

**BEFORE HEALTH INTELLIGENCE LTD.**



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## **DOCUMENT CONTROL**

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Quality System Procedure: QSP-RQ-001

Revision: Rev: 00

Approve for New revision		
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Title: CEO		

Annual Review				
Reviewed by/Date	Approved by/Date	CEO /Date	Risk Assessment CR#:	Next Review Date

## 1. PURPOSE – SCOPE

The purpose of this procedure is to document the procedural controls that Before Health Intelligence Ltd. has developed to control all Quality Management System (QMS) documentation, product data, and production related processes required for the compliant operation of the company.

This procedure applies to all documents, procedures, data, and forms developed and used by Before Health Intelligence Ltd. The procedure is established to assign responsibilities for the creation, review, authorization, change process, issue, distribution and revision of controlled documents.

**Note:** All QMS documentation is considered confidential and must not be copied without the prior approval of the Management Representative (MR) or Regulatory and Quality associate.

## 2. REFERENCE DOCUMENTS

- 2.1. Refer to QM-AD-001 Quality Manual for applicable standards and regulatory requirements for the Quality Management System requirements.
- 2.2. QSP-RQ-003 Control of Records
- 2.3. QSP-RQ-004 Training and Qualification
- 2.4. QSP-RQ-006 Customer Orders
- 2.5. QSP-SD-002 Design and Development
- 2.6. QSP-RQ-012 Internal Audits
- 2.7. QSP-RQ-016 Corrective and Preventive Action
- 2.8. ELT-RQ-001-03 Master Document List
- 2.9. ELT-RQ-001-02 External Document List
- 2.10. ELT-RQ-001-01 Change Request List
- 2.11. FRM-RQ-001-01 Change Request
- 2.12. FRM-RQ-004-07 Signature Log
- 2.13. Appendix A: Adobe PDF Electronic Signatures
- 2.14. Appendix B: Change Notification

## 3. DEFINITIONS

- 3.1. **Controlled Documents:** QMS documentation, such as QSPs or other procedures/work instruction, forms, charts, product specifications, product drawings, DMR, product labeling (including marketing materials), external standards/regulations/requirements and any other QMS related documentation pertaining to the manufacture, distribution, and operation of a product or the QMS.
- 3.2. **Documentation System Structure:**

Tier 1: Quality Manual & Quality Policy

Tier 2: Quality System Procedures

Tier 3: Work Instructions or specific department instructions

Tier 4: Forms, templates, etc. that create Quality Records once completed; Quality records provide objective evidence of compliance to regulatory and procedural requirements

- 3.3. **External Documents:** Documents that originated outside of the company (e.g. standards, regulations, customer documentation, etc.) which Before Health Intelligence Ltd. does not have to change control authority.
- 3.4. **Internal Documents:** Documents that are created by the organization and/or which the organization changes, modifies, and approves via this documentation system.
- 3.5. **Master Document List:** Listing of controlled documents, containing at a minimum the document number, document title, revision level, effective date, and the location of the document.
- 3.6. **Process Changes:** Process changes are changes to a specification, method, process or procedure. This includes the establishment and maintenance of procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated before implementation and these activities shall be documented and approved.
- 3.7. **Records:** Documentation, either hard copy or electronic media, which demonstrates conformance to specified requirements and / or the effective operation of the QMS; most occurrences of these are *completed forms*.

**4. ABBREVIATIONS**

- 4.1. CM – Contract Manufacturer (as applicable)
- 4.2. CR – Change Request
- 4.3. DMR – Device Master Record
- 4.4. ERP – Enterprise Resource Planning
- 4.5. FDA – Food and Drug Administration (US)
- 4.6. MDF – Medical Device File
- 4.7. MDL – Master Document List
- 4.8. MR – Management Representative
- 4.9. NB – Notified Body
- 4.10. QM – Quality Manual
- 4.11. QMS – Quality Management System
- 4.12. QSP – Quality System Procedure
- 4.13. WI – Work Instruction
- 4.14. WIP – Work-in-Progress



- 4.15. UDI – Unique Device Identifier
- 4.16. R&Q associate – Regulatory and quality management associate
- 4.17. CTO – Chief Technology officer
- 4.18. CEO – Chief Executive Officer
- 4.19. SD – Software Developer

