Life Sciences – Systems Segment
Quality Manual

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1.0 QUALITY POLICY

ATS is committed to 100% total customer satisfaction and compliance with regulatory requirements.

Every ATS employee is committed to meet Customer Requirements (Cost, Schedule and Quality).

By continuously improving the operation, we will contribute to the success of our customers, employees, suppliers and stakeholders. ***(Applicable to 9001 sites only)***

By continuously improving our processes and maintaining the effectiveness of the quality system, we will contribute to the success of our customers, employees, suppliers, and stakeholders. ***(Applicable to 13485 sites only)***

2.0 CORE VALUES

We believe that observance of the following **values** is fundamental to the success of our business. These **values** will be reflected in our long-term objectives as well as our current year objectives:

Customer Focused
Our future depends on our contributions to our customers' success. We will exceed our customers' expectations, deliver on our commitments, and treat our customers with professionalism, courtesy and respect.

Profitability is Essential
Long term viability of ATS can only be achieved if adequate profits are generated on a regular basis to make investments for the future in employee training, product development and facilities. This will provide our customers, employees, suppliers and shareholders with security and stability.

A Dedication to High Quality
This must be inherent in all aspects of our operations, products, and services, and reflected in the way we function as an operation. Every employee is responsible for meeting or exceeding the expectations of those who depend upon him/her.

Fostering Innovation Through Controlled Risk
We must continue the entrepreneurial spirit and innovative use of technology that made ATS a leader in its markets. Risk taking will be controlled and undertaken with the understanding that not all innovations are successful.

Continuous Improvement
We believe that in all aspects of our business it is essential to continuously raise the standards of acceptance and efficiency. The search for excellence must never stop.

Human Resources Are Our Most Valuable Asset
Our foremost competitive edge is the Quality of our people. We will promote a sense of teamwork and unity through effective two-way communication, showing respect for the individual along with just and fair management practices.

Be A Good Corporate Citizen
We will be a good corporate citizen. We will take pride in the appearance of our properties, show respect for the environment, and conduct our business in a socially responsible manner. We will join with our employees in supporting the communities where we are located.

Ethical Business Practices Will Not Be Compromised
We will apply the "Golden Rule" and treat others as we wish to be treated. This applies to relationships with customers, suppliers as well as our fellow employees.

3.0 ORGANIZATION AND AUTHORITY FOR QUALITY

The ultimate authority within the ATS Life Sciences – Systems (LSS) management structure shall be the the President Life Sciences - Systems. The management of the Life Sciences - Systems Quality System has been assigned to the Quality Director (North America) and Life Sciences Quality Leader (Europe), collectively called LS Quality Leaders, for the purpose of the LSS BQMS documents. Both are appointed as the Segment Quality Management Representatives. These responsibilities include:

- Responsible for monitoring and reporting the LSS divisions quality system health status to the LSS Management
- The task of overseeing that actions have been taken to achieve planned results and oversight to monitor on going effectiveness of the LSS Segment QMS
- The promotion of awareness of customer requirements throughout the organization and for liaison with external parties on matters relating to the business management system
- Initiate, recommend or provide solutions to quality problems in accordance with the Quality Manual
- Authority to stop an operation, test or shipment in order to verify that all Quality and contract requirements have been achieved
- Notify LSS Management when a stop work order has been issued
- Ensuring that business operating procedures, to implement the requirements of the ISO 9001 and if applicable, ISO 13485 programs, are developed and maintained
- Manage the LSS Segment quality certification account and coordinate contract activities
- Collaboration with individual sites for any proposed BQMS changes

4.0 QUALITY MANAGEMENT SYSTEM SCOPE

The LSS business management system conforms to ISO 9001:2015. The LSS Segment Quality Management system scope is:

Region	Site Information	Business Scope
CANADA	ATS Corporation, Building 2 & 3 730 Fountain Street North Cambridge, ON. N3H 4R7	Design, manufacture, commission and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment.
USA	ATS Life Sciences Chicago 5655 Meadowbrook Industrial Court. Rolling Meadows, IL 60008	Design, manufacture, commission and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment.
GERMANY	ATS Automation Tooling Systems GmbH, Marsstrasse 2 D-85551 Heimstetten, Germany	Design, manufacture, commission and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment.
GERMANY	ATS Automation Tooling Systems GmbH, Am Tannwald 2, St. Georgen, Germany 78112	Design, manufacture, commission and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment.

