True Indicating Quality Manual

ISO 13485:2016
21 CFR 820

Introduction

True Indicating, LLC has developed and implemented a Quality Management System (QMS), which utilizes 21 CFR 820 and ISO 13485:2016, as a framework to support best practices, to satisfy and exceed the requirements and expectations of our Clients and ensure the overall quality management of the company. True Indicating, LLC's leadership is sustained by a commitment to core values. These are to produce high quality products from top grade, environmentally friendly materials; employ highly qualified personnel; continuously evaluate and implement needed increases in capacity; remain flexible to meet and exceed Client expectations; and maintain a safe and efficient facility**.**

True Indicating's commitment to flexibility includes recognizing and embracing industry advancements, while respecting tradition and regulatory compliance. True Indicating responds to Client requests by adapting configurations and product options to meet the requirements of the industry for highest quality, consistent performance and pinnacle levels of service. The result is an experience which exceeds expectations.

Section 1: Purpose

The purpose of this quality manual is to establish and state the general policies governing the QMS. The QMS of True Indicating meets the requirements of the international standard ISO 13485:2016 and U.S. QSR 21 CFR 820. The manual is divided into eight sections that correlate to the referenced standards. Each section expresses True Indicating's obligation to implement the requirements of the OMS section. This manual delineates authorities, interrelationships and responsibilities of the personnel performing within the system. The manual also provides procedures or references for all activities comprising the QMS to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's associates through the various requirements of the ISO standard that must be met and maintained in order to ensure Client satisfaction, continuous improvement and provide the necessary instructions that create an empowered workforce.

This manual is used externally to introduce our QMS to our Clients and other external organizations or individuals. The manual is used to familiarize individuals with the controls that have been implemented and to ensure that the integrity of the QMS is maintained and focused on Client satisfaction and continuous improvement.

Section 2: Scope

The policies stated in this manual apply to all operations and activities at True Indicating.
The scope of activities under ISO 13485:2016 include the design and development, production, storage and distribution of medical devices, specifically sterilization and disinfection monitoring products for the medical and industrial markets.

The scope of activities under 21 CFR 820 include the methods used for the design, manufacture, packaging, labeling, and storage of medical devices for use in humans; including sterilization and disinfection monitoring products for the medical and industrial markets.

It is the responsibility of all management to help define, implement and maintain the procedures required by this manual and to ensure all processes conform to these requirements. It is the responsibility of all employees to follow procedures that implement these policies.

2.1 Exclusions

2.1.1 Due to the nature of the products/devices offered by True Indicating, installation and servicing are not required. As such, the Medical device file (4.2.3.e and 4.2.3.f) or Device Master Record will not refer to these elements.

2.1.2 Due to the nature of the devices/products offered by True Indicating, control of health information (4.2.5) is not required. Health information is not gathered nor contained within True Indicating records as it not applicable related to the sterilization and disinfection monitoring products offered.

2.1.3 While True Indicating provides Instructions For Use and Technical Data Sheets are available for all products, user training (7.2.1.d) is not offered as part of routine determination of requirements related to product. Hence, review of requirements related to product training (7.2.2.d) are not planned on a routine basis.

2.1.4 Design and Development outputs specific to service provisions (7.3.4b) are not incorporated into True Indicating's processes due to the fact that servicing activities are not performed and not required for the products offered.

2.1.5 For devices manufactured and distributed by True Indicating, clinical evaluations (7.3.7) are not required based on the class of devices, international, national and regional regulations.

2.1.6 While True Indicating's products are manufactured in a manner consistent with efforts to minimize contamination and maintain purity for microbiological based products, the products are not cleaned prior to use or subjected to a cleaning process and process agents are not removed during manufacture. As such, cleanliness of product (7.5.2) is not applicable.

2.1.7 True Indicating does not perform installation activities (7.5.3 and §820.170) or servicing activities (7.5.4 and §820.200) thus these sections are not applicable.

2.1.8 True Indicating does not have particular requirements for sterile medical devices (7.5.5) as the products are not sold sterile.

2.1.9 Particular requirements for implantable medical devices (7.5.9.2) are not applicable to the type or nature of True Indicating's products.

Section 3: General Information

3.1 Company Details

True Indicating, LLC.
946 Kane St, Suite A
Toledo, Ohio 43612

Phone: 419-476-7119
www.trueindicating.com

True Indicating, is a limited liability corporation registered in the state of Ohio. The organization is not debarred, suspended, or otherwise ineligible for Federal Programs as may be confirmed in General Services Administration's list of Parties Excluded from Federal Procurement or Non-procurement programs. True Indicating complies with all applicable Ohio State and Federal laws, regulations regarding equal employment opportunities, non-segregated facilities as required by The Civil Rights Act of 1964, including its amendments. True Indicating also complies as applicable with the Rehabilitation Act of 1973, Vietnam Era Veteran's Readjustment Act of 1974 and the Americans with Disabilities Act of 1990.

Federal Employer Identification Number: 82-3237697
FDA Registration Number: TBD

3.2 Facility

The True Indicating facility was completely renovated in 2017 offering ~9000 square feet encompassing:

- Product Development
- Research and Development
- Manufacturing
- Quality
- Warehouse
- Sales, Marketing, Customer Service
- Finance
- Offices, Common area, Kitchen

Additional space is available for expansion and adjacent space allows for access to flexographic, silk screen and digital printing presses.

3.3 Product Development and Research and Development

The Product Development and Research and Development departments support external and internal Clients with timely response and innovative approaches to product line extensions and new product development.

