



- St Jude Medical background
- What is “taxonomy”?
- Why did we undertake a review of taxonomy?
- Process
- Common themes
- Example finding
- Roadmap





## WE ARE ST. JUDE MEDICAL



## WE ARE FOCUSED

on providing innovative, cost-effective medical technologies designed to transform the treatment of some of the

## WORLD'S MOST EXPENSIVE EPIDEMIC DISEASES

- HEART FAILURE
- HEART RHYTHM DISORDERS
- VASCULAR DISEASE
- STRUCTURAL HEART DISEASE
- CHRONIC PAIN
- MOVEMENT DISORDERS

## WE HAVE ACCEPTED THE CHALLENGE

One of the biggest challenges facing health care today is finding ways to **improve patient outcomes while reducing costs**

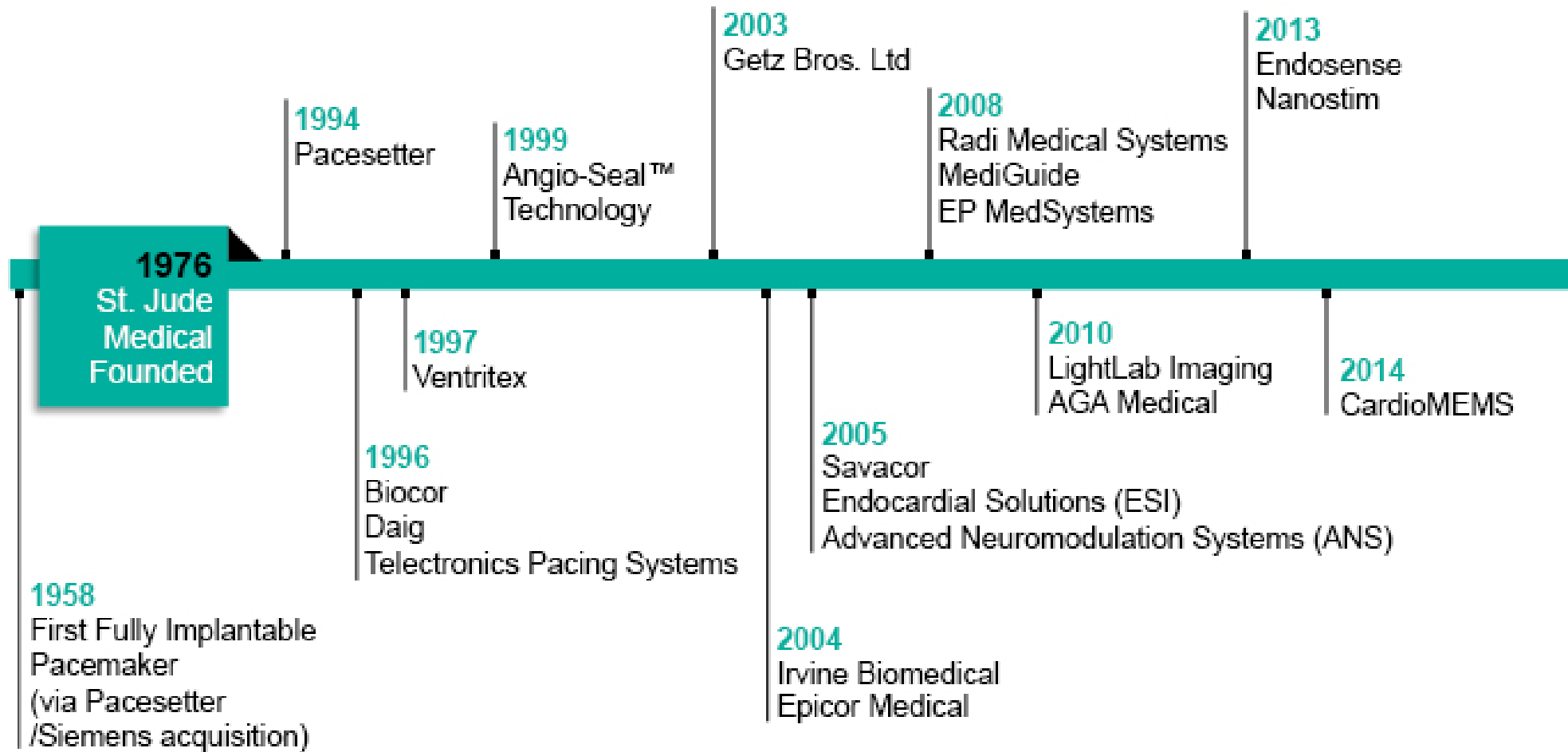


## WE ARE COMMITTED TO

INNOVATION  
QUALITY  
PARTNERSHIP

**12%**  
OF REVENUE  
IS INVESTED IN  
RESEARCH &  
DEVELOPMENT





ST. JUDE MEDICAL™

- Taxonomy includes...
  - How we structure data to enable searching, browsing, and reporting
    - Both internal and regulatory
  - How we identify the information owner / responsible person / group
  - How workflow roles get assigned to specific people
  - Access control model
  - Windchill Product / Library structure
  - How we meet Medical Device data requirements (Structure, Reporting)
    - Design History File (DHF) – Product Development history
    - Device Master Record (DMR) – all Production information



- Move from “business unit” structure, with four (and then two) business units, to “One SJM” organized globally by function
- Corresponding merger of 3 distinct PLM systems into “One SJM” PLM system
- Need flexibility to support future acquisitions and organizational changes



- Conducted interviews with 42 people throughout the company