Specific sites conform to ISO 13485:2016. The Quality Management system scope for this site is as follows:

Region	Site Information	Business Scope
CANADA	ATS Corporation, Building 2 & 3, 730 Fountain Street North, Cambridge, ON. N3H 4R7	Contract design and manufacture of active inoculation diagnostic instruments, IVD centrifuges, and components for electromechanical and in-vitro diagnostics medical devices.

5.0 PERMISIBLE EXCLUSIONS & NON APPLICABLE ITEMS

The LSS management system scope conforms to the requirements of ISO 9001:2015 & ISO 13485:2016 with the following permissible exclusions and non-applicable items:

5.1 CANADA – CAMBRIDGE: BUILDING #2 & 3

NON-APPLICABLE ITEMS, ISO 13485:2016(E)

The following sections of the ISO 13485:2016 standard are not applicable to the scope of registration:

- Clause 6.4.2……..Contamination Control (sterile medical device requirement only)
- Clause 7.3 ……Design
- Clause 7.5.2……..Cleanliness of Product
- Clause 7.5.3……..Installation Activities
- Clause 7.5.4……..Service Activities
- Clause 7.5.5……..Particular Requirements for Sterile Medical Devices
- Clause 7.5.7……..Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2…...Particular Requirements for Implantable Medical Devices
- Clause 7.5.11……Preservation of Product
- Clause 8.2.3……..Regulatory Reporting

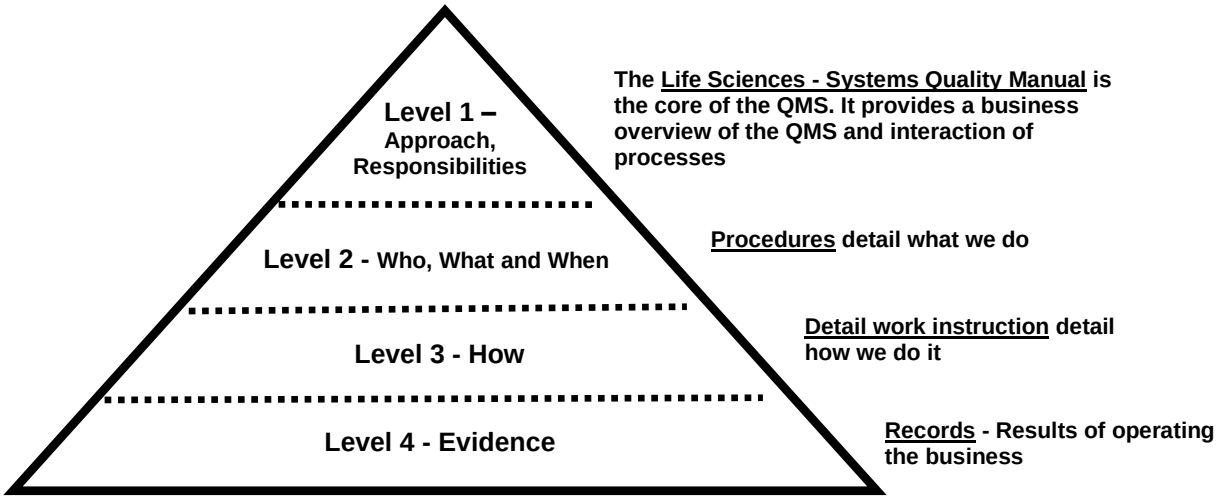
Justification for exclusion of specified sections: ATS Cambridge Building #2 & 3 is a contract medical device manufacturer and not the legal manufacturer. Regulatory reporting is done by the legal manufacturer, however, ATS will support this effort as required. ATS does not have any customer or regulatory obligations to support cleanliness of product, installation or service requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices. As a result, clauses 6.4.2, 7.3, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2, 7.5.11 and 8.2.3 under the ISO 13485 standard are not applicable.

5.2 CANADIAN GOVERNING REGULATIONS (as required by contract)

The Canadian Medical Device Regulations – SOR/98-282, FDA GMP 21 CFR part 820 regulations govern the components and assemblies produced by Building (2 / 3) for the medical device industry where applicable. Audits will be conducted in accordance with the ISO13485 Standard. The following reference document is utilized for guidance: MDSAP (Medical Device Single Audit Program).