The lab and production areas contain a variety of equipment including steam resistometer, autoclaves and ovens, and printing presses which allow for product development of custom Biological Indicators and Chemical Indicators, Integrators and Emulators. Access to the presses allow for generation of Private Labeled products in an efficient manner minimizing cost and lead times.

3.4 Capacity

Current hours of operation are Monday through Friday 8:30 am to 5:00 pm.

The manufacturing operation has the capacity to operate 24 hours a day, 7 days a week as needed.

The additional available square footage allows for expansion of operations through equipment and technological advances as well as for the addition of staff members, as needed.

3.5 Environmental and Chemical Issues

True Indicating considers the environment, health and handling hazards of every component utilized in our products; and, by design have minimized the potential impact of possible toxic compounds in raw materials and our final products.

None of True Indicating's raw materials contain, nor are derived from, any of the following materials:

- Materials listed under California Proposition 65
- Melamine
- Bisphenol A
- Triclosan
- Fluorocarbons
- Polychlorinated Biphenyls (PCBs)
- Jatropha plant derivatives
- Phthlates
- PVC, PVDC or elemental chlorine
- Lead (Pb), Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE)
- Genetically Modified Organisms (GMO)
- Materials of animal origin including Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).
- Latex

Our products conform to:

- REACH Directive 1907/2006/EEC, as substances restricted under Annex XVII of REACH as well as materials on the "substances of very high concern" (SVHC) list and at concentrations of greater than 0.1%, are not utilized.
- Decision 2009/251/CE as Dimethyl fumarate (DMF) is not utilized.
- EC Packaging and Packaging Waste Directives, 94/62/EC and subsequent amendments, as heavy metals at sum concentrations over 100 ppm are not utilized.
- RoHS 2011/65/EU.

Further information can be found on the Safety Data Sheet (SDS) or the Safety Information Sheet (SIS) for all products.

Section 4 (§820.5): Quality Management System

4.1 General Requirements

True Indicating, as a manufacturer, has established, documented, implemented and maintained a QMS in accordance with the requirements of ISO 13485:2016 and 21 CFR 820. The effectiveness of the QMS is maintained and the system continuously improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS True Indicating has:

- Identified the processes needed for the QMS and their application within the organization and documented them in Process Flow Diagrams, Standard Operating Procedures (SOPs) and other associated documents referenced throughout this Quality Manual.
- Applied a risk based approach to control processes needed for the QMS.
- Determined the sequence and interaction of these processes, and illustrated them in the Process Flow Diagrams and procedures as referenced throughout this Quality Manual.
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented in work instructions and specifications as referenced throughout this Quality Manual.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continuous improvement of these processes.
- Implemented actions necessary to achieve planned results and maintain the effectiveness of these processes.
- Established systems to monitor, measure and analyze these processes.
- Established and maintained records needed to demonstrate conformance to ISO 13485:2016 and 21 CFR 820.

Where changes are made, these processes are evaluated for their impact on the QMS, and the medical devices produced under our QMS.

Where any process which affect product conformity has been outsourced, True Indicating has ensured control over such processes and established Supplier Quality Agreement__1-11-2-D3.

True Indicating has documented procedures for the validation of the application of computer software used in the QMS. Validation occurs prior to initial use and where deemed necessary after changes to such software or its application per Software Validation__1-4-9.

4.2 (§820.20(e)) Documentation Requirements

4.2.1 General

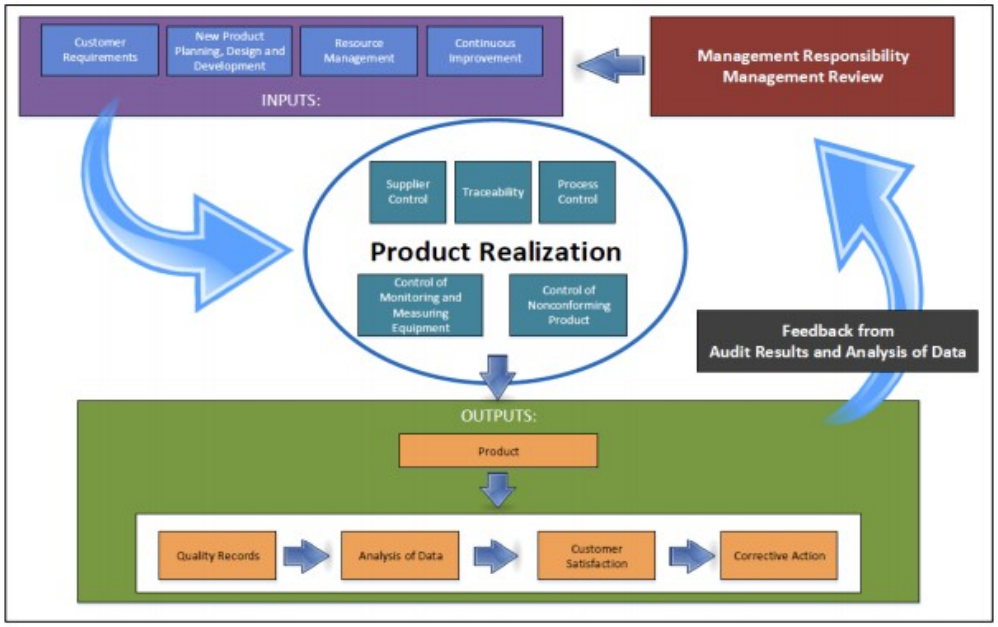
The QMS documentation includes:

- A documented Quality Policy
- Quality Objectives
- Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes
- Quality Records
- Other documentation specified by national and regional regulations.
- Each procedure, activity or special arrangement that has been documented is also implemented and maintained.