## 5. RESPONSIBILITIES

- 5.1. The MR or R&Q associate is responsible for maintaining this procedure in a current state. All employees are responsible for controlling and handling documentation in accordance with this procedure's requirements.
- 5.2. All personnel/departments involved with the change control process are responsible for complying with the requirements of this procedure.
- 5.3. The originator is responsible for ensuring that documents are clear, concise, accurately describe the process being documented, and the change request is complete and accurately describes the changes being made to the documentation or data in the QMS.
- 5.4. R&Q associate is responsible for the implementation and management of the documentation and data control that is produced within the QMS.
- 5.5. Designated functions/organizations within this procedure are responsible for ensuring that they have access to pertinent background information upon which to base their review and/or approval.

## 6. PROCEDURE

- 6.1. This procedure shall be utilized for checking documents related to Before Health Intelligence Ltd.'s QMS documentation and any changes to those documents.
- 6.2. All the forms will be filled out electronically by enabling Track Changes in word Doc.
- 6.3. Follow this procedure when generating or revising a document related to a process or work being accomplished at the company e.g., but not limited to:
  - The Quality Manual or QMS procedures or forms, including work instructions or plan/report templates,
  - Product data, such as specifications, inspection plans, DMR, etc.,
  - Any labels and instruction for use for the product,
  - Marketing materials, such as literature, sales brochures, etc., and
  - Any other document used in the QMS.

**IMPORTANT:** Handwritten corrections or electronic “redlines” to any controlled document without the document being re-issued to the next revision level are not permitted without approval. “Redlined” versions of documents can be used within the review process or archived separately by R&Q associate after approval to record the changes made to a document, but the final approved document issued for use (e.g. printed / PDF) must be a “clean” document.

### 6.4. Document Numbering Scheme

All information contained herein is confidential and proprietary. All design, manufacturing, use, reproduction, & sales rights are expressly reserved. Communication of this information to others is prohibited.



- 6.4.1. All new documents or procedures are assigned a Document Name (Title), Document Number and starting Revision Level. For new documents assign the new number according to the Master Document List (MDL) to ensure this number has not been previously assigned.
- 6.4.2. All the signatures on the document will be manual if electronic signature is validated and comply with CFR part 11 can be used.
- 6.4.3. Only MR or R&Q associates are authorized to assign part or document numbers from the MDL (assignment log)
- 6.4.4. Enter the new document number with starting revision on the MDL, ELT-RQ-001-03.
- 6.4.5. All new documents are assigned a unique and sequential number according to the TYPE-Two Letters designating the department- XXX. Additional digits can be added to create unique and sequential numbering for sub-sets of documents within the section such as revision which add additional two-digit numbers as shown below refer to table 1.

Table 1. Acronym for document types and areas

Document type	Acronym	Department	Acronym
Quality System Procedure	QSP	Software Development	SD
Forms	FRM	Regulatory and Quality	RQ
Log sheet	LOG	Administration	AD
Electronic List	ELT		

As an example, the first QSP number and its' first related documents that would be issued for

Analytical Development Area are:

Quality system procedure: QSP-AD-001

Forms: FRM-SD-001-01

Log sheet: LOG-RQ-001-01

List: LST-RQ-001-01

- 6.4.6. For forms that have been Opened for any test, change request, evaluation, validation ...etc. the numbering will be as follow

Form Name	Reference number
Change Request	CR-YYYY-XXXX
Corrective action and preventative action	CAPA-YYYY-XXXX
Evaluation and validation for non-medical device	EVA-YYYY-XXXX

Where X refers to a number starting from 0001.

Y refers to the year the document was initiated.

- 6.4.7. Document numbers are assigned to various documents within the QMS: procedures, forms, etc., and are not to be reused if the document is later obsoleted.

6.4.8. If a document title is modified (however scope remains generally the same), complete a Change Request (CR) and retain the document number. If the procedure is being replaced with a new procedure/scope, obsolete the old procedure and acquire a new document number.

6.4.9. Documents are also identified with the current revision level, and an effective date.

## 6.5. Creating New Documents

6.5.1. New documents are generally created by the department/function requiring them and are reviewed by the department manager, President and/or MR or other designated personnel.