6.0 LSS BUSINESS AND QUALITY MANAGEMENT SYSTEM STRUCTURE

6.1 QMS STRUCTURE

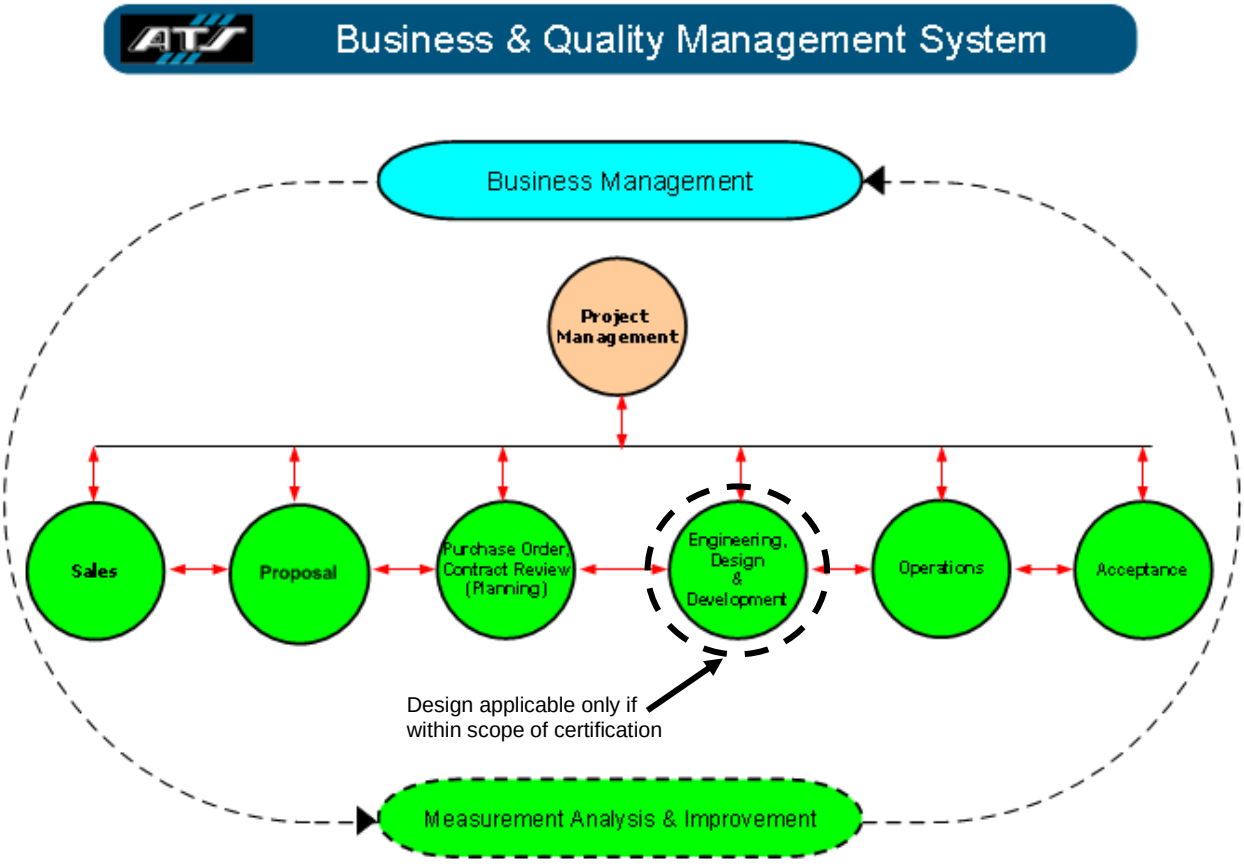


The organization's quality system supports its policy and objectives and is focused on delivering products and services that enhance customer satisfaction.

The sites identified processes are operated under controlled conditions and are monitored, measured and analyzed to ensure ongoing effectiveness and efficiency. The effectiveness of the implemented system is determined by (not limited to): achieving objectives, customer satisfaction and continual improvement. Sites' Quality scorecards shall be submitted monthly to the LS Quality Leaders.