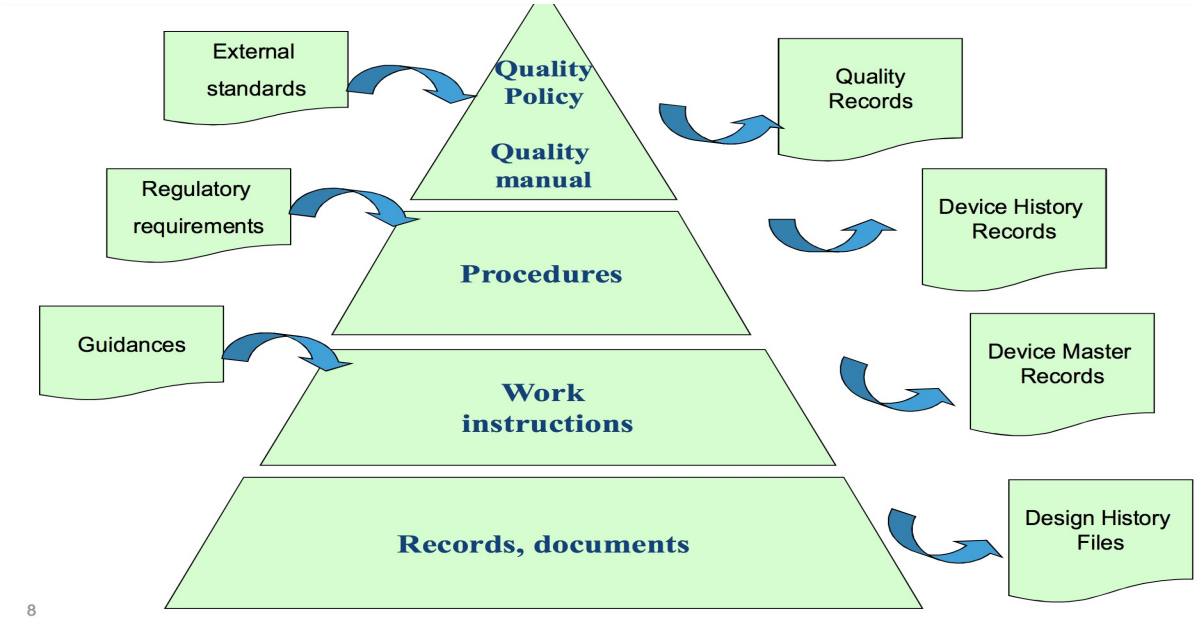
4.2.2 Quality Manual

The Quality Manual is maintained and includes reference to the following:

a) The scope and permissible exclusions (Section 2)
b) The documented procedures
c) The interaction between the processes of the QMS



d) The structure of documentation used in the QMS



4.2.3 (§820.181) Medical Device File

For each device/product type or family, True Indicating has established and maintains a file, referred to as a Device Master Record__1-3-12, which references documents generated to demonstrate conformity to the requirements of ISO 13485 and 21 CFR 820.

The Device Master Record contains reference to:

- General description, intended use/purpose, labeling, Instructions for Use
- Specifications (Labels, Manufacturing, Finished Goods/Product including packaging, storage, handling and distribution)
- Procedures related to measuring and monitoring

4.2.4 (§820.40) Control of Documents

All of the QMS documents are controlled according to the Document Control procedures contained in Document Control__1-16 and supplemented by Control of Records Standard Operating Procedure 1-16-1-SOP1. These procedures define the processes for:

a) Review and approval of documents for adequacy prior to issuance, by a designated individual(s). Approval includes date and signature (electronic) of the individual approving the document (Document Approval 1-16-9).

b) Reviewing, updating as necessary and re-approving documents; approved changes are communicated in a timely manner. Records of the changes including a description of the change, identification of the affected documents, the signature (electronic) of the approving individual(s), the approval date and when the change becomes effective per Document Revisions 1-16-10.

c) Ensuring that the current revision status of and changes to documents are identified per Document Revisions 1-16-10.

d) Ensuring that documents remain legible and readily available at all locations for which they are designated, used or otherwise necessary.

e) Ensuring that documents of external origin, determined by the organization to be necessary for planning and operation of the QMS, are identified and distribution is controlled per Control of External Documents__1-16-2.

f) Preventing deterioration and loss of documents per Electronic Restoration and Backup 1-16-7.

g) Preventing the unintended use of obsolete documents and applying suitable identification to them per Document Obsoletion 1-16-29.

h) Ensuring review and approval is performed by either the original approving function or another designated function that has access to pertinent background information upon which to base a decision

i) Defining the retention period for obsolete controlled documents, specific to the lifetime of the medical devices per Retention and Disposition of Records 1-16-4.

4.2.5 (§820.180) Control of Records

True Indicating maintains records to provide evidence of conformity to requirements and the effective operation of the QMS Per Document Control 1-16 supplemented by the Control of Records Standard Operating Procedure 1-16-1-SOP1. The procedures entitled Identification of Records__1-16-3, Retention and Disposition of Records__1-16-4, Control of Records__1-16-1 and Assess and Storage of Quality System Records__1-11-9 define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

Records are retained in Aboutthree software system, thus are identifiable and retrievable. Changes are identifiable.

Records are maintained for at least the lifetime of the medical device, and not less than two years from the product release date.

Section 5 (§820.20): Management Responsibility

5.1 Management Commitment

Top management has been actively involved in implementing the QMS. It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

Management Responsibility 1-7, and all documents contained within the module are established and maintained. Management Review Meetings are held on a routine basis with implementation plans resulting.

