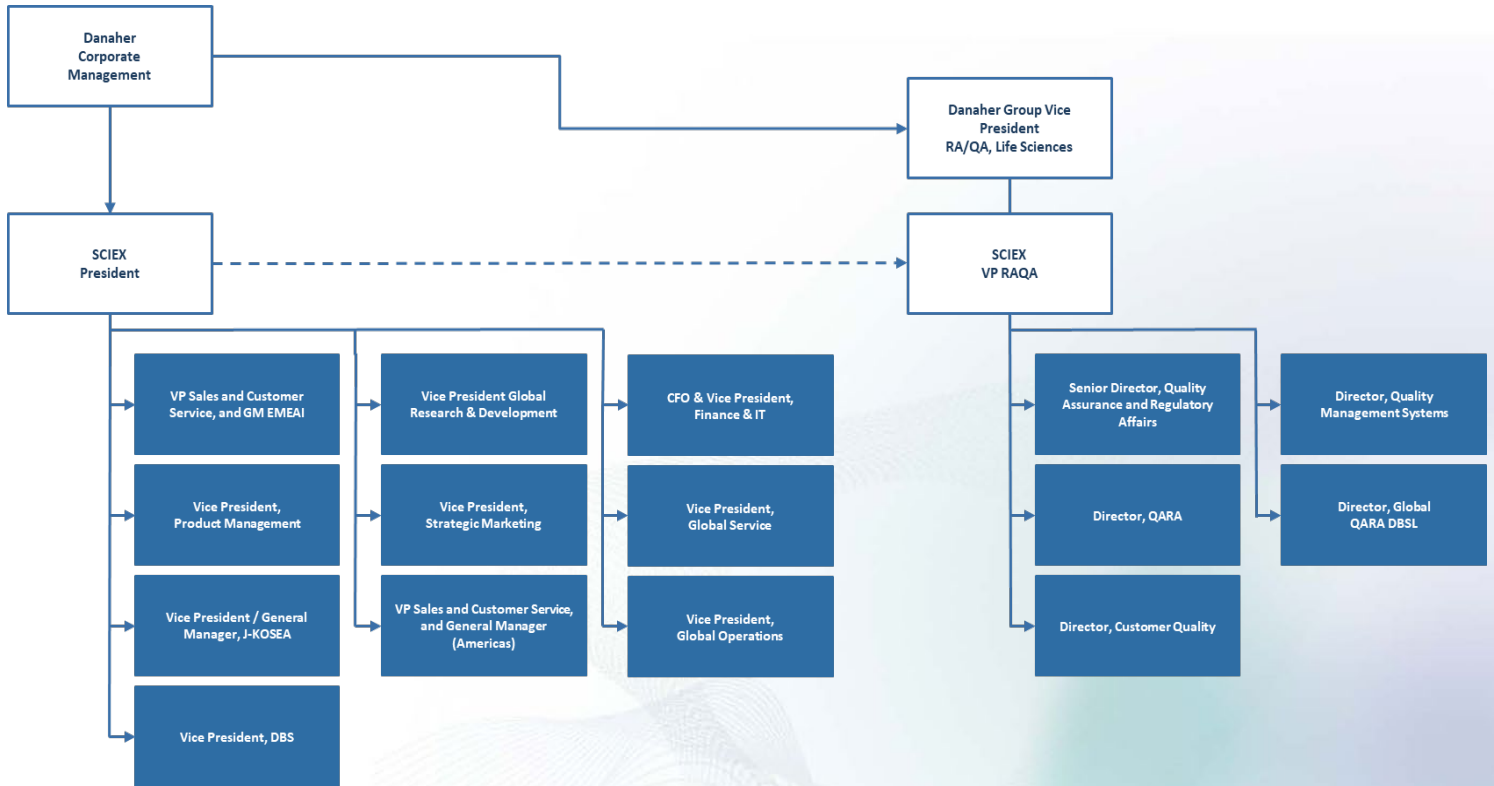
Questions related to conflict minerals, child labor, sustainability, etc. are found on the DHR website, <http://investors.danaher.com/corporate-governance>. Detailed information regarding our compliance with CSR requirements can be referenced in the annual Danaher Sustainability Reports (<https://www.danaher.com/resources-downloads>).