LSS Quality communications and updates shall be the responsibility of the LS Quality Leaders. Communications specific to the sites shall be managed by the General Manager / Site Leader as defined by internal requirements.

As a general overview of the interaction of processes see diagram below.
All site specific relationships between ISO 9001/ ISO 13485 (applicable to 13485 sites only) shall be maintained by each respective site to supplement this manual.



LS Segment procedures shall be implemented and enforced by each site. Key Quality objectives will be reported to the LS Quality Leaders on monthly intervals and monitored for performance. Reporting to LS Segment Divisional Management according to C8.5.1-2P.

The LS Quality Leaders reserve the right to audit any LS site as required or deemed necessary by the LS Segment Management.

6.2 DOCUMENTATION REQUIREMENTS

The Quality System documentation includes:

- This Life Sciences – Systems Segment Quality Manual
- A Quality Policy Statement
- Quality Objective planning

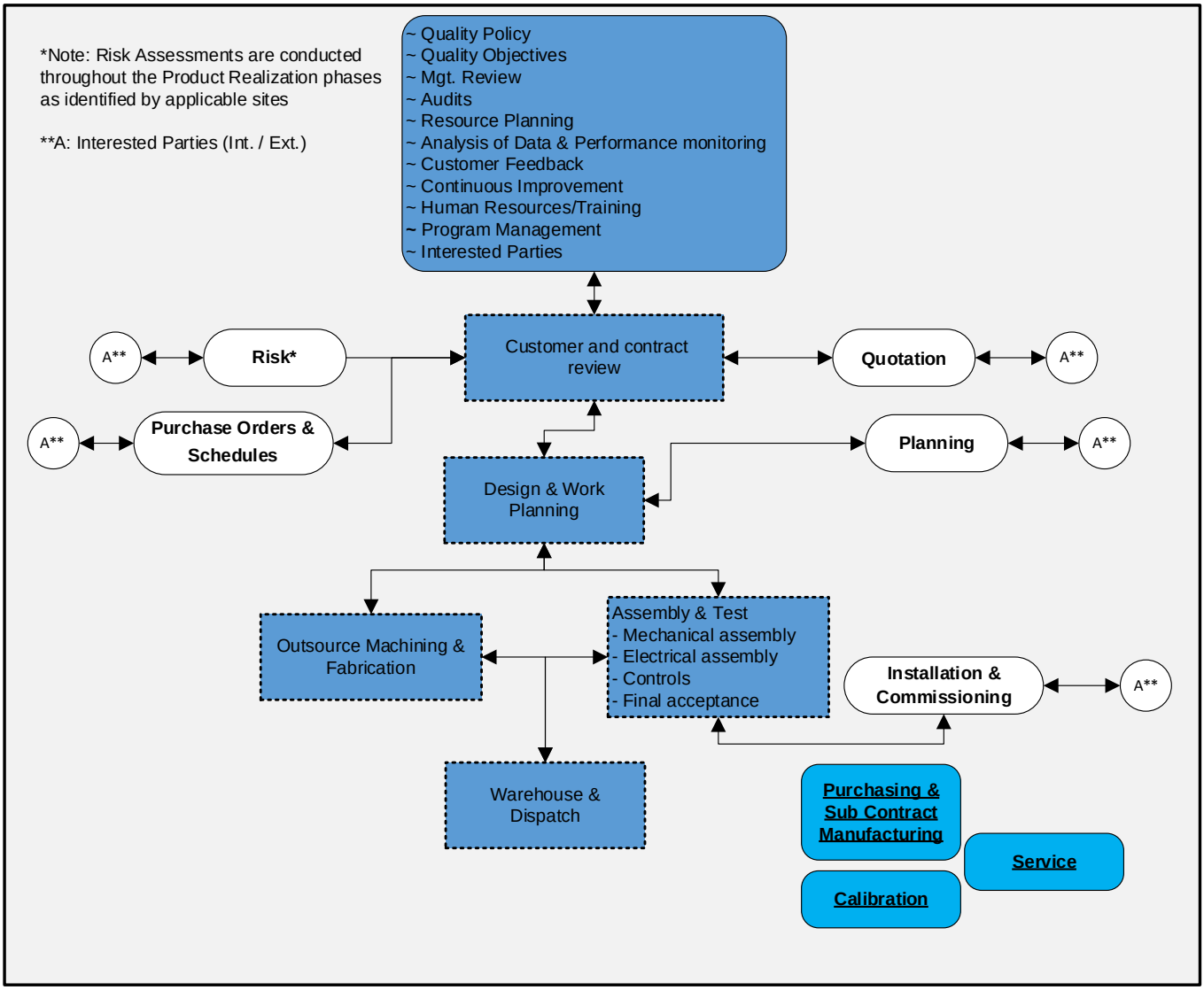
Documents needed by the organization to ensure the effective planning, operation and control of its processes (defined by each site), including work instructions, forms, and records as applicable