  - Represent all (former) business units
  - Represent users of all three PLM systems – PTC Windchill, Teamcenter, and CATSWeb
  - Represent key functional areas involved with PLM
    - Quality Systems and Document Services
    - Product Development
    - Design & Development Quality
    - Operations / Supply Chain
    - Program management
    - Clinical
    - IT
    - Security
- Developed list of common themes and opportunities
- Presented findings to key stakeholders
- Prioritized and built roadmap



- Make it easier to find information
- Too much information is inside forms
- Change management processes are not scaling to reflect data maturity
- Integrate CAD





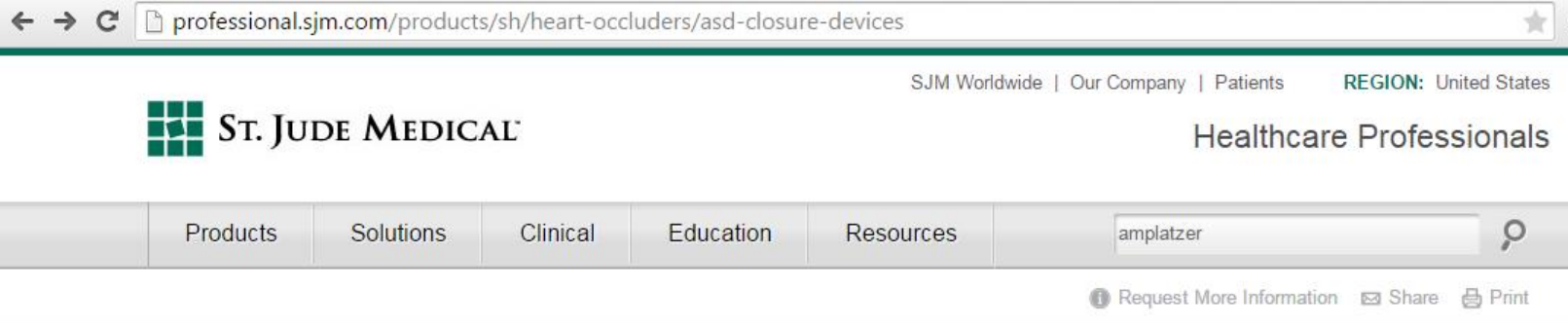
## Design History File – “node”

- **What is a Design History File?**
  - FDA requirement (21CFR820) for Medical Devices “A compilation of records which describes the design history of a finished device”
- **Current approach – former business unit X**
  - PTC Windchill Folder structure
  - Challenges: Can’t reuse documents, no history of folder moves, no explicit link between DHF folders and DMR (BOM)
- **Current approach – former business units Y, Z**
  - Excel spreadsheet index of documents
  - Documents stored in PDM system
  - Challenges: Maintenance effort and contention on spreadsheet
- **New approach – One SJM**
  - “Nodes” (subtype of WTPart) replace folders
- **Benefits**
  - Capture DHF at points in time (PTC Windchill baseline, effectivity)
  - Reuse DHF documents (PTC Windchill Reference / Describe links)
  - Search DHF “Nodes” (PTC Windchill advanced search)
  - Relate DHF & DMR documents & nodes (PTC Windchill configurable links)