16. High-Level Quality Procedures per QMS Process

Table 1. QMS Process

QMS Process	Document Number	Governing Quality Procedure
1) Management of the Organization, Management Review	QMS-QP-00082	QP-100 Quality Management System Manual
	QMS-QP-00127	QP-101 Management Review of Quality System
2) QMS Change Management and Quality Planning	QMS-QP-00117	QP-202 QMS Change Management and Quality Planning
3a) Human Resource	QMS-QP-00097	QP-300 Training Program - Associates, Contingent and Visitors
	QMS-QP-00050	QP-308 Programs for Managing SCIEX Associates
3b) Resource - Monitoring and Measuring	QMS-QP-00122	QP-306 Global Preventative Maintenance Procedure
	QMS-QP-00067	QP-307 Measuring Equipment Management
	QMS-WI-00178	WI-307-14 Global Service Measuring Equipment
3c) Facilities Infrastructure Management	QMS-QP-00057	QP-332 Infrastructure and Work Environment Management
	EHS-PP-00076	EHS-029 Management of Change
	QMS-WI-00346	WI-332-22 Electrostatic Discharge (ESD) Control
3d) IT - Global	QMS-QP-00025	QP-304 Non-Product Software Validation Procedure
	QMS-QP-00024	QP-357 IT Back-up and Restore Procedure
4) Document Control	QMS-QP-00022	QP-400 Document and Record Control Procedure
5) Design and Development	QMS-QP-00015	QP-500 Product Development Lifecycle Process
6) Control of External Suppliers	QMS-QP-00021	QP-600 Global Purchasing Controls
7) Shipping, Identification and Traceability, Handling, Storage and Distribution	QMS-QP-00120	QP-702 Factory Receiving, Shipping Operations and Control
	QMS-QP-00071	QP-703 Distribution Center's Operation and Control
	QMS-QP-00034	QP-704 Product Identification and Traceability
	QMS-QP-00093	QP-801 Consumables Manufacturing Process
8) Production	QMS-QP-00091	QP-802 Manufacturing Process
	Multiple	Drawings, assembly and test procedures
9) Service	QMS-QP-00090	QP-915 Installation and Service Overview
	QMS-QP-00019	QP-1010 Customer Order Process
10) Sales and Marketing, Order Management	QMS-QP-00032	QP-1011 SCIEX MAPSS Procedure
	QMS-QP-00052	QP-1100 Application and Technical Support Overview
11) Application and Technical Support	QMS-QP-00123	QP-1105 Working with the Customer
12) Audits	QMS-QP-00014	QP-1203 Global Internal Audit Program
13a) Complaints	QMS-QP-00094	QP-1300 Complaint Handling Procedure
13b) Customer Feedback	QMS-QP-00089	QP-1301 Voice of the Customer
13c) Post Market Surveillance	QMS-QP-00062	QP-1302 Post-Market Surveillance Process
13d) Post Market Actions	QMS-QP-00009	QP-1305 Medical Device Reporting
	QMS-QP-00069	QP-1306 Field Actions, Corrections and Removals
	QMS-WI-00528	WI-1306-6 Global Stop Shipment Execution (GSSO)
14) CAPAs	QMS-QP-00059	QP-1400 Corrective and Preventive Action (CAPA) Process
15) Analysis	QMS-QP-00088	QP-1500 SCIEX Data Analysis Process
	QMS-QP-00018	QP-1501 Customer Defect Tracking & Resolution Process
	QMS-QP-00133	QP-1504 Statistical Tools for Data Analysis
	QMS-QP-00009	QP-1305 Medical Device Reporting
16a) Regulatory Requirements	QMS-QP-00075	QP-1613 Global Product Regulations & Standards Identification, Maintenance, Control & Change Impact Assessment
	QMS-QP-00104	QP-1610 Application and Maintenance of Licenses and Registrations
	QMS-QP-00042	QP-526 Label Content and Requirements
16b) Clinical Affairs	QMS-QP-00041	QP-1650 Clinical Study Procedure
16c) Product Compliance	QMS-QP-00075	QP-1613 Global Product Regulations & Standards Identification, Maintenance, Control & Change Impact Assessment
	QMS-QP-00135	QP-1670 Product Compliance Laboratory Management

17. Functional Organizational Chart



18. 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 & India	customerquestionnaires.emea@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

19. DOCUMENT REVISION HISTORY

Rev	Date yyyy-mm-dd	Author	DCR #	Description of Change
A	Refer to Effective Date	Miranda Hu	DCR-GLB-05057	Initial Release