6.5.2. Utilize controlled templates where available in creating the documentation.

6.5.3. Secure all comments and suggestions for new / revised documents from appropriate personnel.

6.5.3.1. Revised documents are reviewed and approved in accordance with **Step 6.5**.

6.5.3.2. New documents are reviewed and approved in accordance with **Step 6.7**.

6.5.3.3. QSP Document Formatting for Compliance

- Page size: letter.
- Font: Calibri.
- Font size: 12.

6.5.3.4. Forms, Log sheets, Lists, and Electronic Lists

- Page size: letter.
- Font: Calibri.
- Font size: preferably 12, but it can be reduced to a minimum of 9 to fit all the necessary information to facilitate data comparisons.

## 6.5.4. Header and Footer

The minimum features that the header should include are the company logo, the document title, and the document number. the Change Request Number (CR#) and revision number. The footer should display page numbers. It should be ensured that the information contained in the header and footer is not too close to the edge of the page, since it can be lost when printing or scanning the document.

## 6.6. Updating Controlled Documents

### 6.6.1. A desired change is found that impacts:

- QMS documentation,
- Marketing material,
- Product (including materials, labeling, data, quality, etc.), or
- New product (design transfer or other identified design documents)

6.6.2. An initial review of the changes to be made should involve all applicable parties prior to initiation of the CR process.

6.6.3. A CR, Form FRM-RQ-001-01 Change Request can be used by any employee to initiate a change for a new controlled document or update to an existing document.

6.6.4. Attach red lines, drawings, documents, labels, or other supporting information applicable to the request. The information for the proposed change, along with the supporting documentation, must be sufficient to carry out the intended change without need for interpretation.

**Note:** The triennial review table is to record the Triennial Review information if the QSP was decided not to be modified during review. Thus, for new QSPs this table should be blank, and it is designed for manual entries only. Since Related Documents are reviewed and assessed together with QSP review, there is no need to include a "Next Review" date on the Approval Table nor a Triennial Review table. For these documents, the risk assessment should be captured in the same Change Request as the QSP.

## 6.7. Document Review

6.7.1. Documents are reviewed for the following, including but not limited to:

- Content and suitability, including clear directions.
- Compliance with applicable regulatory requirements, standards, regulations.
- Associated procedures, work instructions, forms, or records; and
- Ensuring a complete list of affected items on the CR.

6.7.2. Any discrepancies, changes or clarification required will be reviewed with the initiator of the document/revision and appropriate changes made and reviewed as described above.

6.7.3. Changes to documents are reviewed and approved by the same function or department that approved the initial document, unless specifically designated otherwise.

**Note:** For example, if an original document was generated by Engineering, an Engineering representative should review the information for the change requested.

6.7.3.1. Ensure the designated functions/organizations have access to pertinent background information upon which to base their review.

6.7.4. The next sequential, unique CR number is assigned from the Change Request List, ELT-RQ-001-01 by the MR or R&Q associate.

6.7.5. The format must be CR-YYYY-XXXX where YYYY are the year of initiation and XXXX is the number starting from 0001

**Note:** The CR number may not be known at the time personnel are completing the CR form but can be assigned once the initial CR information is gathered and confirmed acceptable.

6.7.6. Complete the CR with all applicable information and ensure the form is complete prior to submission. The following information will be completed:

**Note:** When initiating a CR, determine whether the design of the product is impacted, if applicable, the requirements of QSP-SD-002 Design and Development regarding design changes may also need to be followed.



**Note:** the change request form encompasses both documentation and the intricacies of software version control.

**6.7.6.1. Section A: Description of Change**

- Change Request Number
- Initiator
- Initiation Date
- Document Information (Number, Title, Current Revision, New Revision), if applicable
- Initiated From (as applicable: Complaint, CAPA, other CR, etc.; provide ref. #)
- Change Type; check all applicable boxes, if Other is checked explain change type
- Description of Change. Summary description of the change, attach redlines, drawings, labeling, etc. when applicable.
- Reason for Change / Justification. The reason and justification for the change. Justification shall include a statement of evidence and reference to necessary verification or validation activities to substantiate the change, if applicable.
- Version control related features are included within the form.

**6.7.6.2. Section B: Documents Impacted / Material Disposition (e.g. Inventory, WIP)**

- Record any other documents affected, that are not part of this CR and what actions are required; if none, check box N/A.
- Record materials affected and dispositions, if none, check N/A box.

