

## 1. GENERAL

### 1.1. Introduction

GT Medical Technologies, Inc. (hereinafter “GT Medical”) recognizes its responsibility as a provider of quality medical devices. Therefore, GT Medical has developed and documented a Quality Management System (QMS).

The QMS complies with:

- Food and Drug Administration (FDA) 21 CFR Part 820: Quality System Requirements.
- ISO 13485:2016
- Other regulatory authorities, as required by regulation

GT Medical may establish internal provisions or reference a regulatory guidance document as it relates to requirements for regulatory communications.

This manual provides comprehensive evidence of what specific controls are implemented to ensure product quality. This document defines the statements and requirements associated with the GT Medical's Quality Manual.

### 1.2. References

- F-001A, Document Change Notice
- F-001B, Document Control Index
- F-001C, Audit Response Form
- F-001D, Audit Response Log
- F-001E, Training Sign-In Sheet
- F-001F, Design and Development Plan
- F-001G, Device Master Record Template
- F-001H Design and Regulatory Change Assessment
- SOP-002, Purchasing and Suppliers Controls
- SOP-003 Complaint Handling, Reporting, and Recall
- SOP-004 Labeling and Unique Identification (UDI)
- SOP-005 Electronic Tools Procedure
- SOP-006 Order Entry Process

### 1.3. Scope

This document outlines the activities necessary for GT Medical to fulfill the requirements of the regulations cited in Section 1.1. The following Table 1 illustrates inclusions and exclusions as applied to the medical device quality system activities performed by GT Medical.

Table 1 : 21 CFR 820 Inclusions/Exclusions

Subpart, per 21 CFR 820	ISO 13485	Comments/Justifications/Exclusions regarding scope of QMS	Reference
<b>Subpart A</b> – General Provisions	1-3,4.2	Included.	N/A – this QSR section covers scope and definitions
<b>Subpart B</b> – Quality System Requirements	4.1-4.2, 5.1-5.6, 6.1-6.2, 8.2.4, 8.5	Included.	Fully contained in this Quality Manual: SOP-001, Quality Manual
<b>Subpart C</b> – Design Controls	7.3	Subcontracted. Activities are subcontracted, and subcontractor is responsible for documenting activities in this part.	N/A – see details in section of this Quality Manual
<b>Subpart D</b> – Document Controls	4.2.4	Included.	SOP-001, Quality Manual and SOP-005, Electronic Tools
<b>Subpart E</b> – Purchasing	7.4	Included.	SOP-002, Purchasing and Suppliers Controls
<b>Subpart F</b> – Identification and Traceability	7.5.8-7.5.9	Subcontracted. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for documenting activities in this part.	Quality Agreement
<b>Subpart G</b> – Production and Process Controls	6.21, 6.3, 6.4, 7.5, 7.6, 8.2.5	Subcontracted. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for documenting activities in these parts.	Quality Agreement SOP-006 Order Entry Process
<b>Subpart H</b> – Acceptance Activities	7.1, 7.4.3, 7.5.9.2, 8.2.6,	Subcontracted. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for documenting activities in these parts.	Quality Agreement
<b>Subpart I</b> – Nonconforming	8.3	Subcontracted. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for documenting activities in these parts.	Quality Agreement
<b>Subpart J</b> – Corrective and Preventive Action (CAPA)	8.5.2-8.5.3	Included.	SOP-002, Purchasing and Suppliers Controls
<b>Subpart K</b> – Labeling and Packaging Controls	4.2.3, 7.5.8	Included. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for activities in this part, with the exception of the Unique Device Identification (UDI) implementation.	SOP-004, Labeling and Unique Device Identification (UDI)
<b>Subpart L</b> – Handling, Storage, Distribution, and Installation	7.1, 7.5.3, 7.5.11,	Subcontracted. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for documenting activities in this part.	Quality Agreement
<b>Subpart M</b> – Records	4.2.5, 7.1, 8.2	Included.	SOP-003, Complaint Handling, Reporting, and Recall SOP-005, Electronic Tools
<b>Subpart N</b> – Servicing	7.5.4	Excluded. No GT Medical products require servicing.	N/A
<b>Subpart O</b> – Statistical Techniques	8.1	Excluded. All GT Medical products are contract manufactured and as such, the contract manufacturers are responsible for activities in this part.	N/A

## 2. SUBPART B – QUALITY SYSTEM REQUIREMENTS

### 2.1. Quality Policy Statement

GT Medical Technologies is committed to improve the lives of patients with brain tumors, the quality of patient care, the effectiveness of Quality Management System and to comply with applicable requirements

### 2.2. GT Medical

#### 2.2.1. Company overview

GT Medical has developed an innovative approach to the treatment of brain neoplasms by combining a conformable collagen matrix with brachytherapy (radiation) seeds. GT is focused on solving a fundamental problem: the safe, effective, and cost-efficient treatment of neoplasms that cannot be entirely removed by surgery alone.

### **2.2.2. GT Medical device products**

Currently, GT Medical's device products are based on the GammaTile Technology and are Class II devices (non-exempt, 510k).