Top management provides evidence of its commitment to the development and implementation of the QMS and maintaining its effectiveness by:

- Communicating the importance of meeting Client, statutory, and regulatory requirements.
- Establishing quality objectives.
- Establishing quality policy.
- Conducting management reviews.
- Ensuring the availability of resources and adequate organizational structure.

Management with executive responsibility are focused on meeting those requirements that have as their objective the design, manufacture, distribution and support of safe and effective medical devices. During the product realization process, requirements that are focused on ensuring safe and effective devices are identified.

5.2 Customer Focus

True Indicating's top management ensures that current and future customer requirements and regulatory requirements are determined and are met.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures, Client Communication__1-1-4. Customer requirements are determined, converted into internal requirements, and communicated to appropriate people in our organization.

5.3 (§820.20a) Quality Policy

Top management ensures that the quality policy includes a commitment to comply with requirements and to maintain the effectiveness of the QMS. The Quality Policy is communicated to all employees. It is included in new employee training and is posted in True Indicating's facility.

True Indicating Quality Policy and Objectives

True Indicating strives to conduct its business with a total commitment to our Clients and their requirements. We define quality as conformance to our Client's needs, both internal and external; and conformance to all quality requirements. We are committed to comply with requirements and to maintain effectiveness of our Quality Management System through the following principles and behaviors:

- Commitment to thoroughly understand the needs of our Clients in order to build mutually beneficial relationships ensuring long-term success
- Honor our commitments for quality, cost and timeliness
- Standardize and document best practices through lessons learned, at all levels, to predict future results and manage risk
- Drive continuous improvement and innovation based on efficient business processes, well-defined measurements and Client feedback
- Commitment to develop staff competencies through empowerment, appropriate training and accountability.

True Indicating is committed to providing the highest level of quality, value and service experience to every Client, every time.

Quality objectives are established, communicated, implemented, and reviewed throughout the organization to ensure objectives our clearly understood and performed.

Quality Objectives include:

- Meet or exceed our customer's delivery expectation 95% or more of the time.
- Maintain an internal rejection rate of less than 1%.
- Maintain compliance with statutory and regulatory requirements. This objective is measured by zero actions that lead to violations or findings from regulatory inspections.
- To obtain and maintain ISO 13485 certification. The objective is measured by no major non-conformance findings on surveillance audits.

The Quality Policy is reviewed by Management during Management Review Meetings to ensure continued suitability for our organization, and its relevance to the quality objectives.

5.4 (§820.20d) Planning

5.4.1 Quality Objectives

Quality objectives are established, including those needed to meet regulatory requirements and the requirements for product at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy; they are reviewed against performance goals during periodic management reviews.

A quality plan that defines the quality practices, resources and activities relevant to products has been established. The plan includes how the requirements for quality will be met per Quality Planning__1-7-3.

5.4.2 Quality Management System Planning

The quality system has been planned and implemented to meet the general requirements outlined above as well as the quality objectives set forth for the organization. Quality planning takes place as changes that affect the quality system are planned and implemented, hence the integrity of the QMS is maintained.

5.5 Responsibility, Authority and Communication

5.5.1 (§820.20b1) Responsibility and Authority

An organizational structure has been established to show the interrelation of personal in the organization. Job Descriptions__1-1-2 define the responsibilities and authorities of each position. Job descriptions and the organizational structure are reviewed and approved by top management for adequacy.

These documents are available to Associates to help them understand responsibilities and authorities. Top management ensures that the personnel who manage, perform and assess work affecting quality have sufficient independence and authority necessary to perform these tasks. The most current organization structure is available in the Aboutthree document system.

5.5.2 (820.20b3) Management Representative

A member of management is assigned the role of Management Representative and regardless of other responsibilities, has the responsibility and authority to ensure that processes needed for the QMS are documented, the effectiveness of the QMS and any need for improvement is reported to top management, and ensuring the promotion of awareness of regulatory and QMS requirements throughout the organization. This responsibility is outlined on the Management Representative Job Description 1-1-2-1-JD7.

5.5.3 Internal Communication

Appropriate processes are established to ensure communication regarding the effectiveness of the QMS takes place. Processes related to communication of effectiveness may occur related to individual parts of the QMS, such as a design review meeting (DRM 1__1-3-3, DRM 2__1-3-4 or DRM 3__1-3-11), email, signage in the building and all company meetings held periodically deemed necessary or in whole at a Management Review Process__1-7-2.

5.6 (§820.20c) Management Review

5.6.1 General

Top management reviews the QMS at management review meetings held at least twice annually. This review assesses the continuing QMS suitability, adequacy and effectiveness and identifies opportunities for improvement and needed changes. Records for each management review meeting are maintained.

5.6.2 Review input

Assessment of the QMS is based on review of information inputs to management review. These inputs include the following:

a) Client feedback
b) Complaint handling
c) Reporting to regulatory authorities
d) Audits
e) Monitoring and measurement of processes
f) Monitoring and measurement of product
g) Corrective Action
h) Preventive Action

i) Follow up action from previous management reviews
j) Changes that could affect the QMS
k) Recommendations for improvement
l) Applicable new or revised regulatory requirements

5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the input items reviewed and any decisions related to:
a) Improvement needed to maintain suitability, adequacy and effectiveness of the QMS and its processes
b) Improvement of product related to Client requirements
c) Changes needed to respond to applicable new or revised regulatory requirements
d) Resource needs

Section 6: Resource Management

6.1 Provision of Resources

During planning and budgeting processes and as needed throughout the year, Top management will determine and ensure the appropriate resources are available to implement and maintain the QMS, and continuously improve its effectiveness and enhance customer satisfaction by meeting regulatory and customer requirements.