**6.7.6.3. Section C: Verification and Validation Assessment**

- Assess whether verification or validation testing is required or justify why not with rationale and who approved.
- All design and production process control changes must be verified.
  - Verification activities include tests, inspections, analyses, measurements, or demonstrations.
  - Design and production process control changes must also be validated, unless only conducting verification can be justified and documented.
- Where a design or production process control change cannot be 100% verified by subsequent inspection and test, it must be validated.
- Initial production items or their equivalent shall be used in validation/verification activities.
- When equivalent devices are used for verification or validation, it must be documented in detail how the production is similar to/different from initial production.
  - Where there are differences, it must be documented why the validation results are valid for the production items.
- Process validations may be conducted concurrently with design validations; however, verifications and validations will be completed prior to release of product for sale.

- Provide details and ensure that items are completed prior to the CR approval date or a plan must be established for these activities if more time is needed to complete.
- Record objective evidence (verification and validation performed / test reports), when received and where located.

#### 6.7.6.4. Section D: Risk Assessment of Change

- Record Risk Management documentation reviewed against the change and document whether there are any effects to risk, e.g. new hazard, change in severity /frequency, etc.
- If there are any changes in the Risk Management documentation, record on the CR what updates were made and verification activities that occurred.

#### 6.7.6.5. Section E: Implementation Plan

outlines the steps required to put the approved change into effect. It's essentially a checklist and task assignment section to ensure the change is rolled out correctly.

- Tasks: It lists the specific actions that need to be completed to implement the change.
- Responsibilities: It assigns each task to a specific person or team.
- Status Tracking: It provides a way to track the progress of each task.
- Due Dates: It sets deadlines for completing each task.
- Jira Integration: It includes a field to link to a Jira ticket, if your organization uses Jira for task management.

#### 6.7.6.6. Section F: Additional Items to Consider for Change

Any potential broader impacts or requirements related to the change beyond just the immediate documentation or material disposition.

- Training Requirements: Does this change necessitate training for users or personnel?
- Impact on other processes or systems: Does this change affect anything else not directly listed in Documents Impacted?
- Regulatory implications: Are there any specific regulatory requirements triggered by this change?

#### 6.7.6.7. Section G: Additional Items to Consider for Change

- Review the list and identify any additional affected items.
- For items marked 'Yes', the initiator will ensure that these items are completed prior to the CR Closure/Effective Date, or a plan must be established for these activities if more time is needed to complete.
- Record Completion Dates for each item marked 'Yes'.
- Record data to support completion in the 'Objective Evidence' section of the CR form. Copies of the data can be attached to the CR form.

**Note:** Refer to Appendix B: Change Notification for guidance on reporting to regulatory authorities.

### 6.8. Document Approval

- 6.8.1. The document, including all details and any impacted items, will be reviewed and approved for adequacy prior to use.
- 6.8.2. Obtain required signatures / approvals on the CR form (see Section F: Authorization for Change Approval)
- 6.8.3. CR review and approval is required from individuals identified below at a minimum:

Document type	Minimum Approvers
Quality Policy, Quality Objectives	<ul style="list-style-type: none"> <li>• CEO</li> </ul>
QM	<ul style="list-style-type: none"> <li>• CEO</li> <li>• R&amp;Q associate or MR</li> </ul>
QSPs & associated Forms	<ul style="list-style-type: none"> <li>• CEO, Department Manager, CTO, SD or MR</li> </ul>
Work Instructions & Associated Forms	<ul style="list-style-type: none"> <li>• Department Manager/Supervisor, and/or R&amp;Q associate, MR, CEO, CEO or SD</li> </ul>
Product Labeling, including Marketing Materials	<ul style="list-style-type: none"> <li>• Development Manager, and/or R&amp;Q associate or MR, CTO</li> </ul>
Other QMS Documents	<ul style="list-style-type: none"> <li>• To be determined by R&amp;Q associate ME or SD</li> </ul>

- 6.8.4. Each person is responsible for thoroughly reviewing the CR and the associated documents, as well as their respective 'impact' areas related to the change prior to approval. The decision must be unanimous to proceed with the CR.

- 6.8.5. If any changes are made to the CR, the documents are then re-routed for approval.