### **2.2.3. GT Medical operation and limitations**

GT Medical is responsible for specification development, but activities related to manufacturing, packaging, and labeling shall be subcontracted to the manufacturing partner(s). The device is manufactured and distributed under GT Medical's own name.

Customer orders are received and processed by GT Medical, prior to placing an order with the contract manufacturer. Only documented customer orders will be accepted. Customer orders are reviewed by GT Medical prior to acceptance/commitment to supply product. This review 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 are met;
- d) any user training/licensing is complete
- e) customer order requirements can be met

Records of the results of the review and actions arising from the review shall be maintained.

### **2.2.4. Risk Based Approach to the QMS**

GT Medical applies a risk-based approach to control processes needed for the quality management system to ensure compliance to applicable regulatory requirements. The approach includes the balance of interactions across business risk, product risk, process risk and regulatory risk. This is evident throughout the process and is detailed further in procedures where a specific approach to identifying, evaluating, mitigating and improving risks is necessary to support informed management decisions to not only maintain compliance of the quality system but also better allocate resources for optimal benefit to the organization, our products, the environment, our customers and ultimately the patient.

The following systems have been identified as the most critical QMS processes for incorporating a risk-based approach. The procedures associated with these subsystems specify provisions for risk-based thinking:

- Management Review (SOP-001 Quality Manual)
- Purchasing & Supplier Management (SOP-002 Purchasing and Supplier Controls)
- Training and Documentation of Training (SOP-001 Quality Manual)

Risk-based approach is evaluated throughout the quality management system holistically via the internal audit program (SOP-001 Quality Manual). Areas of strengths are noted as best practices. Opportunities and threats are noted as recommendations; whereas, weaknesses are captured as non-conformities. Preventive or Corrective actions are opened as appropriate to address recommendations or non-conformities.

### 2.2.5. Software

If the output of a quality management system process depends on software, the software shall be subject to validation. Software shall be validated in accordance with FDA Guidance (General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Jan 11, 2002 or latest revision), unless other provisions are established in the design and development plan.

### 2.2.6. Organizational Structure

- a) The organization chart is maintained electronically in Box, in the Quality Records/Organizational Chart folder.

### 2.2.7. Company Contact Information

**Address:** 1809 S Holbrook Ln, Ste. 107, Tempe, AZ 85281

**Website:** <https://www.gtmedtech.com/>

### 2.2.8. Management Representative

The Vice President of Operations is the designated management representative. The management representative's responsibilities include:

- b) ensuring that processes needed for the effectiveness of the quality management system are documented;
- c) reporting to top management on the effectiveness of the quality management system and any need for improvement;
- d) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.
- e) ensuring the organizational chart reflects organizational changes within a reasonable amount of time. The organizational chart is maintained on Box, in the Quality Records/Organizational Chart folder.

## 2.3. Management Review

### 2.3.1. General

Annually, top management shall review the organization's Quality Management System to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Management shall make an executive decision based on the available data as to what evidence constitutes acceptable performance or an adverse trend, where applicable. Records from management reviews shall be maintained. The procedure for management review is contained within this quality manual and defined below.

During management review, data relevant to the following quality objectives is reviewed:

**Objective 1: Improve customer satisfaction by providing safe, effective products for the treatment of tumors**

- Demonstrated by number of customer complaints, identifying potential trends, survey feedback, etc.

**Objective 2: Complying with applicable customer and regulatory requirements**

- Demonstrated by internal/external audit findings.

**Objective 3: Maintaining high levels of supplier performance**

- Demonstrated by evaluating suppliers, monitoring supplier performance, and requiring corrective action as necessary.

**2.3.2. Review Input**

The input to management review shall include information on:

**a) Follow-up actions from previous management reviews**

Any action items determined from the previous management reviews will be tracked in subsequent management reviews to monitor and report progress of items needed for the improvement of the quality management system.

**b) Results of audits**

The results of internal and external audits will be reviewed to address deficiencies in the quality management system. (See requirements relevant internal audits in subsequent sections.) The schedule for and appropriateness of the internal audit frequency will also be assessed in each management review.

**c) Customer feedback**

The complaint system will be reviewed for the following metrics:

- Number of complaints received by case
  - Number of complaints that were reportable events by case
  - Number of complaints by defect
- \*A case is defined by a surgical procedure in which a GammaTile is used in a patient.

**d) Process performance and product quality**

The Supplier Corrective Action Request (SCAR) System will be reviewed for the following metrics:

- Total number of SCAR's issued for the year by vendor
- Total number of open SCAR's
- SCAR's for each vendor by defect

**e) Changes that could affect the Quality Management System**

Any changes that could affect the quality management system will be discussed to ensure resource availability and the adequacy of the current quality system to support the changes planned. These changes can include but are not limited to: organizational changes, new products, product changes, vendor changes for subcontracted services, etc.

**f) Recommendations for improvement**

After review of the quality metrics, top management will make a determination regarding the effectiveness of the quality management system. Any recommendations for improvement will be tracked as action items and will be reported in the next management review.

**g) New or revised regulatory requirements impacting GT Medical products or quality system**

An overview of any new or changing regulatory requirements relevant to the GT Medical products or the quality management system will be presented in each management review. The review can include the assessment of requirements for new markets into which the product could expand.

