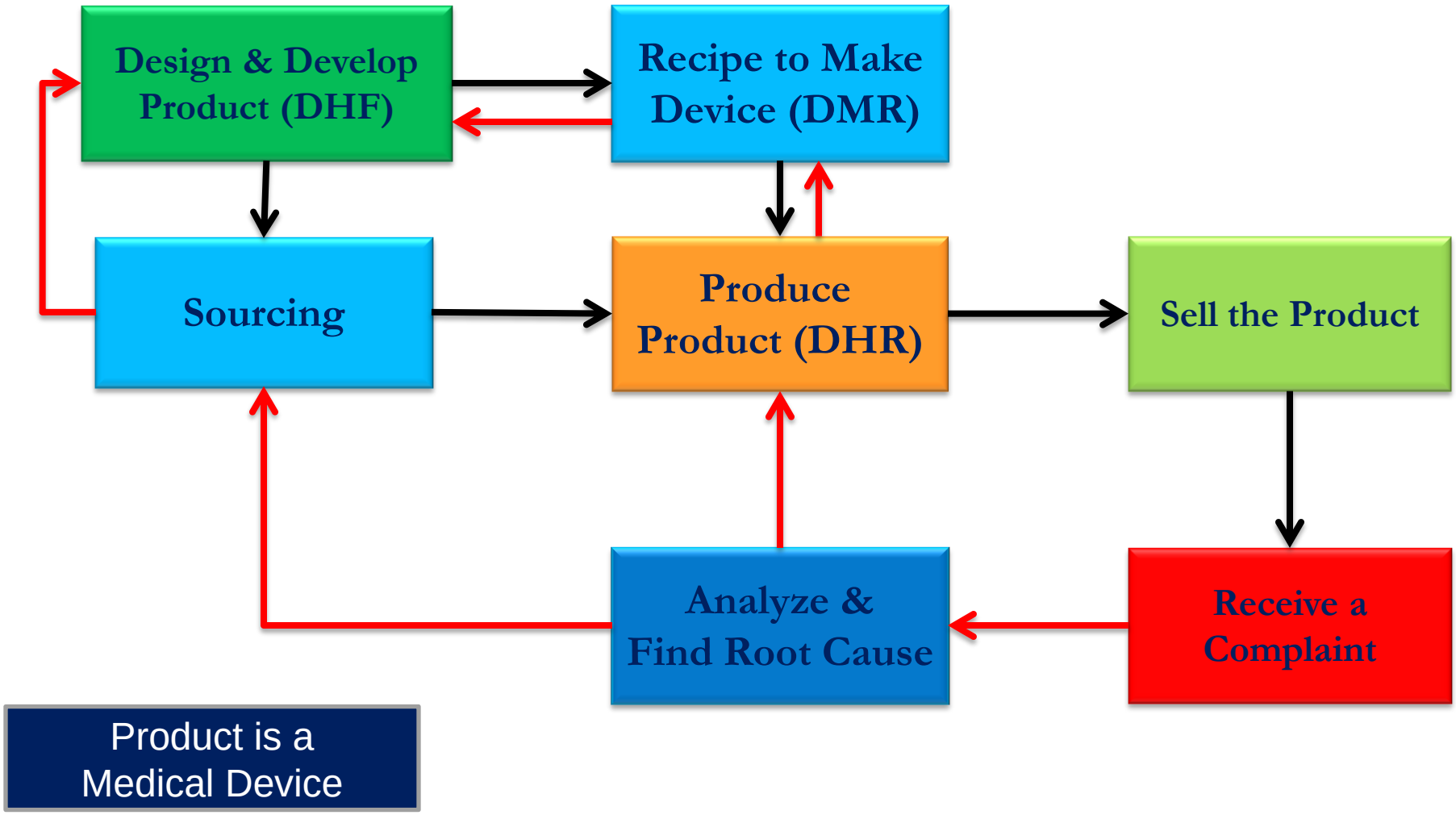


Warning Letters and Compliance

Rama K Pidaparti

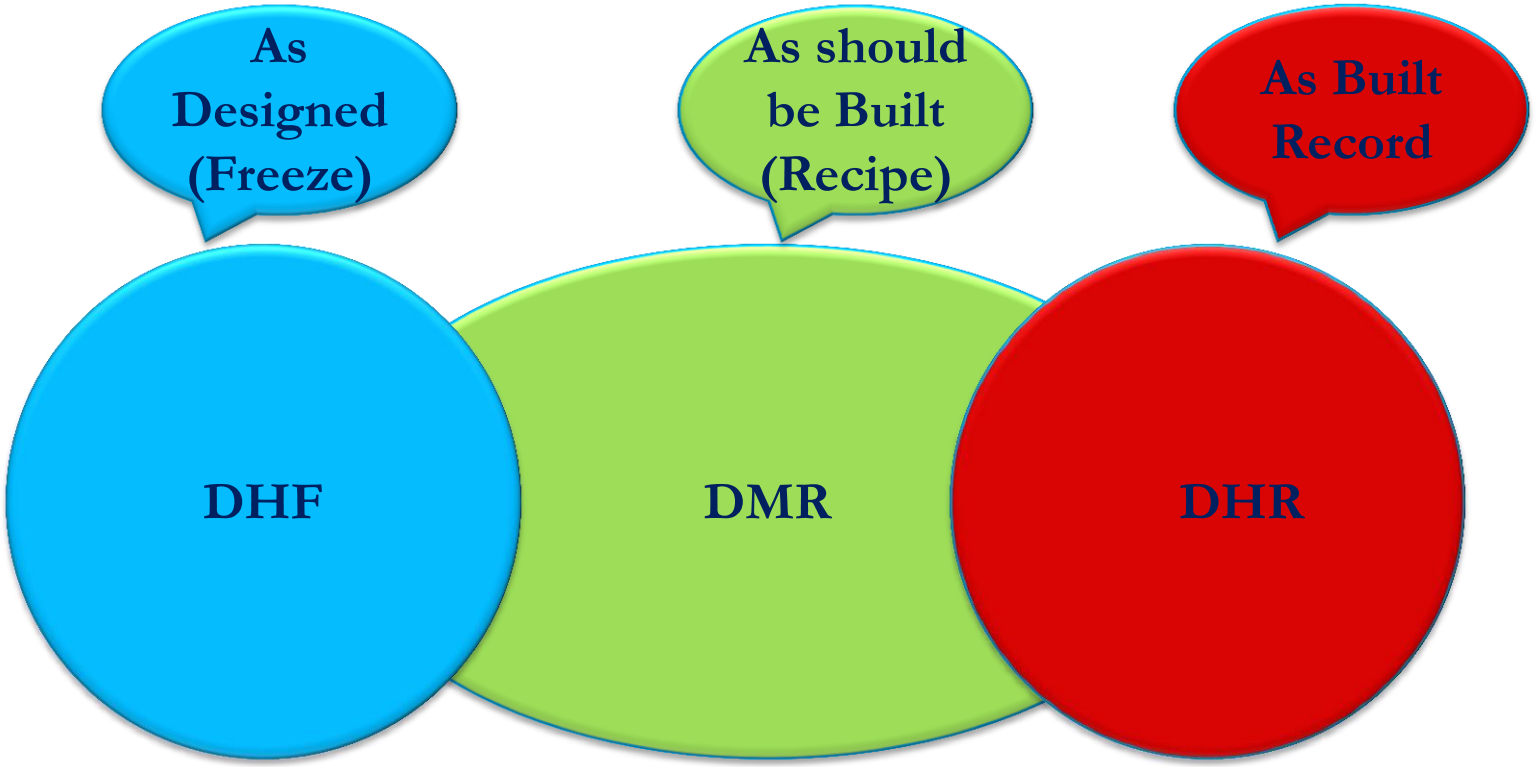
Medical Devices SME - QARA

Lifecycle of a Product – System view



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Relationship between – Design History File (DHF), Device Master Record (DMR) & Device History Record (DHR)