**Note:** If the CR is rejected, an explanation must be documented and communicated to the initiator. The CR Log will be updated, and the rejected CR documentation will be retained per QSP-RQ-003 Control of Records.

- 6.8.6. Once the CR has been approved, the R&Q associate or MR will complete Section H: Notification to 3<sup>rd</sup> Parties on Form FRM-RQ-001-01 Change Request and notify all affected parties (including as appropriate a Supplier, CM, or Customer), that the CR has been approved and the change is ready to implement.
- 6.8.7. Record when any 3rd party was notified as well as any (required) confirmation of the change. Attach copies of any notification / confirmation to the CR.

### 6.9. Training Requirements

- 6.9.1. Following the approval of the change, the MR and R&Q associate will document on the CR whether training is required prior to implementation, reference QSP-RQ-004 Training and Qualification.
  - If training is not required, record rationale.
  - If required, record the date of the notification to affected parties and attach a copy of the notification.

- Training is generally required prior to the use of new or revised procedures/documents.
- Training of staff is coordinated by department managers.  
**Note:** Training is generally not required on drawings, specifications, labeling, DMR, etc.

6.9.2. The CR form includes the Effective Date of the change.

#### 6.10. Master Document List

6.10.1. After the CR form and log are finalized, update the MDL. The MDL is maintained by and available from the R&Q associate (or is available on-line in a protected format).

6.10.2. The MDL contains the following information: document number, document title, current revision level, effective date, next review date (see **Step 6.13**), who reviewed the document with date reviewed, CR#, and location/distribution points.

**Note:** External documents are listed on ELT-RQ-001-02.

6.10.3. If the Implementation Date is different from the Effective Date (e.g. due to the need to provide training) then note this on the CR and document the Implementation Date after all training is completed.

6.10.4. Update the MDL date located at the top of the form once documents have been approved via the change control process.

#### 6.11. Distribution of Documents (Internally Created)

6.11.1. The MDL identifies all locations of the documentation (point of use) (as applicable). Each distribution point maintains released controlled versions of the documents.

6.11.2. Notify all affected parties of changes (i.e. via e-mail) when document implementation is complete.

6.11.3. All the effective documents related to quality assurance and regulatory will be available for training electronically on (google workspace).

6.11.4. Google workspace is considered the electronic platform in which all Before Health Intelligence can access quality and regulatory documents and archive.

6.11.5. Documents directly related to the Development of (SaMD) and to its development progress are distributed to document stations or accessible in an electronic form in the development areas. For custom device orders, specifications are enclosed with the development work order as applicable, reference QSP-RQ-006 Customer Order Process.

6.11.6. Electronic documents are posted on the network and are available for viewing and printing as authorized. When a document is revised, the old edition is removed from the network location to another electronic location and is replaced with the revised document.

6.11.7. Electronic documents are regularly backed up from the computer and these back-ups are moved to a special folder in google workspace for storage retention purposes, reference QSP-RQ-003Control of Records.

6.11.8. All approved documents will be archived manually in a physical place with in Before Health Intelligence main site.

6.11.9. Documents that are printed from the computer without an authorized signature on the physical document are considered uncontrolled copies for one-time use only.

**Note:** Personal copies of any document are not permitted. Only controlled copies of documents are to be available in the location(s) identified on the MDL.

6.11.10. Documents issued to personnel and outside parties who are not affected by the document, but need a copy for information only, are stamped UNCONTROLLED across the title page (or if electronic, watermarked by Document control before providing). Such documents are not followed up with revisions.

6.11.11. Originals of documents are retained by the MR or R&Q associate.

6.11.12. All obsolete copies are to be stamped or marked OBSOLETE. At least one (1) copy of the obsolete document is maintained in a separate location from active documents and the storage location clearly identified, another electronic copy will be stored in the electronic database and in a physical place in a paper form. Refer to QSP-RQ-003 Control of Records.

## 6.12. Periodic Document Review

6.12.1. The primary responsibility for carrying out periodic reviews is with the end user, who must ensure that documents are complete and current, or are needing revision / no longer applicable.

6.12.2. Company personnel are also encouraged to continually evaluate the documents they use and request revisions for changes to processes, correction of errors, and inconsistencies.