**h) Adequacy of product risk management plan**

Risk management plans for Class II devices should be included in management review. Plans should be reviewed considering post market surveillance information obtained through the complaint system, literature review, and other feedback channels to determine:

- If original severity and occurrence estimates were correct for identified risks.
- If any new risks were identified not originally captured in the risk analysis.

Review of the risk management file will be conducted prior to management review and result reported during the course of the management review meeting.

**2.3.3. Review Output**

The output from the management review shall include any decisions and actions related to:

- a) Improvements needed to maintain the effectiveness of the quality management system and its processes,**
- b) Improvement of product related to customer requirements, and**
- c) Adequacy and allocation of resources to support QMS activities.**
- d) Changes needed to respond to applicable new or revised regulatory requirements.**

Meeting minutes will be maintained documenting attendees, date, inputs, and outputs reviewed. Conclusions statements about each of the above outputs will be recorded.

**2.4. Internal Quality Audits****2.4.1. General**

Due to the number of outsourced activities related to the product, low anticipated annual product volumes and the limited number of product lines GT Medical sells, internal auditing of the QMS will be undertaken at least every other year by a contracted third party.

**2.4.2. Internal Audit Planning and Conduct**

GT Medical makes provisions for internal audits at planned intervals of every other year to determine whether the QMS:

- Conforms to the planned arrangements of the QMS, and
- Is effectively implemented and maintained.

GT Medical uses the internal audit program to continually evaluate the risks associated with Quality Management system processes, in accordance with the established risk-based approach of this

Quality Manual. This risk-based approach encompasses the activities of identifying, evaluating, mitigating, and improving areas within the quality management system in order to facilitate the mitigation of risks. These activities are comprehensively covered by the following internal audit activities.

To ensure auditor independence, GT Medical contracts an independent third-party to conduct quality system audits. The contracted independent third-party is responsible for planning, conducting, and reporting audit results.

The independent third-party organization will provide an audit report summarizing audit results and findings. Audit reports shall contain three types of objective evidence to support a risk-based approach

- Strengths- this may include controls that exceed regulatory requirements/guidance or are industry best practice.
- Weaknesses- May also be considered as opportunities for improvement or observations. These are not nonconformities, but may feasibly contribute to a sequence of events that would lead to a nonconformity, or generally be below industry best practices
- Non-conformities- if any are identified, nonconformities shall be documented.

All observations made during the internal audit shall be evaluated and shared with appropriate management, production, quality control, and/or lab personnel.

GT Medical is responsible for reviewing the audit report, taking the items identified in the audit report, issuing F-001C, Audit Response Form for each audit finding and completing F-001D, Audit Response Log with the corresponding information. Response target is 30 days using the F-001C, Audit Response Form. Verification activities shall be conducted and reported in F-001C, Audit Response Form to document the actions taken and effectiveness verification. A person other than the one completing the corrective or preventive actions will perform verification. Where appropriate, a root cause analysis or risk assessment shall be conducted and documented in F-001C, Audit Response Form. GT Medical is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes.

## **2.5. Training/Personnel**

### **2.5.1. General**

Personnel performing work affecting product quality are competent based on appropriate education, training, skills, and experience.

GT Medical must ensure that their suppliers have the appropriate controls in place to ensure that personnel supervising or performing medical device manufacturing or control have the education, training, and/or experience to perform their assigned functions. Training programs for contract manufacturers are verified through SOP-002, Purchasing and Supplier Controls.

### **2.5.2. Competence, Awareness, and Training**

GT Medical documents competency requirements in job descriptions, and subsequently selects personnel based on education, skills, and experience. All personnel must be trained in the Quality Manual to ensure and overall awareness of the quality system requirements as a whole. All personnel conducting activities within the QMS are trained in the procedures and supporting forms associated with that activity to ensure an awareness of process and product quality requirements. Training records are kept per Figure 1 of SOP-005 Electronic Tool Procedure.



Because GT Medical is a small company, all personnel assume multiple roles. This training matrix serves as a general guideline of minimum training requirements for personnel that are tasked with specific responsibilities. Before new tasks are assigned to any personnel, they must be trained accordingly in order to appropriately carry out assigned responsibilities. Completed training should be documented on F-001E, Training Sign-In Sheet.

Effectiveness of training is evaluated and documented per the methods included on the F-001E, Training Sign-In Sheet. Trainee self-evaluation is appropriate unless the training is in response to addressing a nonconformance.

When the training is being conducted due to a nonconformance (SCAR, complaint, etc.), a trainer is required conduct the training. The Trainer shall be the document owner, one designated as the initiator of the document updates (if applicable), and/or be competent in the area of the training material.

The training procedure is entirely contained within this Quality Manual. There is no stand-alone document that serves as the Training/Personnel procedure.

### 3. SUBPART C – DESIGN CONTROLS

As a specification developer, GT Medical is responsible for ensuring Design Controls are applied for the planning and controlling the design of Class II medical devices. Because GT Medical outsources design activities, it does so exclusively with subcontractors with Design Control systems compliant with 21 CFR 820.30. GT Medical engages in the design process through the subcontractor's Design Control system. GT Medical oversees the design documentation and provides final approval. In the event that a design change is necessary, GT Medical is responsible for assessing the impact of design changes to regulatory filings. This assessment shall be documented using the F-001H Design and Regulatory Change Assessment form.