## Product Family Group

- Problem

- Top-level of product structure in PTC Windchill (End Item) is a region-specific orderable device
- People think of products at a higher level



Reorder Number	Device Size/ Waist Diameter (mm)	Waist Length (mm)	Right Atrial Disc Diameter (mm)	Left Atrial Disc Diameter (mm)	Min. Recommended Sheath Size (AMPLATZER™ TorqVue™ Delivery System)
9-ASD-004	4	3	12	16	6 F; 45° Curve
9-ASD-005	5	3	13	17	6 F; 45° Curve
9-ASD-006	6	3	14	18	6 F; 45° Curve
9-ASD-007	7	3	15	19	6 F; 45° Curve

### Structural Heart Products

- Heart Occluders
  - ASD Closure Devices
  - Delivery Systems
  - PDA Closure Device
  - VSD Closure Device
- Mechanical Heart Valves
- Tissue Heart Valves
- Valve Repair

#### Atrial Septal Defect (ASD) Closure Devices



##### AMPLATZER™ Multi-Fenestrated Septal Occluder - "Cribriform"

- Specifically designed to meet multiple needs when occluding multi-fenestrated atrial septal defects
- Has a double disc comprised of Nitinol mesh and polyester fabric and a narrow waist

Reorder Number  
Indications, Safety & Warnings



##### AMPLATZER™ Septal Occluder

- The standard of care for minimally invasive atrial septal defect (ASD) closure
- Double disc occluder is comprised of Nitinol mesh with polyester fabric

Reorder Number  
Indications, Safety & Warnings



## Product Family Group

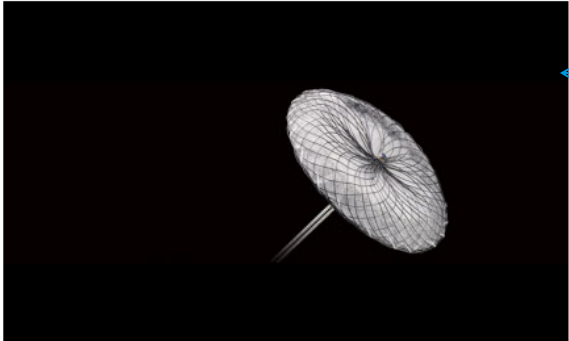
- Solution
  - Product Family Group (type of WTPart) to organize end items at a higher level



### AMPLATZER™ Septal Occluder

AMPLATZER Septal Occluder (ASO) is designed for minimally-invasive atrial septal defect (ASD) closure.<sup>1</sup> This double-disc occluder is comprised of Nitinol mesh with polyester fabric. The ASO is designed to appose the septal wall on each side of the defect and create a platform for tissue in-growth after implantation.

[Related Products](#) | [Reimbursement](#) | [Product Manuals](#)



Overview | **Tech Specs** | Evidence | Indications, Safety & Warnings

### AMPLATZER™ Septal Occluder

Ordering Information [View Catalog](#)