6.12.3. At any time when content is found needing updating, the end user must initiate a CR and amend or "red-line / track-change" a copy of the document and forward the CR as detailed in **Step 6.6**.

## 6.13. Annual (Internal) Document Review

6.13.1. On at least an annual basis the MR and designated personnel are responsible for a review of the following documents:

- Quality Manual,
- QSPs and associated forms, and
- WIs and associated forms.

6.13.2. The purpose of this review is to ensure the continuing suitability of the QMS documentation in describing the quality activities of Before Health Intelligence Ltd.

6.13.3. Input from affected functional groups will be requested, as necessary.

- When a new document has been identified proceed to **Step 6.4**.
- When changes have been identified, issue a CR per **Step 6.5**.

6.13.4. Document reviews are recorded on the MDL, ELT-RQ-001-03, including, but not limited to the following items:

- Document reviewed (including document number and title),
- Current revision,
- Effective date,
- Reviewer,
- Date reviewed,
- Whether changes are required or not (include CR # if applicable), and
- Next review date.

6.13.5. Any proposed changes, as a result of the review, will be discussed with the affected department /function and made in accordance with this Procedure.

6.13.6. Update the MDL date located at the top of the form and maintain in accordance with QSP-RQ-003 Control of Records.

#### 6.14. External Documents

**Note:** See Sec. 3 for the definition of an external document

6.14.1. External documents applicable to Before Health Intelligence Ltd. are documented on ELT-RQ-001-02 External Document List.

6.14.2. New or revised external documents are to be reviewed by a knowledgeable individual (e.g. Engineering, President, Sales, and/or MR) who checks Applicability to Before Health Intelligence Ltd.'s products and/or QMS.

6.14.3. If applicable for Before Health Intelligence Ltd., review uploaded external document for changes, updates, or new requirements to the QMS, product testing, product records, etc.

6.14.4. Proceed to **Step 6.5** and complete a CR form for the new or revised external document as needed.

6.14.5. CEO, MR or R&Q associate representatives may use various external resources for documents and standards (e.g.: FDA, ISO, GHTF, ANSI, AAMI, ASQ, CLSI or other) to assure most current versions are identified.

6.14.6. External documents currently on file at Before Health Intelligence Ltd. are reviewed at a minimum annually to ensure they are the latest / most current document revision. The reviews of external documents can be performed using the following websites:

- [www.newapproach.org/Directives/Default.asp](http://www.newapproach.org/Directives/Default.asp)
- [www.emergobyUL.com](http://www.emergobyUL.com)
- [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm)
- <http://global.ihs.com/>
- [www.emergobyul.com/rams](http://www.emergobyul.com/rams)
- <https://iec.ch/academy/online-learning-platform>
- <https://www.iso.org/about>

**Note:** As websites change from time to time, staff may need to search for the current/updated website.

6.14.7. Record the search date and the personnel who performed the search(es) on ELT-RQ-001-02 External Document List.

6.14.8. Identify any new, revised, or updated regulations, standard and/or guidance documents. If applicable in order, obtain or reference the hyperlink of the regulations, standards and/or guidance documents.

6.14.8.1. For purchased external documents, complete ELT-RQ-001-02 External Document List.

6.14.8.2. For publicly available external documents, use the CR to update documents containing hyperlinks

6.14.9. If it has been determined that an existing external document is no longer applicable to Before Health Intelligence Ltd., use the CR process to remove/obsolete the document, and/or update the External Document List.

**Note:** When changes to standards, regulations, guidance documents, etc. have been made, the differences between the versions need to be reviewed to determine whether or not the QMS, related product records or testing is still sufficient, or if these need to be updated. If necessary, contact the test laboratory or supplier that performed the original testing for assistance. This data is also to be documented on the CR.