Initial project scope, roles and responsibilities, and objectives are defined within F-001F Design and Development Plan. GT Medical then initiates the project with the subcontractor as specified in the design and development plan. GT Medical maintains F-001G Device Master Record documenting device specifications. Contract manufacturers are responsible for maintaining as Device Master Record documenting production process, quality assurance, and packaging and labeling specifications. In the event that the contract manufacturer provides a Device Master Record with design specifications, this document can be maintained in lieu of GT Medical's form F-001G Device Master Record.

### 4. SUBPART D – DOCUMENT CONTROLS

**4.1.** GT Medical has established and maintains an internal Electronic Document Control System. It ensures that documents:

- are reviewed and approved for adequacy prior to issuance,
- are updated, reviewed and approved for re-issue as necessary,
- are identified with their current revision status,
- are available at point of use,
- are legible, readily identifiable and retrievable,
- of external origin are identified and their distribution is managed,
- that are obsolete are prevented from unintended use and are suitably identified if they are retained for any purpose.

This procedure is in the Quality Manual and in SOP-005, Electronic Tools Procedure. There is no stand-alone document that serves as the Document Control procedure.



**4.2.** The levels for GT Medical quality documentation are as follows:

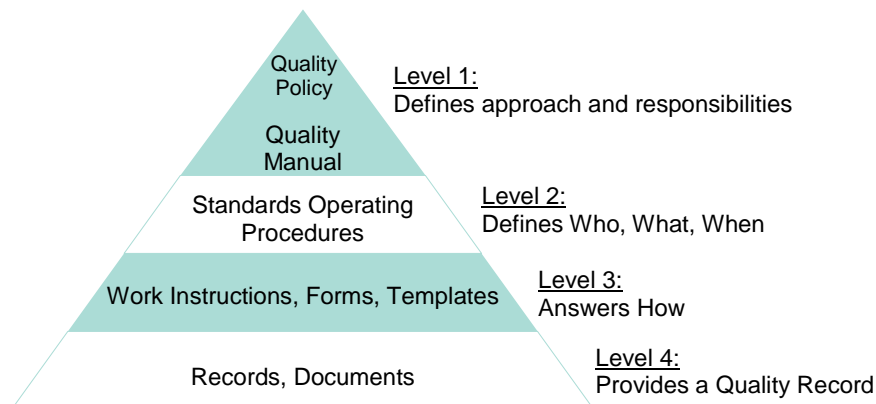


Figure 1 – GT Medical's documentation hierarchy

GT Medical maintains a log listing Quality Management System Documentation with current revision levels (see F-001B, Document Control Index), for Levels 1-3. For Level 4 Documents and Records, See Box (reference SOP-005 Electronic Tools Procedure).

**4.3.** Quality System Documents are uniquely identified through document titles and revisions. Revisions are serially assigned numeric values, beginning with 1 (Revision is abbreviated 'Rev').

**4.3.1.** Procedures shall be titled in the format, SOP-XXX followed by the procedure title, where XXX is a serially assigned number, beginning with 001.

**4.3.2.** Forms shall be titled with the format, F-XXX Y, where XXX is the corresponding number of the procedure and Y is a serially assigned letter, beginning with A.

**4.3.3.** Work instructions, where determined to be necessary, shall be titled with the format WI-XXX where XXX is a serially assigned number, beginning with 001.

**4.3.4.** Drawings shall be titled with the prefix DWG.

**4.3.5.** Protocols and engineering study plans shall be titled with the prefix PLN.

**4.3.6.** Reports (i.e. validation or engineering study) shall be titled with the prefix RPT.

**4.3.7.** Purchasing specifications shall be titled with the prefix PSP.

**4.3.8.** Other documents may be created as needed and uniquely identified.

**4.3.9.** Products shall be identified with GT-XXX, where XXX is a serially assigned number beginning with 001.

**4.4.** Personnel desiring to create or make a change to a QMS document need to make a formal request via form F-001A, Document Change Notice. Changes shall be evaluated for their impact on the quality management system and on the medical devices within scope of the quality management system. From this evaluation the impact of the change is determined. The impacted quality management system documents are listed in F-001A, and further details of the change evaluation and/or the impact of the change may be documented in the form text box. The document change notice also captures the reason for the change, the document level revised from and to, a copy of the redlined documents showing changes to the previous revision, and a copy of the final document with the revisions

incorporated. After the DCN package is reviewed, appropriate functions sign the form F-001A with any relevant documents attached to affirm the changes has been evaluated and approved.