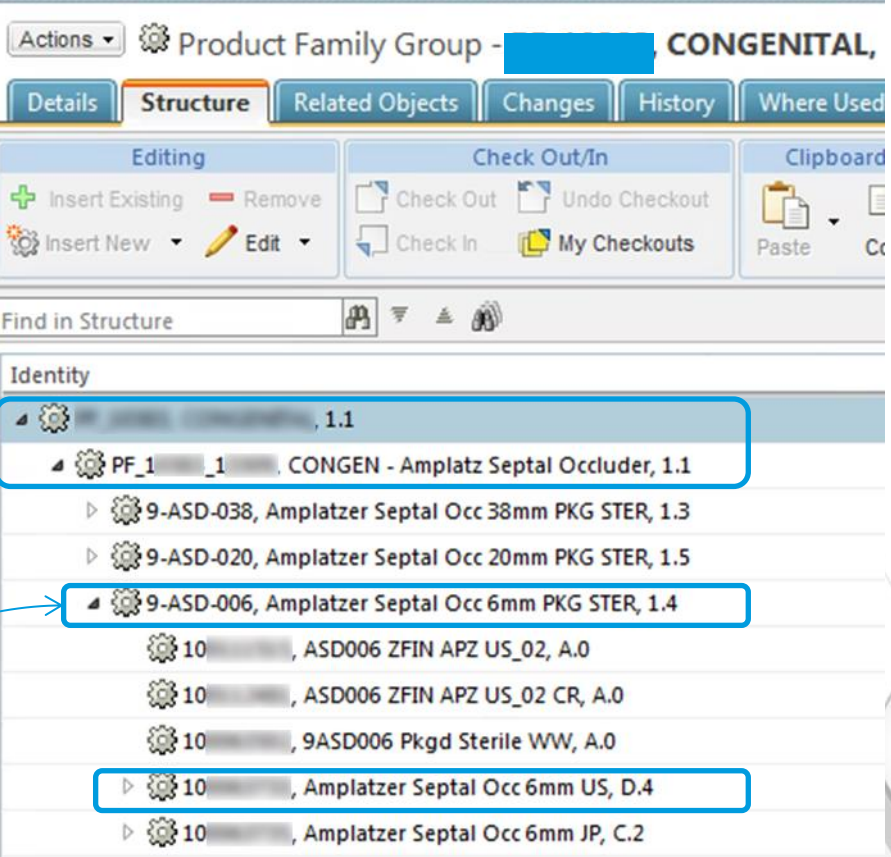
Contents: 1 occluder

Reorder Number	Device Size/ Waist Diameter (mm)	Waist Length (mm)	Right Atrial Disc Diameter (mm)	Left Atrial Disc Diameter (mm)	Min. Recommended Sheath Size (AMPLATZER™ TorqVue™ Delivery System)
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9-ASD-006	6	3	14	18	6 F; 45° Curve
9-ASD-007	7	3	15	19	6 F; 45° Curve

Product Family Groups

Model

End Item



# Example findings

## Visual Navigation of Quality System documentation

- **Background / Problem**
  - Making it easy to find Quality System process / procedure documentation
  - Documentation is maintained in Windchill but not practical for browsing
    - Thousands of documents
    - Must either search by keyword (often too broad) or know the specific number
- **Original solution**
  - Sharepoint site with Quality System Image
  - Hotspots link to Sharepoint List
  - List contains links to specific PTC Windchill documents
- **Challenges**
  - Manual maintenance of Sharepoint data
- **New solution**
  - Reorganize QS documentation under “Nodes” (PTC Windchill: WTDocument subtype), using Document Structure
  - Image hotspots link to the “Node”
- **Benefits**
  - Self-maintaining in a single system