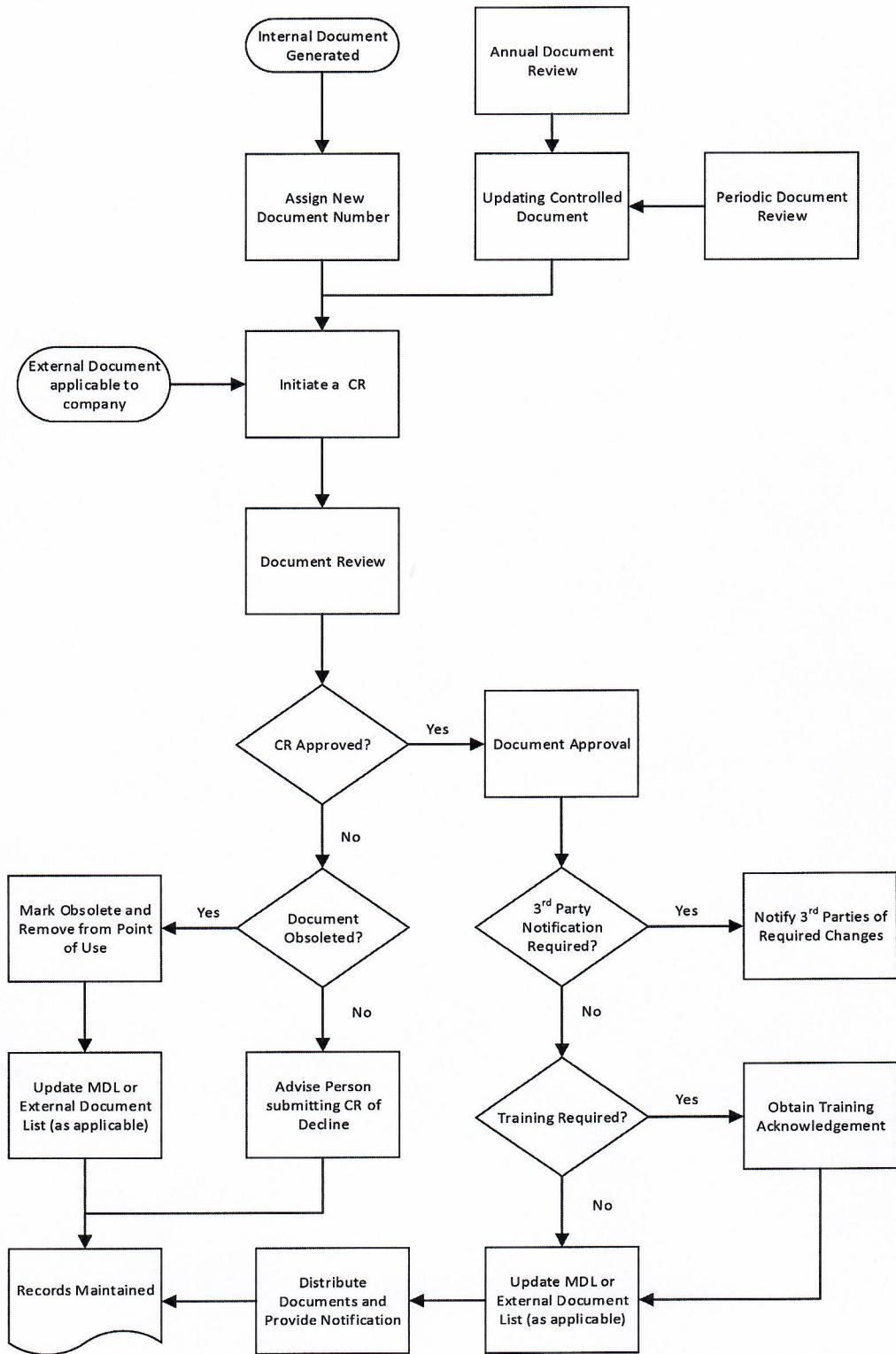
**Note:** When new standards, regulations, guidance documents, etc. are identified and obtained, the documents need to be reviewed to determine whether or not the QMS, related product records or testing is still sufficient, or if these need to be updated. If necessary, contact the test laboratory or supplier that performed the original testing for assistance. This data is also to be documented on the CR.

6.14.10. Changes affecting internal documents from any external document are discussed with the affected department(s) and/or function(s) and processed via **Step 6.7**.

## 7. QUALITY RECORDS

- 7.1. QMS documents are maintained in a controlled location to prevent loss or deterioration and allow accessibility of the documents.
- 7.2. R&Q associate maintain and update the MDL.
- 7.3. Maintain all prior (obsolete) versions of documents. Only one copy, clearly identified as "OBSOLETE" shall be maintained.
- 7.4. File all completed CRs in sequential order.
- 7.5. External document reviews, which are documented on the External Document List, ELT-RQ-001-02 are retained in a designated file.
- 7.6. Documents and records listed throughout this procedure are retained in accordance with QSP-RQ-003 Control of Records.