- 4.5. Once form F-001A is approved, the newly revised, active document will be filed in the appropriate QMS location as specified in SOP-005, Electronic Tools Procedure. Only the most active version of the documents will be maintained in the 'ACTIVE QMS Document' folder. Previous revisions of documents in the QMS will be placed in the appropriate location under the 'OBSOLETE Documents' folder.
- 4.6. Some document changes require contract manufacturer notification. The person initiating the change is responsible for coordinating contract manufacturer notification for the applicable documents.
- 4.7. The remainder of the Document Change Notice package (approved DCN form and redlines) will be archived into the corresponding 'QMS Records' folder.
- 4.8. Electronic Tool Permissions are defined in F-005A, Electronic Tool Permissions Log as per SOP-005, Electronic Tools. To ensure that only current, approved revisions are utilized, documents shall only be referenced or retrieved from the restricted electronic file location.
- 4.9. In the case of forms/logs/templates intended for use in creating quality records, an electronic version may be used to create records and it may be sent to others by email. Users are to verify they are using the most current copy of the template. Fixed portions of a template may only be revised by processing a change against the template itself. It is the user's responsibility NOT to alter the fixed parts of the template.

## **5. SUBPART E – PURCHASING**

GT Medical sources, assesses, selects, and maintains suppliers that will fully meet the requirements for GT Medical products. Documented procedures ensure that all purchased material and services conform to specified purchase requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluation and any necessary actions arising from the evaluation shall be maintained.

The complete Purchasing procedure (SOP-002, Purchasing and Supplier Controls) exists as a stand-alone document.

## **6. SUBPART J – CORRECTIVE AND PREVENTIVE ACTION (CAPA)**

Because GT Medical subcontracts the majority of the processes related to product realization and order fulfillment, the company has focused its resources on developing and implementing a Supplier Corrective Action system. This process is defined by SOP-002, Purchasing and Supplier Controls and is monitored in accordance with the management review section of this procedure.

GT Medical also subcontracts activities associated with development and support for the Quality System with external quality professionals. Should the need for an internal corrective action arise, GT Medical will issue a Supplier Corrective Action Request (SCAR) to the quality consultant. The consultant will develop the plan and assign actions as necessary to GT Medical personnel, other consultants, or subcontractors as necessary.

## **7. SUBPART K – LABELING AND PACKAGING**

- 7.1. GT Medical will ensure that product packaging and shipping containers are designed and constructed to protect the product from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

**7.2.** Because GT Medical subcontracts the majority of the processes related to labeling and packaging, the company has focused its resources on Unique Device Identification (UDI) implementation. The requirements for these two elements are defined SOP-004, Labeling and Unique Device Identification (UDI). Subcontractors will control the labeling activities such as label integrity, label inspection, labeling storage, labeling operations and control number. Therefore, these activities are not covered in this Quality Manual or in the procedure SOP-004, Labeling and Unique Device Identification (UDI).

## **8. SUBPART M – RECORDS**

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. QMS records should be retained in electronic format. Records shall remain legible, readily identifiable, and retrievable.

Quality records, including obsolete records, required by this Quality Manual and supporting procedures will be maintained for a period of 10 years to ensure that records are maintained for the lifetime of the product or at least two years beyond commercial distribution of the product (whichever is longer). Records related to product design, submission, and reportable events will be maintained indefinitely.

### **8.1. Complaint File**

GT Medical routinely monitors customer feedback and reviews product complaints, consumer adverse event reports, and product recall via SOP-003, Complaint Handling, Reporting and Recall.

Feedback is categorized and reviewed according to the Management Review section of this procedure to provide an early indicator of quality problems. If quality problems are detected, GT Medical may require investigation from the contract manufacturer and issue a SCAR (as applicable) to the appropriate supplier according to SOP-002, Purchasing and Supplier Controls.

The complete Complaint procedure exists as a stand-alone document in SOP-003, Complaint Handling, Reporting and Recall.

## **9. APPENDICES**

**9.1.** Appendix A – Recurrent activities required to maintain QMS<sup>1</sup>

**9.2.** Appendix B – Event-related activities required to maintain QMS<sup>1</sup>

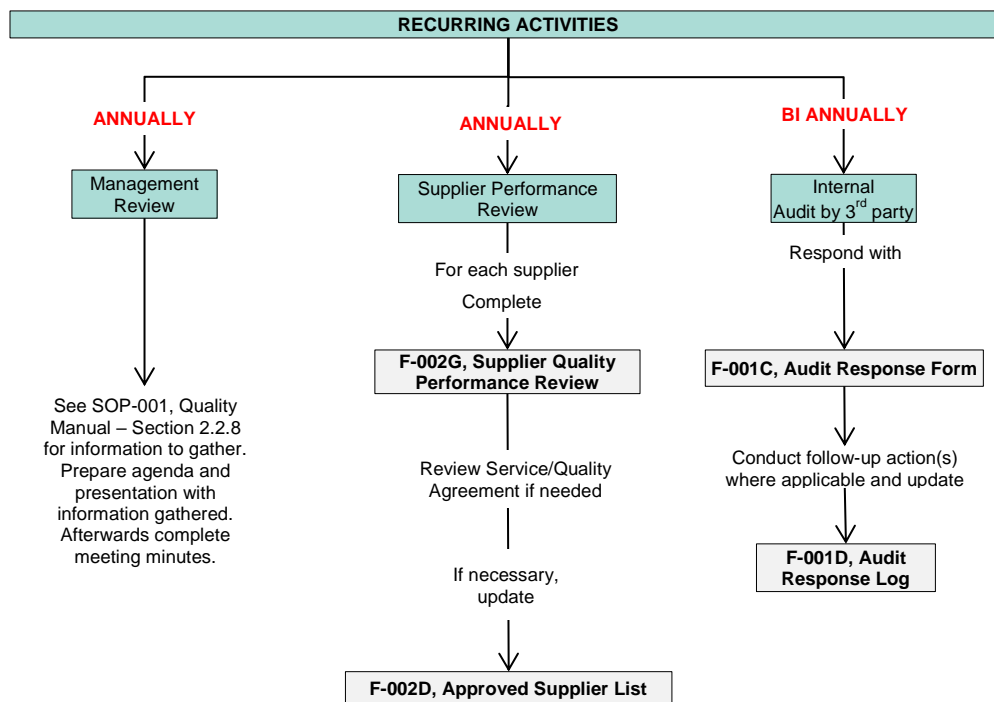
<sup>1</sup> Note that the flowcharts in Appendices A and B are for illustration purposes only. Complete instructions can be found in the individual procedures.