6.2 (§820.25) Human Resources

Qualifications for personnel are defined in job descriptions, which include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

Training is provided to achieve and maintain competence. Training may be accomplished through reading procedures, on-the-job training or certification or through off-site training programs. Training includes ensuring personnel are aware of device defects which may occur from the improper performance of their specific jobs.

Upon hire, when an employee changes positions or the requirements of a position change, qualifications are reviewed. If differences are identified between the requirements and employee's qualifications, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if the actions taken were effective.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Records related to education, training, skills and experience are maintained.

6.3 Infrastructure

True Indicating's top management provides the infrastructure necessary to achieve conformity to product requirements. During the budgeting and strategic planning processes, building, equipment, workspace, and associated utilities are evaluated and provided. When new personnel are added, hiring managers coordinate activities to ensure appropriate process equipment including hardware and software, if required, and supporting services such as telephones, laptops, etc. are available. Requirements for maintenance activities, and their frequency, are documented and maintained, if product quality could be affected.

6.4 Work Environment

6.4.1 Work Environment

A safe work environment suitable for achieving product conformance is maintained. Procedures have been established to document the requirements for the work environment where it can have an adverse effect on product quality. These procedures include requirements for health, cleanliness, and gowning practices of personnel in contact with the product work environment where the quality could be impacted.

True Indicating ensures personnel who are required to work temporarily under special environmental conditions within the work environment are either trained or supervised by a trained person.

6.4.2 (820.70e) Contamination Control

In order to prevent contamination of other product or the work environment, special arrangement to control contaminated or potentially contaminated product is a documented process.

Section 7: Product Realization

7.1 Planning of Product Realization

True Indicating has established procedures for the planning and development needed for product realization. Included in the product realization process is, Risk Management__1-3-6, as well as:

a) Quality objectives and requirements for the product are developed during the Design Control – Idea Phase__1-3-1.
b) Establishment of processes, documentation and resources specific to the product, including infrastructure and work environment
c) Verification, validation, monitoring, inspection and test requirements
d) Criteria for product acceptance
e) Necessary records to provide evidence that the realization process and resulting product meet requirements

The output of quality planning includes documented quality plans, resource requirements, processes, equipment requirements, procedures, test data and design outputs.

7.2 Customer-Related Processes

7.2.1 (§820.160) Determination of requirements related to the product

Customer requirements are determined according to the Review of Order Requirements__1-2-2
Before acceptance of an order, customer requirements are determined including the following:

a) Previous customer requirements which pertain to the current part number being ordered,
b) Requirements for delivery and post-delivery activities
c) Requirements not stated by the customer but necessary for specified or intended use, as known
d) Regulatory requirements related to the product
e) Additional requirements determined by True Indicating

7.2.2 Review of requirements related to the product

True Indicating has a process in place for review of requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

a) Product requirements are defined and documented
b) Contract or order requirements differing from those previously expressed are resolved
c) Applicable regulatory requirements
d) True Indicating has the ability to meet the defined requirements

7.2.3 Communication

In keeping with our commitment to customer satisfaction, True Indicating views effective customer communication as an essential element of customer satisfaction. Appropriate handling of communications can reduce customer dissatisfaction in situations and in many cases, turn a dissatisfying scenario into a satisfying experience.

True Indicating has implemented processes for communicating with customers including:

a) Marketing, Sales and Customer Service handle external communications and are the primary contacts for product information
b) Sales and Customer Service are responsible for ensuring customer inquiries, contracts and order handling including amendments are managed expeditiously and professionally. Sales and Customer Service also receive customer feedback, including complaints. All complaints are processed per Product Complaints__1-11-6 or Service Complaints__1-11-10.
c) Quality Assurance is involved in handling of all complaints.
d) Regulatory Assurance and Marketing are responsible for issuing advisory notices as necessary.

7.3 (§820.30) Design and Development

7.3.1 (§820.30a) General

Tue Indicating has established procedures for design and development; procedures are a part of Design Controls__1-3.

7.3.2 (§820.30b) Design and Development Planning

True Indicating utilizes the Design and Development Plan__1-3-2-D3 form to plan and control the design and development of product. The plan is maintained and updated as the design and development process progresses.

The Design and Development Plan captures:

a) The design and development phases and stages, which are outlined below
- Idea Phase
- Input and Feasibility Phase
- Design Input Review Stage
- Design Verification
- Design Validation
- Design Outputs
- Design Output Review Stage which ensures the design outputs meet the design inputs
- Design transfer

- Design Records
- Design Transfer Review Stage
- Design Change

b) Design Review Meetings are conducted at the three stages identified above
c) The responsibilities and authorities for the design and development
d) Resources needed including training of personnel

7.3.3 (§820.30c) Design and Development Inputs

Inputs relating to the product requirements are determined, documented, reviewed for ambiguity and ability for verification or validation and to ensure no conflict with each other and approved per Design Input and Feasiblity__1-3-2.

Inputs include:
a) Functional, performance, usability and safety requirements, according to the intended use
b) Regulatory requirements
c) Outputs of Risk Management__1-3-6
d) Information derived from previous similar designs
e) Other requirements essential for design and development of the product and processes.

7.3.4 (§820.30d) Design and Development outputs

Outputs of concepts and/or detailed designs and development activities are documented according to Design Output__1-3-8. The outputs are documented in a manner which allows for verification against the inputs and are approved prior to release. The Design Outputs are documented on Design Output Document__1-3-8-D1 which is retained per the Design History File__1-3-9 procedure.