8.2.3 Sites which maintain an ISO 13485 certification must have documented information as per the requirements of ISO 13485:2016.

8.2.4 Sites which maintain an ISO 9001 certification must have documented information as per the requirements of the ISO 9001:2015 and shall maintain documented procedures and associated templates for the following processes at minimum:

- Design & Development, Design Verification, Design Review, Design Revisions and Change Control (refer to ISO 9001:2015, section 8.3, Design & Development of Products and Services)
- Assembly, Machining (refer to ISO 9001:2015, section 8.5, Production and Service Provisions, section 8.6 Release of Product and Services)
- Identification & Traceability, Storage, Preservation (refer to ISO 9001:2015, section 8.5.2, Identification and Traceability, 8.5.4. Preservation)
- Purchasing, Verification of Purchased items (refer to ISO 9001:2015, section 8.4, Control of Externally Provided Processes, Products and Services)
- Control of Nonconforming Product (disposition authorities) (refer to ISO 9001:2015, section 8.7, Control of Nonconforming Outputs)
- Service Processes (refer to ISO 9001:2015, section 8.5, Production and Service Provisions)
- Training Requirements, Competence, Roles, Responsibilities and Authority
- (refer to ISO 9001:2015, section 7.1.6, Organizational Knowledge, 7.2, Competence, 7.3 Awareness)
- Calibration Requirements (refer to ISO 9001:2015, section 7.1.5.2, Measurement Traceability
- Program Management (refer to ISO 9001:2015, section 8.1, Operational Planning and Control)
- Preventative Maintenance of equipment/building (refer to ISO 9001:2015, section 7.1.3, Infrastructure - documented process is required)

7.0 PROCESS INTERACTIONS OVERVIEW (Reference scope for applicable items per site)



8.0 DOCUMENT MATRIX FOR KEY SEGMENT DOCUMENTATION

The relationship between the organizations's documented procedures and the requirements of ISO 9001:2015 & ISO 13485:2016 are described below.

Document Ref No.	LS Segment Quality Management Procedures	Standard Cross Reference	Standard Cross Reference
		ISO 9001	ISO 13485
C4.3-1M	**Life Sciences – Systems Segment Quality Manual**	**ATS Requirement**	**4.2.2**
C7.4.1-1M	**Global Supplier Quality Manual** Note: Owned and maintained by Corp. Supply Chain Management	**8.4.1, 8.4.2**	**7.4.1, 7.4.2**
C4.2.3	**Global Document Management**	**7.5**	**4.2.4**
C4.2.4	**Global Record Control Requirements**	**4.2.4**	**4.2.5**
C5.6	**Global Management Review Process**	**9.3**	**5.6**
C7.4.1	**Global Supplier Performance System** Note: Owned and maintained by Corp. Supply Chain Management	**8.4, 9.1.3, 10.0**	**7.4, 8.4, 8.5.2, 8.5.3**
C7.4.1-2P	**Global Supplier Development & Evaluation** Note: Owned and maintained by Corp. Supply Chain Management	**8.4.1**	**7.4.1**
C8.2.2	**Global Quality Management System Program**	**9.2**	**8.4**
C8.3	**Global Control of Nonconforming Product**	**8.7**	**8.3**
C8.5.1 C8.5.1-2P	**Global Continual Improvement Process Global KPI Requirements**	**9.1.1, 9.1.2, 10.1, 10.2, 10.3**	**8.5.2, 8.5.3, 8.5.1, 8.2.1, 8.4**
C6.1-1P	**ATS Risk Management Process**	**6.1, 4.4.1**	**4.1.2, 7.1**
C4.2.1-1P	**Organizational Context & Interested Parties**	**4.1, 4.2**	**NA**