## 10. DOCUMENT HISTORY

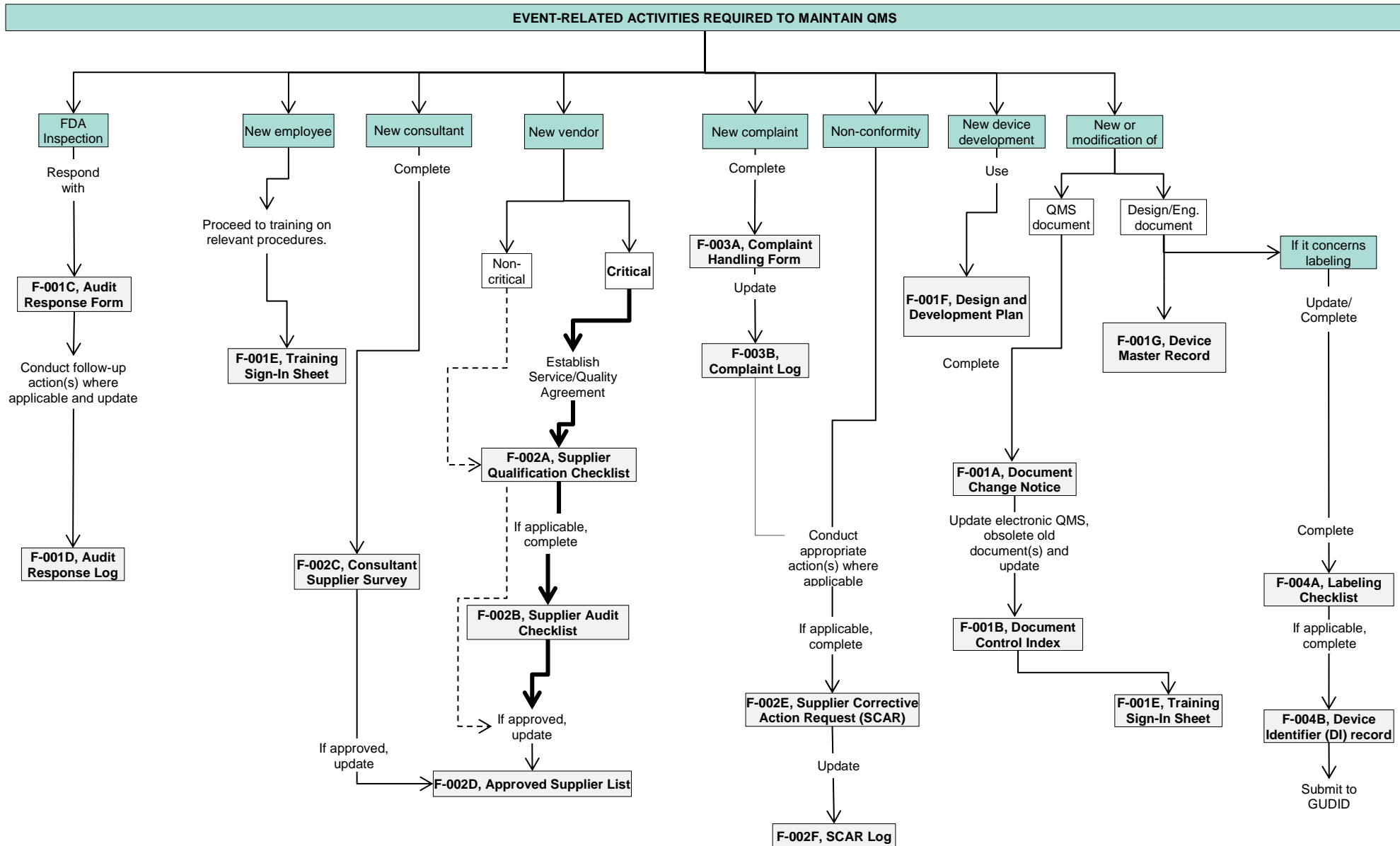
Functional Area	Signature & Date
CEO	<p>Matt Likens</p> <p><b>Matt Likens</b> 29 Nov 2018 10:46:015-0800</p> <p>REASON: I am approving this document.</p> <p>5bf0b4d9-9e03-49a6-8272-9817f015e0e4</p>
Operations	<p>Hernan Lopez</p> <p><i>Hernan Lopez</i> 30 Nov 2018 05:22:013-0800</p> <p>REASON: I am approving this document.</p> <p>72eef047-7bbe-4092-82b1-f04e00c2e31e</p>
Quality	<p>Michelle Lott</p> <p><i>Michelle Lott</i> 26 Nov 2018 11:40:051-0800</p> <p>REASON: I am approving this document.</p> <p>f7e7590f-6690-4b5c-92a2-9498dd850663</p>
Regulatory	<p>Jessica Newhard</p> <p><i>Jessica Newhard</i> 03 Dec 2018 06:49:002-0800</p> <p>REASON: I am approving this document.</p> <p>3bd17091-2c34-4925-88ed-391ad6b1da50</p>