Outputs:
a) Meet the input requirements
b) Provide appropriate information for purchasing and production
c) Contain or reference product acceptance criteria
d) Specify the characteristics of the product that are essential for safe and proper use

7.3.5 (§820.30e) Design and Development Review

At suitable stages, systematic review of design and development is performed in accordance with planned activities:

- To evaluate the ability of the results of design and development to meet requirements, and
- To identify any problems and propose necessary action
- Include representatives of functions concerned with the design and development stage being reviewed as well as other specialist personnel.

True Indicating has Design Review Meetings intended to meet the requirements outlined above. Work flows, DRM 1__1-3-3, DRM 2__1-3-4 and DRM 3__1-3-11, are performed at suitable stages to provide systematic review of design and development. Meeting minutes, DRM Minutes__1-3-3-D1, capture the evaluation of results, verification of met requirements, identification of any problems and necessary actions. The results of the design review ensure that the medical device design is correctly translated and transferred into production specifications per QSR 820.30.h.

Completion of design review meetings are documented in the Design and Development Plan__1-3-2-D3, and meeting minutes are retained in the Design History File__1-3-9 per §820.30e.

7.3.6 (§820.30f) Design and Development Verification

Design verification is planned and performed to ensure that the design outputs have satisfied the design and development input requirements. This stage of review occurs with Design Review Meeting 2, per DRM 2__1-3-4.

Completion of design review meetings are documented in the Design and Development Plan__1-3-2-D3, and meeting minutes are retained in the Design History File__1-3-9 per §820.30f.

7.3.7 (§820.30g) Design and Development Validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified application or intended use.

True Indicating performs validation per Design Verification and Validation__1-3-5 in accordance with the Design and Development Plan__1-3-2-D3. Validation Protocols include the methods, acceptance criteria, and as appropriate statistical techniques with rationale for sample size.

Whenever possible, the validation is conducted on representative product. The rationale for the choice of product used for the validation is recorded.

If the intended use requires that the device/product be connected to, or have an interface with, other medical devices/product, validation includes confirmation that the requirement for the specified application or intended use have been met when connected or interfaced.

7.3.8 (820.30h) Design and Development Transfer

True Indicating documents the transfer of design and development outputs to manufacturing per Technology Transfer__1-3-10. Procedures ensure than the outputs verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Confirmation of transfer is documented as part of Design Review Meeting 3, DRM 3__1-3-11.

7.3.9 (820.30i) Control of Design and Development Changes

Design and Development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent pasts and product already delivered.

True Indicating records the results of the review of changes and necessary actions in Design Change Plan__1-3-13-D1 per Design Changes__1-3-13.

7.3.10 (§820.30j) Design and Development Files

True Indicating maintains a design and development file for each product type or family per Design History File__1-3-9. The DHF contains reference to records generated to demonstrate

conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 (§820.50) Purchasing Process

True Indicating has established procedures, Purchasing Process__1-10, to ensure that purchases materials conform to specified purchase requirements.

Suppliers are evaluated and selected based on their ability to supply product in accordance with True Indicating's requirements and on the effect of the purchased product on the quality of the medical device as outlined in Supplier Evaluation Requirements__1-11-2-D1. Record of the results of evaluations are captured and any necessary actions arising from the evaluations are maintained per Supplier Assessment and Qualification Process__1-11-2.

Suppliers are re-evaluated per Supplier Maintenance__1-11-12; Suppliers ability to meet requirements is monitored during management review meetings and are considered during the evaluation process.

Non-fulfillment of purchasing requirements is addressed per Supplier Corrective Action Request__1-11-4 proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Supplier files are established and results from evaluations, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities are maintained in said file.

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:
a) Product Specifications
b) Requirements for product acceptance, procedures, processes and equipment
c) Requirements for qualification of supplier personnel, and
d) QMS requirements

True Indicating uses purchase orders (PO's) to describe the product or services to be purchased. PO's are created by designated individuals, within the ERP system. In conjunction with PO's, Purchase Specifications__1-10-1, Label Specifications__1-10-7 and Manufacturing Specifications__1-10-6 are established. PO's and specifications are utilized as the control for products which are off-the shelf items. Where products are developed custom for True Indicating or a Supplier is manufacturing a final product, Supplier Quality Agreements are established to aid in ensuring changes in the purchased product prior to implementation are communicated.

Traceability of materials is maintained through the ERP system, PO's and specifications as well as labeling.

7.4.3 (§820.80b) Verification of Purchased Product

True Indicating has established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Verification of purchased product is performed and documented per Acceptance Activities__1-10-2.

When True Indicating becomes aware of any changes to the purchased product, it is determined whether or not the change affects the product realization process or the medical device. This evaluation is may be documented in a document change to the specification (if minimal or no impact is determined) or per Design Change__1-3-13 if the product or device will be affected.

If True Indicating or one of our Clients intends to perform verification at the Supplier's premises, True Indicating would state the intended verification activities and method of product release in the purchasing information.

Record of verification are maintained on the specifications.

7.5 (§820.70) Production

7.5.1 (§820.70a) Control of Production

Production is planned, carried out, monitored and controlled to ensure that product conforms to specification. Production controls include, but are not limited to:

a) Documentation of procedures and methods to control production
b) Qualification of infrastructure
c) Implementation of monitoring and measurement of process parameters and product characteristics
d) Availability and use of monitoring and measuring equipment
e) Implementation of defined operations for labeling and packaging
f) Implementation of product release delivery and post-delivery activities

True Indicating has established and maintains record for each batch that provides traceability and identifies the amount manufactured and amount approved for distribution. Records are verified and approved.