## Quality System overview

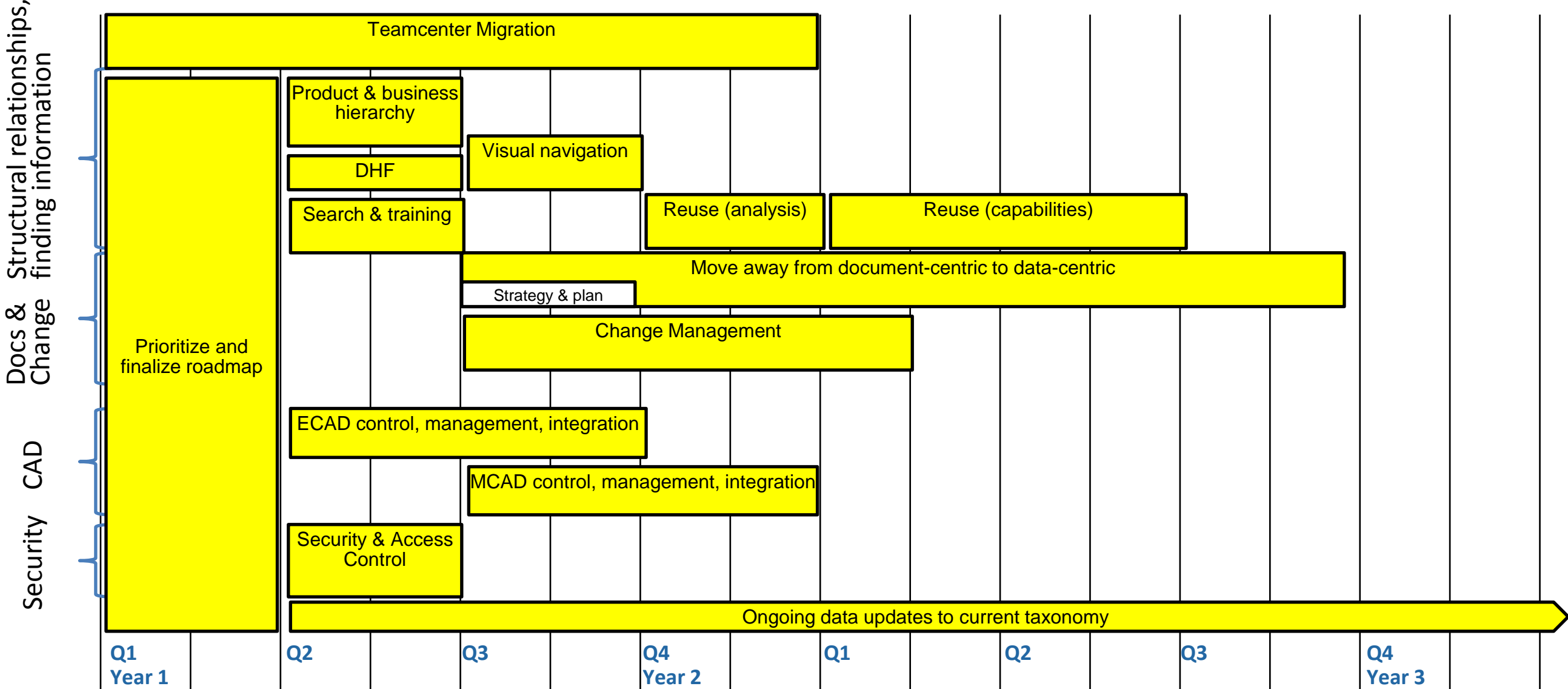
The screenshot displays the Windchill PDMLink interface for 'SJM Quality Systems'. The dashboard is organized into several sections: Management Controls (Resource Management, Training, Environmental Management System, Quality Manual and Quality Policy), Product Development (Labeling, Test Method Validation, Process Validation, Design Controls, Product Development Process, Biocompatibility, Non-Device SW Validation, Device Software Development, Risk Management, Packaging), Procurement (Supplier Selection, Material Qualif, Supplier Monitoring, Receiving Ins), Issue Management (Complaint Handling, Restocking (incl. Returns Processing), CAPA, Field Action, NCMR, Servicing, SCAR, Ship Holds), and Support Systems (IT Infrastructure, Statistical Methods, Global Glossary, Change Control, Records Management). A 'Customer Input/ Feedback' box is also visible. A sidebar on the right contains navigation options like 'Help', 'Clipboard', 'Import Job Monitor', 'WVS Job Monitor', 'Event Management', 'My Settings', 'My Notebook', 'Software Downloads', 'Email Page', 'Copy Page', 'Manage User Roles and Groups', and 'Download Primary File'. A 'Quick Links' menu is at the top right.

## View documents

The screenshot shows a document list in Windchill for 'SJM Quality Systems'. The list is organized into folders for 'Issue Management' and 'CAPA'. The 'CAPA' folder is expanded, showing a list of documents with columns for Name, Number, Category, and Version.

Name	Number	Category	Version
Issue Management	QS1004	SJM Quality Systems	A.0
CAPA	QS1012	Issue Management	A.1
One SJM Global CAPA Extension Form		Form	A.0
One SJM Global CAPA VoE Execution Form		Form	A.1
One SJM Global EMS Master RIR Form		Form	A.0
One SJM Global CAPA Closure Exec Summary		Form	A.1
One SJM Global EMS RIR Work Instruction		Work Instruction	A.0
One SJM Global CAPA Risk Assessment Form		Form	A.0
One SJM Global Product RIR Work Inst		Work Instruction	A.0
One SJM Global Product Master RIR Form		Form	A.0
One SJM Global CAPA - Future Use Form		Form	A.0
One SJM Global CAPA Update Form		Form	A.0

We updated our PLM roadmap to include initiatives to improve taxonomy



- Your feedback is valuable
- Don't miss out on the chance to provide your feedback
- Gain a chance to win an instant prize!
- Complete your session evaluation now

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