## 8. PROCESS FLOWCHART



All information contained herein is confidential and proprietary. All design, manufacturing, use, reproduction, & sales rights are expressly reserved. Communication of this information to others is prohibited.



## Appendix A: Adobe PDF Electronic Signatures

1. The Adobe PDF electronic signature has been recognized by the FDA as an acceptable method. This is considered a “flat” signature that contains the name and the date/time signed.
2. The Adobe PDF signature requires the user to enter a password to complete their signature.
3. Adobe PDF signatures:
  - a. Only authorized roles shall sign QMS-related documents according to this procedure and as specified in other QSPs and/or WIs.
  - b. Adobe PDF signatures require the following:
    - Name
    - Title
    - Email
    - Company
  - c. Adobe PDF signatures are set up at time of hire and information is documented on a Signature Log, referring to FRM-RQ-004-07, Signature Log.
4. Password and desktop security clause:
  - a. Keep passwords secure and do not share accounts. Authorized users are responsible for the security of their passwords and accounts.
  - b. PCs, laptops and workstations should be secured with a password-protected screensaver with the automatic activation feature set at 10 minutes or less, or by logging off when the host will be unattended.
  - c. Strong Passwords have the following characteristics:
    - Contain at least three of the five following character classes:
      - Lower case characters
      - Upper case characters
      - Numbers
      - Punctuation
      - “Special” characters (e.g. @#\$%^&\*() +|~-=\{}[]:;';<>/ etc.)
    - Contain at least fifteen alphanumeric characters.
  - d. Weak passwords have the following characteristics:
    - The password contains less than fifteen characters
    - The password is a word found in a dictionary (English or foreign)
    - The password is a common usage word such as:
      - Names of family, pets, friends, co-workers, fantasy characters, etc.
      - Computer terms and names, commands, sites, companies, hardware, software.
      - The words "<Company Name>", "sanjose", "sanfran" or any derivation.
      - Birthdays and other personal information, such as addresses and phone numbers.
      - Word or number patterns like aaabbb, qwerty, zyxwvuts, 123321, etc.
      - Any of the above spelled backwards.
      - Any of the above preceded or followed by a digit (e.g., secret1, 1secret)

## Appendix B: Change Notification

**Types of changes that may need to be reported to the following:**

Changes	FDA	NB
Changes in the location of the firm	X	X
Change in ownership of the firm	X	X
Change in Management Representative and/or Official Correspondent	X	X
Significant changes in the QMS, including new or revised ISO 13485 certificate	X*	X
Change in trade name and/ or reorder numbers	X	X
<u>USA:</u>		
- Significant changes in the Medical Devices products sold in US (510(k); Device Listing; etc.), including new or deleted products, new product classifications – update to Device Listings	X	
- Changes in US FDA Establishment type (e.g. manufacturer, specification developer, etc.)		
- Exporting only of US manufactured products		

\*Change is type of Establishment Registration

**Note:** Timeframes for notifications may apply in some situations. Refer to specific country procedures and/or regulations.

For assistance in determining if the change is significant, refer to the following guidance document links:

### US (FDA)

Changes to Establishment Registrations and Device Listing updates should be made at any time throughout the year to ensure information is current.

Examples of changes that would require updates include:

- Another device being introduced for distribution in the US
- Change to previously listed device, such as where manufactured
- Change in proprietary or trade names
- Removing device from commercial distribution in the US

- Change in establishment location or establishment type
- Change in Official Correspondent / FURLS account contact

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm)

For guidance on device changes refer to : [www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514771.pdf](http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514771.pdf)

For guidance on device software changes refer to: [www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514737.pdf](http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514737.pdf)

For guidance on device software changes related to Artificial Intelligence / Machine Learning (AI/ML) Enabled Device Software Functions refer to:  
[www.fda.gov/media/166704/download](http://www.fda.gov/media/166704/download)

**Note:** Although this says in the title it is for AI/ML devices, the FDA has discussed predetermined change control plans as potentially being applicable for any devices – so should especially be considered for software devices. This is a draft guidance as well.

**END OF DOCUMENT**

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