7.5.6 (§820.75) Validation of Processes For Production

Processes for production where the resulting output cannot be or is not verified in subsequent monitoring and measurement and, as a consequence, deficiencies become apparent only after the product is in use are validated.

Validation demonstrates the ability of these processes, including:
a) defined criteria for review and approval of the process
b) equipment qualification and qualification of personnel
c) use of specific methods, procedures and acceptance criteria
d) statistical techniques with rationale for sample sizes
e) requirements for records
f) revalidation, including criteria for revalidation
g) approval of changes to the processes

Validation of the application of computer software used in production occurs per Software Validation__1-4-9. Software validation is conducted prior to the initial use and, as appropriate, after changes to such software or their application. The approach in validation and revalidation are proportionate to the risk associated with use of the software, including the effect on the ability of the product to conform to specifications.

Results and conclusion of validation are recorded and maintained.

7.5.7 Particular Requirements for Validation of Processes For Sterilization and Sterile Barrier Systems

Validation of processes for sterilization and sterile barrier systems are conducted prior to implementation and following product or process changes. Results and conclusion of validation and necessary actions from the validation are recorded and maintained.

7.5.8 (§820.60) Identification

True Indicating has established procedures for product identification and identify product by suitable means through product realization. Unique product codes are assigned to each device/product type and configuration, per Establish a New Product Code__1-3-15. Each lot or batch of a given product type or configuration is assigned a lot number per Assign a Lot Number__1-9-6.

Identification of product status is maintained throughout production, and storage of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched or used.

Where product is returned to True Indicating, the product is identified and distinguished from conforming product per Returned Goods Processing__1-2-3.

7.5.9 (§820.65) Traceability

7.5.9.1 General

True Indicating has established procedures which ensure traceability of each raw material/component and lot or batch or product. The type of products manufactured by True Indicating are not intended for surgical implant into the body or to support or sustain life and are not reasonably expected to result in significant injury to user if not used in accordance with the instructions for use.

7.5.10 Customer Property

True Indicating identifies, verifies, protects and safeguards customer property provided for use while under our control. If customer property is lost, damaged or otherwise found to be unsuitable for use, the True Indicating will communicate this to the customer and maintain records.

The process for governing this process is entitled Client Property__1-1-6.

7.5.11 (§820.130)Preservation of Product

Per §820.140, True Indicating has established procedures to ensure that mix-ups, damage, deterioration, contamination or other adverse effects to product do not occur during handling. Preserving the conformity of product to requirements during processing, storage, handling and distribution is documented in Finished Good Specification__1-9-4, Product Storage, Handling and Distribution__1-2-1 and Shipment and Packaging Specifications__1-15-1. True Indicating's products are simple devices, without a great deal of constituent parts, but preservation applies to all components.

True Indicating protects product from alteration, contamination and damage when exposed to expected conditions and hazards during processing, storage, handling and distribution by:

a) designing and constructing suitable packaging and shipping containers

b) documenting requirements for special conditions as needed if packaging alone cannot provide preservation.

Per §820.150, True Indicating has established procedures related to control of the storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete product is used or distributed. Where product quality deteriorates over time, it is stored in a manner to facilitate proper stock rotation. Stock rotation, including receipt from and dispatch to storage areas and stock rooms, is controlled per Product Storage, Handling and Distribution__1-2-1.

Per §820.160, True Indicating has established procedures for control and distribution of product to ensure that only those devices approved for release are distributed per Review and Release of Final Product__1-11-8.

7.6 (§820.72) Control of Monitoring and Measuring Equipment

True Indicating has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Measuring equipment is:
a) calibrated or verified, or both at specified intervals, or prior to use against measurement standards traceable to international or national measurement standards
b) Adjusted or readjusted as necessary; such adjustments or readjustments are documented.
c) Identified in order to determine its calibration status
d) Safeguarded from adjustments that would invalidate the measurement result
e) Protected from damage and deterioration during handling, maintenance and storage

True Indicating performs calibration and verification per Equipment Calibration__1-4-5. Assessment of the validity of previous measuring results is performed on a routine basis. Where equipment is found not to conform to requirements, True Indicating takes appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification are maintained.

Per §820.70g, maintenance schedules and inspection of equipment are established and maintained per Equipment Preventive Maintenance__1-4-6. Any inherent limitations or allowable tolerances are posted on or near the equipment.

Validation of the application of computer software used for the monitoring and measurement of requirements is validated prior to initial use and, as appropriate, after changes to such software or their application. Records of the results and conclusion of validation and necessary actions from the validation is maintained.

Section 8: Measurement, Analysis and Improvement

8.1 General

True Indicating plans and implements monitoring, measurement, analysis and improvement processes which include determination of appropriate methods including statistical techniques, and the extent of their use, needed to:
a) demonstrate conformity of product
b) ensure conformity of the QMS
c) maintain effectiveness of the QMS

8.2 Monitoring and Measurement

8.2.1 Feedback

Client feedback is one measure of effectiveness of the QMS. True Indicating gathers and monitors information related to whether we have met customer requirements. The method for obtaining this information is outlined in Client Feedback__1-1-7.

The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

8.2.2 (§820.198) Complaint Handling

True Indicating has established a procedure for complaint handling, Product Complaints__1-11-6, which includes responsibilities and minimum requirements for:

a) Receiving and recording information
b) Evaluation of information to determine the feedback constitutes a complaint
c) Investigation of complaints
d) Determination of the need to report the information to the appropriate regulatory authorities
e) Handling of affected product
f) Determination of need for correction or corrective actions

Where investigation is not performed, determined per Complaint Investigation Decision Process 1-11-6-1, the justification is documented as are any correction or corrective actions taken in association with the complaint handling process. If the investigation determines activities outside True Indicating contributed to the complaint, relevant information shall be exchanged between True Indicating and the external party involved.

