Gap Analysis- QMS

DHF/DMR/DHR/TF

- Per *21 CFR 820.30 (j): Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part. (FDA QS Regulation, 2015)*
    - We need to establish a DHF and DHF SOP per the FDA and our own Quality Manual §4.2.1.3
- QMS Procedures – Relationship to Regulations and Standards Map
    - Establishing the relationship of current QMS to all MD standards.
- Need a Technical File (TF) perMedical Device Directive (MDD; EU Council Directive 93/42/EEC)
- Trackability Matrix - Verification/Validation tracking
- See DHF/DMR/DHR/TF BOM

Requirements Document

- Missing a full list of product requirement inputs
- Requirement document drives inputs that then drive metrics
    - Engineering metrics can be derived from the requirements doc for product testing.
- Metrics drive verification.
    - Robust verification reduces validation (lean manufacture)

Drawing update

- Drawings are under standardized
    1. Templates
        - New format: All drawings (A3) sheet
        - (A4) Sheet will be set aside to specs, WI, SOP's, etc.
    2. Drawing standards SOP
- Not enough information for inspection
    1. Tolerance analysis

2. V&V inputs for outputs

- Not enough input requirements.
    1. Requirements map
- Label drawings and/or Label SOP
- Apply design controls
    1. Read only/locked Folder for released/signed drawings

Missing Files

There are many missing or orphaned files in the QMS.

- DMR index (required)
- Updated existing drawings
- Create drawings for missing products, processes, or procedures.

SOP Update

- Many SOPS are out of date, we need an SOP review/audit
- ~~SOP's should have an approval page, usually on the title page.~~

Review and Approval			
Author: Author's Name Title: Author's Title	Signature:	Date: .....
Reviewers		
Quality: Reviewer's 1 Name Title: Quality Manager	Signature:	Date: .....
Content: Reviewer's 2 Name Title: Reviewer's 2 Title	Signature:	Date: .....
Final Approval: Final Approver's Name Title: Final Approver's Title	Signature:	Date: .....

- Need to modify SOP naming convention (Drop Rev letters in title)
    - SOPS titles should drop “rev” in the title. This triggers too many changes to other “Related Documents” SOPs when making small changes.
    - Once Rev is dropped all SOP’s need to reference “(Latest Revision)”.
    -
    - Example listing related documents: Old way
        - *SRG_QMS_02SOP_A500-**A*** Management Responsibility Procedure
        - *SRG_QMS_02SOP_M710-**A*** Planning of Product Realization Processes Procedure
        - SRG_QMS_1TLP_001-**C** Quality Manual

      Industry Standard
        - *SRG_QMS_02SOP_A500*- Management Responsibility Procedure (Latest Revision)
        - *SRG_QMS_02SOP_M710*-Planning of Product Realization Processes Procedure (Latest Revision)
        - SRG_QMS_1TLP_001- Quality Manual (Latest Revision)
    - SOP Numbers should be short and straightforward. (i.e. WI301156, SRGFRM431-1, etc)
    - ~~Numbers need to be imbedded in document in the heeder or footer.~~
    - There is no ERP system to maintain or track changes though out the QMS.

- Implement ECN SOP.
- No barcode SOP
- Messing or orphan SOP’s: Part Number SOP, SOP to write SOP’s, LOT and Batch generation.

- Manufacturing SOPS's need updating. (SLICK Man is out of date and does not reflect what's being produced)
- Need to modify SOP naming convention (Drop Rev letters in title)
    - SOP Numbers should be short and straightforward. (i.e. WI301156, SRGFRM431-1, etc)
    - Numbers need to be imbedded in document in the heeder or footer.
- Need to implement a title block to all SOPS

Work Instructions

- Work instructions need to be updated to include V&V QC
- New SOP for next Gen WI.
- Update all WI

Risk documentation

- Three is no risk management plan or documentation per our own "SRG_QMS_2SOP_E711-B Risk_Management"
- Fault tree, HA, FMEA and other risk identification and mitigation documentation are needed.

Quality documentation

- Quality test documentation is out of date
- Date of manufacture is missing from quality sheets.
- Quality Sheets are missing "label"
- Changes:
    - Change Doc control SOP (SRG_QMS_1TLP_003-C QMS Doc_Structure)
        - Add DHF §1.4, DHR §1.5 & TF/DD §1.6
        - SRG_QMS_2SOP_A423-C Document_Control
            - Remove "rev" requirement from Doc ID §6.7
            - Example (SRG_QMS_2SOP_M752-B Valid_of_Proces_For_Prod_Real) refers too:
                - RG_QMS_02SOP_E730-A

        - SRG_QMS_2SOP_A423-A
        - If the above docs are changed then the relative doc will need to change too.

- SRG_QMS_1TLP_006-D Surgionix Organisation Chart
    - Need to update Org Chart
- SRG_QMS_2SOP_E711-B Risk_Management
    - Not following Risk Management
        - Need HA, FMEA (new forms)
- SRG_QMS_2SOP_E730-D Design&Development
    - Refers to R&D Manger. That role isn't mentioned anywhere.
- SRG_QMS_2SOP_M753-B Identification&Traceabilty
    - Needs to include a section of inwards goods identification for traceability
    - Refers too **(SRG_QMS_02SOP_Q830-A),** another Rev issue. Latest revision is Rev B.
- SRG_QMS_2SOP_M824-B MM&A_of_Prod_Real_Processes refers too SRG_QMS_02SOP_M710-A, furute Rev issue.
- SRG_QMS_2SOP_M760-A Ctrl_of_Meas&Monit_Devices
    - No Eq coordinator.
    - Equipment is uncalibrated.
    - No internal calibration control or stickers indicating calibration date(s)
        - Can't find:
            - Calibration List
            - Equipment Logs
            - Calibration Certificates and Records