REVISION HISTORY		
Rev. #	Released Date (YYYY-MM-DD)	Author
1	2018-05-14	Michelle Lott
2	2018-09-04	Raines DeMint
3	2018-11-26	Raines DeMint

## APPENDIX A – Recurrent activities required to maintain QMS



## APPENDIX B – Event-related activities required to maintain QMS






# MySignatureBook V3.12


Validation Report as of: 04 Dec 2018 13:37:042-0800


1



Subject CN MSB  
Subject DN EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US  
Email operations@msbdocs.com  
Serial # 277155780700783329438831339513496021584  
Issuer DN CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US  
Signing Time 03 Dec 2018 06:49:003-0800

 The Certificate chain was successfully built to a Trusted Root Certificate.

 The Signer's identity is valid.

 The Document has not been modified since the signature was applied.

This page was added to the original document by the MySignatureBook Validation Service (SVS) as part of the process to convert active signature block content into inactive text. A full validation report of each signature is generated and cross-referenced using a numeric footnote annotation.

# Audit Trail Report

Date	User	Document	Action	Details
26 Nov 2018 11:22:022-0800	Maria Laitenberger		Started	The custodian composed the ePak successfully. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
26 Nov 2018 11:22:055-0800	Michelle Lott		RequestSent	Sign request sent to ePak recipient. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663
26 Nov 2018 11:22:055-0800	Maria Laitenberger		RequestSent	Sign request sent to ePak recipient. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
26 Nov 2018 11:22:055-0800	Raines DeMint		RequestSent	Sign request sent to ePak recipient. User UUID : 2ee4a9ef-4d1a-4598-bb7f-8eeac6189470
26 Nov 2018 11:22:055-0800	Matt Likens		RequestSent	Sign request sent to ePak recipient. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4
26 Nov 2018 11:22:055-0800	Hernan Lopez		RequestSent	Sign request sent to ePak recipient. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e
26 Nov 2018 11:22:055-0800	John Baker		RequestSent	Sign request sent to ePak recipient. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5
26 Nov 2018 11:22:055-0800	David Brachman		RequestSent	Sign request sent to ePak recipient. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2
26 Nov 2018 11:22:055-0800	Craig Bushnell		RequestSent	Sign request sent to ePak recipient. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34
26 Nov 2018 11:22:055-0800	Jessica Newhard		RequestSent	Sign request sent to ePak recipient. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50
26 Nov 2018 11:22:055-0800	Austin Feldman		RequestSent	Sign request sent to ePak recipient. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe
26 Nov 2018 11:24:045-0800	Maria Laitenberger	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have reviewed this document. User UUID : fff18bac-7002-4b20-9ce3-567169aab764 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
26 Nov 2018 11:25:002-0800	Maria Laitenberger	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : fff18bac-7002-4b20-9ce3-567169aab764 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054
26 Nov 2018 11:39:053-0800	Michelle Lott	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
26 Nov 2018 11:40:052-0800	Michelle Lott	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
26 Nov 2018 11:41:024-0800	Michelle Lott	SOP-002 Purchasing and Supplier Controls Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 2215ca50-eb11-4abe-a50a-34fe27715153
26 Nov 2018 11:41:043-0800	Michelle Lott	SOP-003 Complaint Handling, Reporting, and Recall Rev4.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 8a13de9f-3f26-4e97-899a-51bb7d5ad693
26 Nov 2018 11:42:002-0800	Michelle Lott	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 40b9fbb3-45bd-4dd4-b84b-f339cbe81db
26 Nov 2018 11:42:028-0800	Michelle Lott	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
26 Nov 2018 11:43:000-0800	Michelle Lott	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
26 Nov 2018 11:43:030-0800	Michelle Lott	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : f7e7590f-6690-4b5c-92a2-9498dd850663 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054
27 Nov 2018 11:39:053-0800	Maria Laitenberger		StarredByDelegation	EPak starred by a delegation. User UUID : fff18bac-7002-4b20-9ce3-567169aab764
27 Nov 2018 11:39:053-0800	Maria Laitenberger		Delegated	Maria Laitenberger<marial@leanraqasystems.com> delegated the ePak to another signer Raines Demint<rainesd@leanraqa.com> Previous Signer: Raines DeMint<rainesd@leanraqasystems.com> Message: User UUID : fff18bac-7002-4b20-9ce3-567169aab764
27 Nov 2018 11:41:017-0800	Raines Demint	TSS-001_2018-11-26_LeanRAQA.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 7321d07e-0a33-4508-bc91-bbfbbd41c5c6 Document UUID : f90c82d5-449f-4fea-ad27-873a9d59b054