Complaint handling records are maintained.

8.2.3 Reporting to Regulatory Authorities

Where situations which meet specified reporting criteria of adverse events or issuance of advisory notices, True Indicating provides notification to the appropriate regulatory authorities per Medical Device Reporting__1-12-6.

Records of reporting to regulatory authorities are maintained in regulatory files.

8.2.4 (§820.22) Internal Audit

Audits are conducted per Internal Audits__1-11-7 on an annual basis to determine whether the QMS conforms to planned and documented arrangements, requirements of ISO 13485 and 21 CFR 820, internal requirements and applicable regulatory requirements and to confirm the QMS is effectively implemented and maintained.

The Internal Audit procedure outlines the responsibilities and requirements for planning, conducting audits, recording and reporting audit results.

The audit program is planned and takes into consideration the status and importance of the processes and area to be audited, as well as previous audits. The audit criteria, scope, and methods are defined and recorded.

The selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors are independent of the work being audited.

An internal audit report is generated which includes audit results, identification of the processes and areas audited and the conclusions.

Prompt action is taken where applicable by management responsible for affected area. Follow up activities are conducted to verify the actions taken and verification is reported.

8.2.5 Monitoring and Measurement Process

True Indicating has established suitable methods for monitoring, and as appropriate measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When results are not achieved correction and corrective action is taken.

8.2.6 Monitoring and Measurement of Product

True Indicating has established Finished Good Specifications to outline characteristics of the product which need to be monitored and measured to ensure requirements have been met. The Specification provides evidence of conformity to the acceptance criteria, where applicable, the test equipment used to perform measurement activity and the identity of the person authorizing release of the product.

Quality Assurance performs the review and release of product once it has been confirmed that the planned and documented arrangements have been satisfactorily completed.

8.3 (§820.90) Control of Nonconforming Product

8.3.1 General

True Indicating ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Nonconformance__1-8-1 and Control of Nonconformitiies__1-8-1-SOP1 define the controls related to responsibility and authority for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery

When a nonconformance associated with a product is identified prior to distribution, action is taken per Nonconformance__1-8-1. Action includes elimination of the nonconformity, preclusion of the original intended use or authorization of use, release and acceptance under concessions. Where acceptance under concession, justification is documented, approval is secured and applicable regulatory requirements are met. Records are maintained including identification of the authorizing individual associated with the concession.

8.3.3 Actions In Response to Nonconforming Product Detected After Delivery

When nonconforming product has been identified after delivery or use has started, True Indicating takes action to the effects or potential effects per Recalls, Corrections and Withdrawals__1-12-5. Per this procedure, advisory notices in accordance with regulatory requirements can be issued at any time.

All actions taken are documented and records are maintained.

8.3.4 (§820.90b2) Rework

True Indicating has established rework procedures, Product Rework__1-8-8, which takes into account the potential adverse effect of the rework on the product. This procedure is handled in the same manner as the review and approval.

When product is reworked, it is verified to ensure that it meets acceptance criteria and regulatory requirements.

Records of rework are maintained.

8.4 Analysis of Data

Appropriate data is identified, collected and analyzed to demonstrate the suitability, adequacy and effectiveness of the QMS per Data Integrity and Documenation__1-1-5.

Per §820.250, where appropriate, True Indicating has established procedures for identifying valid statistical techniques required for establishing controlling and verifying the acceptability of process capability and product characteristics. Sampling plans, when used, shall be written and based on valid statistical rationale per Statistical Techniques and Sampling Plans__1-9-8.

8.5 (§820.100) Improvement

8.5.1 General

True Indicating identifies and implements changes necessary to ensure and maintain continued suitability, adequacy, and effectiveness of the QMS as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 Corrective Action

Action taken to eliminate the cause of nonconformities in order to prevent recurrence are documented per Corrective Action__1-8-3. Corrective Actions are to be identified and implemented expeditiously. Corrective Actions are proportionate to the effects of the nonconformities encountered.

The Corrective Action process requires:

a) Review of Nonconformities, including complaints (reference Product Complaints__1-11-6).
b) Determination of the cause per Conduct of Root Cause Investigation__1-8-2
c) Evaluation of need for action to ensure that the nonconformities do not recur
d) Planning, documenting and implementing actions after verification that such action does not adversely affect compliance to regulatory requirements or the safety or performance of the medical device
e) Review of effectiveness per Effectiveness Check__1-8-4

Records of the corrective action process are maintained.

8.5.3 Preventive Action

True Indicating determines action to eliminate cause for potential nonconformities in order to prevent their occurrence per Preventive Action__1-8-6.
The process allows for:

a) identification of potential nonconformities,
b) determination of their causes per Conduct of Root Cause Investigation__1-8-2.
c) Planning, documentation and implementing of actions needed which do not adversely affect the ability to meet regulatory requirements or the safety performance of the device
d) Reviewing the effectiveness of the preventive action taken per Effectiveness Check__1-8-4.

Records of the preventive action process are maintained.

§820.186 Quality System Record

True Indicating maintains a Quality System Record (QSR) which includes reference to the procedures and documentation activities required that are not specific to a particular type of device, including but not limited to the records required by §820.20 Management responsibility. The QSR is prepared and approved in accordance with §820.40 Document Controls.