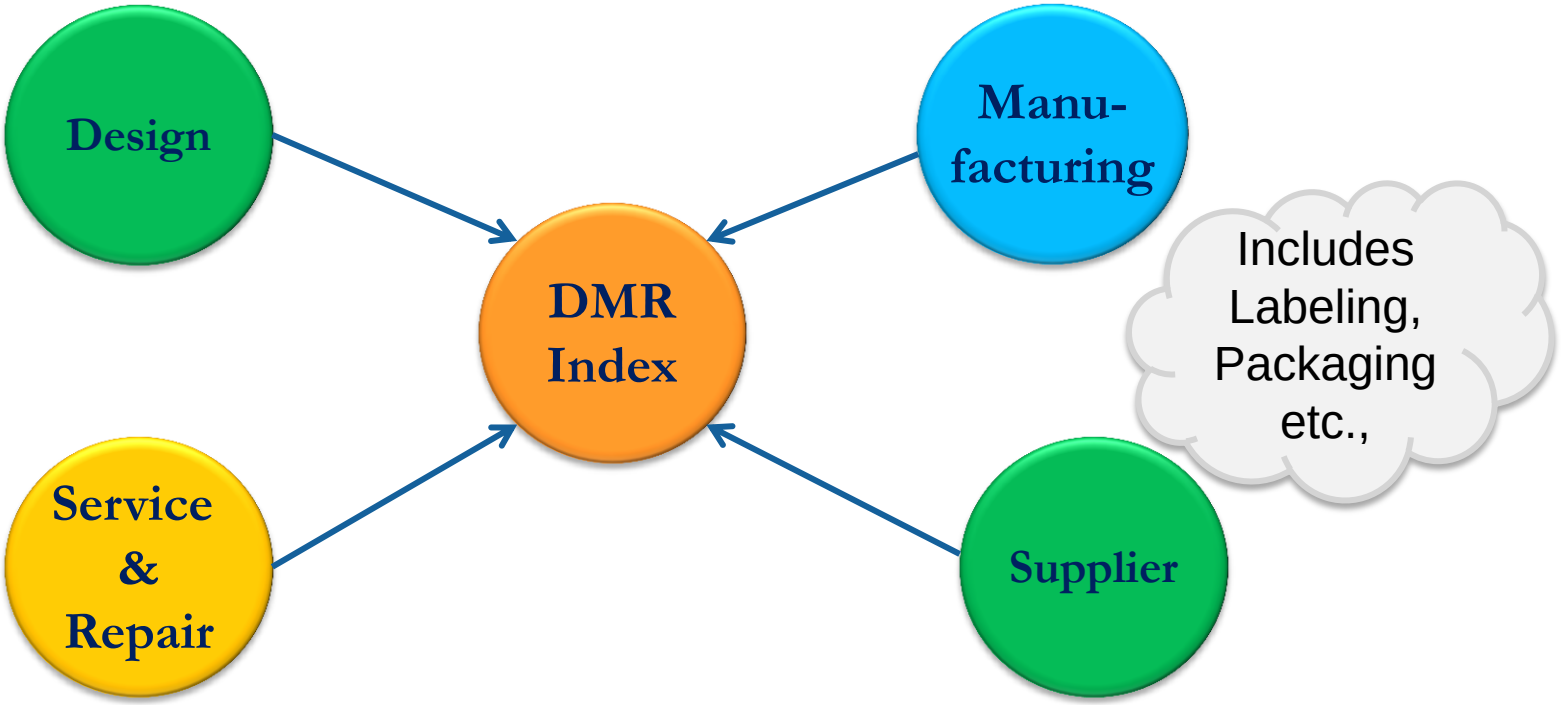


Commonality is NOT to scale

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DMRs

DMR is a Regulatory Requirement (820.181)
DMR Index is created enhance the identification and rapid retrievability of documents that make up a DMR (recipe)



DMR Index can also illustrate traceability in support of finding the root cause of a complaint handling process after DHR review

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Elements of DMR

Design Specifications

- Drawings
- Product Specifications
- Medtronic General Specifications

Sourcing / Purchasing Documents

- Inspection Procedures (IPs)
- Supplier Quality Agreements (SQA)
- Preparatory procedures – e.g. cleaning, passivation, sterilization, parts trimming

Manufacturing Documents

- Process Plans (PPs)
  - MES
  - Process Plans
  - Process Planning Matrix (PPMs)
  - Master Validation Plan (MVPs)
  - Process Validation

Service and Repair Documents

- Assuming product is serviceable
- Service Documents

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Systems Accessed

Product Design Specifications	• **PLM**
Manufacturing Documents	• **MES** • **Document Management Systems (DMS)**
Sourcing Documents	• **ERP** • **Supplier Quality Agreements in ERP or DMS** • **Inspection Procedures in DMS**
Service and Repair Documents	• **CRM or DMS systems**

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DMR Index Assembling

- 4 BOMs
  - Design
    - Manufacturing (Assembly)
    - Supplier (Inventory)
    - Service
- Some Business Rules
  - Document only what is needed – not everything in a BOM
    - Watch out for Phantoms
    - How far do you go traversing the BOM – when do you stop
- Assemble it, get it reviewed and approved by an independent person
  - Like everything else in the GxP world.

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Case Studies



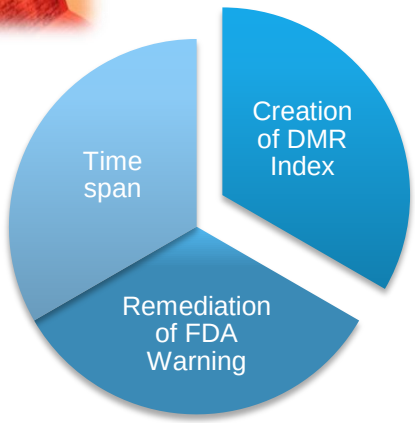
FDA WL Remediation – DMR Index

Client Situation

- ✓ Medical device manufacturer focusing on Neuromodulation involving direct stimulation of the nervous system with electrical signals and used as a treatment for unmanageable chronic pain and/or movement disorders.









Scope

- ✓ Create an Device Master Record(DMR) Index for Implantable Infusion Pump and Deep Brain Simulator

Business Challenge

- ✓ Satisfy customer by providing remediation for FDA warning letter
- ✓ Complete PILOT DMR Index for implantable Infusion Pump within very short period of time.
- ✓ Complete DMR Index for nearly 400 products

Our Approach

- ✓ Wipro defined multiple processes for creating DMR Index, spanning, design, manufacturing and purchasing (including supplier Quality) as a result of which customer could expedite creating DMR Index Work instruction.

Key Features

- ✓ Record maintenance using various tools like PLM< ERP, MES and Document Management Systems

Benefits

- ✓ Improved Quality system meeting FDA guidelines 820.181
- ✓ Creating Errorless DMR Index
- ✓ Reduced time to create DMR Index
- ✓ Reduced cost due to automation and Offshore/Onsite model
- ✓ Inspection is stress free

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Q & A

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Thank You

Rama K Pidaparti
Medical Devices QARA SME

ramakrishna.pidaparti@wipro.com
781-742-5387

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