28 Nov 2018 14:45:051-0800	Matt Likens	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
28 Nov 2018 18:24:027-0800	Craig Bushnell	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
28 Nov 2018 18:25:023-0800	Craig Bushnell	TSS-001_2018-11-26_CBushnell.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : eb484e21-4f88-4aba-9555-bae790d4bb34 Document UUID : 1fcb0910-90f4-415c-a752-b6987530c164
29 Nov 2018 10:36:014-0800	Austin Feldman		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe
29 Nov 2018 10:36:017-0800	Jessica Newhard		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50
29 Nov 2018 10:36:020-0800	David Brachman		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2
29 Nov 2018 10:36:023-0800	John Baker		StarredByReminder	EPak starred by a reminder to the signer. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a217b5
29 Nov 2018 10:36:025-0800	Hernan Lopez		StarredByReminder	EPak starred by a reminder to the signer. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e
29 Nov 2018 10:46:015-0800	Matt Likens	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
30 Nov 2018 05:21:052-0800	Hernan Lopez	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
30 Nov 2018 05:22:013-0800	Hernan Lopez	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
30 Nov 2018 05:22:031-0800	Hernan Lopez	SOP-002 Purchasing and Supplier Controls Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 2215ca50-eb11-4abe-a50a-34fe27715153
30 Nov 2018 05:22:053-0800	Hernan Lopez	SOP-003 Complaint Handling, Reporting, and Recall Rev4.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 8a13de9f-3f26-4e97-899a-51bb7d5ad693
30 Nov 2018 05:23:011-0800	Hernan Lopez	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 40b9fbb3-45bd-4dd4-b84b-ff390cbe81db
30 Nov 2018 05:23:033-0800	Hernan Lopez	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
30 Nov 2018 05:24:005-0800	Hernan Lopez	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
30 Nov 2018 05:24:028-0800	Hernan Lopez	TSS-001_2018-11-26_HLopez.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 72eef047-7bbe-4092-82b1-f04e00c2e31e Document UUID : cdbca299-3d3a-4aef-b7d4-6564c23fb711
02 Dec 2018 07:45:010-0800	Austin Feldman	TSS-001_2018-11-26_AFeldman.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 1c114c17-69e8-4b01-a1b6-296d858c2abe Document UUID : 698858a6-fc6a-4d39-954d-01ab205d63c4
02 Dec 2018 10:25:017-0800	David Brachman	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
02 Dec 2018 10:26:014-0800	David Brachman	TSS-001_2018-11-26_DBrachman.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 415147a7-d17f-48eb-bc3f-3280b7f2b6d2 Document UUID : ded7a4d6-e150-4610-8327-329844249aea

03 Dec 2018 06:48:040-0800	Jessica Newhard	DCN-010_compiled.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 841ceab7-674a-4a2e-a74e-77b432dd7ca2
03 Dec 2018 06:49:003-0800	Jessica Newhard	SOP-001 Quality Manual Rev3.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 60b089e2-a878-4db6-9682-5448eecd707
03 Dec 2018 06:49:022-0800	Jessica Newhard	SOP-002 Purchasing and Supplier Controls Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 2215ca50-eb11-4abe-a50a-34fe27715153
03 Dec 2018 06:49:041-0800	Jessica Newhard	SOP-003 Complaint Handling, Reporting, and Recall Rev4.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 8a13de9f-3f26-4e97-899a-51bb7d5ad693
03 Dec 2018 06:49:059-0800	Jessica Newhard	SOP-004 Labeling and Unique Device Identification (UDI) Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 40b9fbb3-45bd-4dd4-b84b-f390cbe81db
03 Dec 2018 06:50:019-0800	Jessica Newhard	SOP-005 Electronic Tools Procedure Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 9ae0e0f0-81dd-4206-84cb-7e83a707d8fe
03 Dec 2018 06:50:043-0800	Jessica Newhard	SOP-006 Order Entry Process Rev2.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I am approving this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 5b065ba7-7993-4140-9097-ecedababd14b
03 Dec 2018 06:51:019-0800	Jessica Newhard	TSS-001_2018-11-26_JNewhard.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 3bd17091-2c34-4925-88ed-391ad6b1da50 Document UUID : 9732b790-2038-4f44-80b8-fcfc2f949bc
03 Dec 2018 19:43:053-0800	John Baker	TSS-001_2018-11-26_JBaker.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : bb1eb73e-fbbf-45f9-a42e-142e3a2717b5 Document UUID : 5278beff-309d-4378-8cae-cf40ad9de034
04 Dec 2018 13:20:059-0800	Matt Likens	TSS-001_2018-11-26_MLikens.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I have read and understood the contents of this document. User UUID : 5bf0b4d9-9e03-49a6-8272-9817f015e0e4 Document UUID : 6e427ba3-e577-42c7-9352-5d9b984a124c
04 Dec 2018 13:20:059-0800	Maria Laitenberger		Completed	The ePak completed the workflow successfully custodian. User UUID : fff18bac-7002-4b20-9ce3-567169aab764