COGNITION®
NAVIGATING PRODUCT DEVELOPMENT

TRACEABILITY MADE EASY

HARNESSING DATA CONNECTIONS TO OPTIMIZE EFFICIENCIES & COST SAVINGS

Sally Carter, PMP, Master of Engineering

INCOSE Healthcare Working Group, April 2024

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Intro



- Sally Carter, Director of Application Engineering and Quality
  - ME in biomedical engineering, certified project manager
  - Over 30 patents issued for medical device designs
  - 20 years in medical device industry from concept through production

- Cognition Corporation
  - 20+ years dedicated to product development for the life sciences
  - Only design control solution developed specifically for medical devices called Compass® PRO
  - Available as both an out-of-the-box solution or with highly configurable workflows
  - Seamlessly integrates requirements, risk, and test management
  - Streamlines medical device development process while enhancing safety and quality
  - A trusted resource to 5 of the top 6 medical device manufacturers

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OVERVIEW

- Definition per Standards and Regulations
- Common Definition
- Data Traceability
- History Traceability
- Impact Analysis
- Production/Manufacturing Traceability
- Cost Savings
- Conclusion

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TRACEABILITY BY THE STANDARDS

- FDA's 21 CFR 820.65 Definition:
  - Identify control number for each unit, lot, or batch of finished devices and, where appropriate, components, and document in Device History Record (DHR).

- ISO 13485 Traceability References:
  - 7.1 Planning
  - 7.3.2 Trace of outputs and inputs
  - 7.5 Records of components, materials, and conditions for work environment use (including 7.4.2 purchasing, 7.5.1 control for production, 7.5.5 Requirements for sterile medical devices, and 7.6 control of equipment

- Merging of ISO 13485 with US Regulation:
  - January 2024: Final rule amended the current device good manufacturing practice of the quality system regulation to align more closely with the international consensus standard for QMS, ISO 13485:2016 – Quality Management System Regulation, takes effect February 2026

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Traceability Beyond the Standards

But common definition also includes:

Data trace: outputs to inputs, needs to inputs, tests to inputs/outputs, risks to tests, or inputs or outputs

- Traceability matrix from the Design Control Guidelines as a way to confirm verification

Change traceability, detailed object information, or order level

- Change history, audit log of who changed what, where, and when

Impact analysis: if change X, what else must be updated?

- Identifying all the cross-references in documents and between objects to ensure a change is assessed for impact to risk management, existing testing, retesting, and requirements

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Where Are There Issues in QMS Process?

A **survey of 100 companies** stated top challenges faced by their organizations related to managing design controls:

- Resource limitations
- Managing information in disparate systems
- Change management

Easy to get data misaligned in a manual system

- Time to review each individual document for alignment
- Ensure data is consistent across documents and projects
- Gather all content into change systems to adjust at once

Address issues by a ***structured database approach***

- ✓ Ensures that the system is instantly aligned and remains aligned
- ✓ Reduces resource load to reconfirm each datapoint in disparate documents
- ✓ Allows visibility to all the places a point of change touches

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Traditional Manual Approach

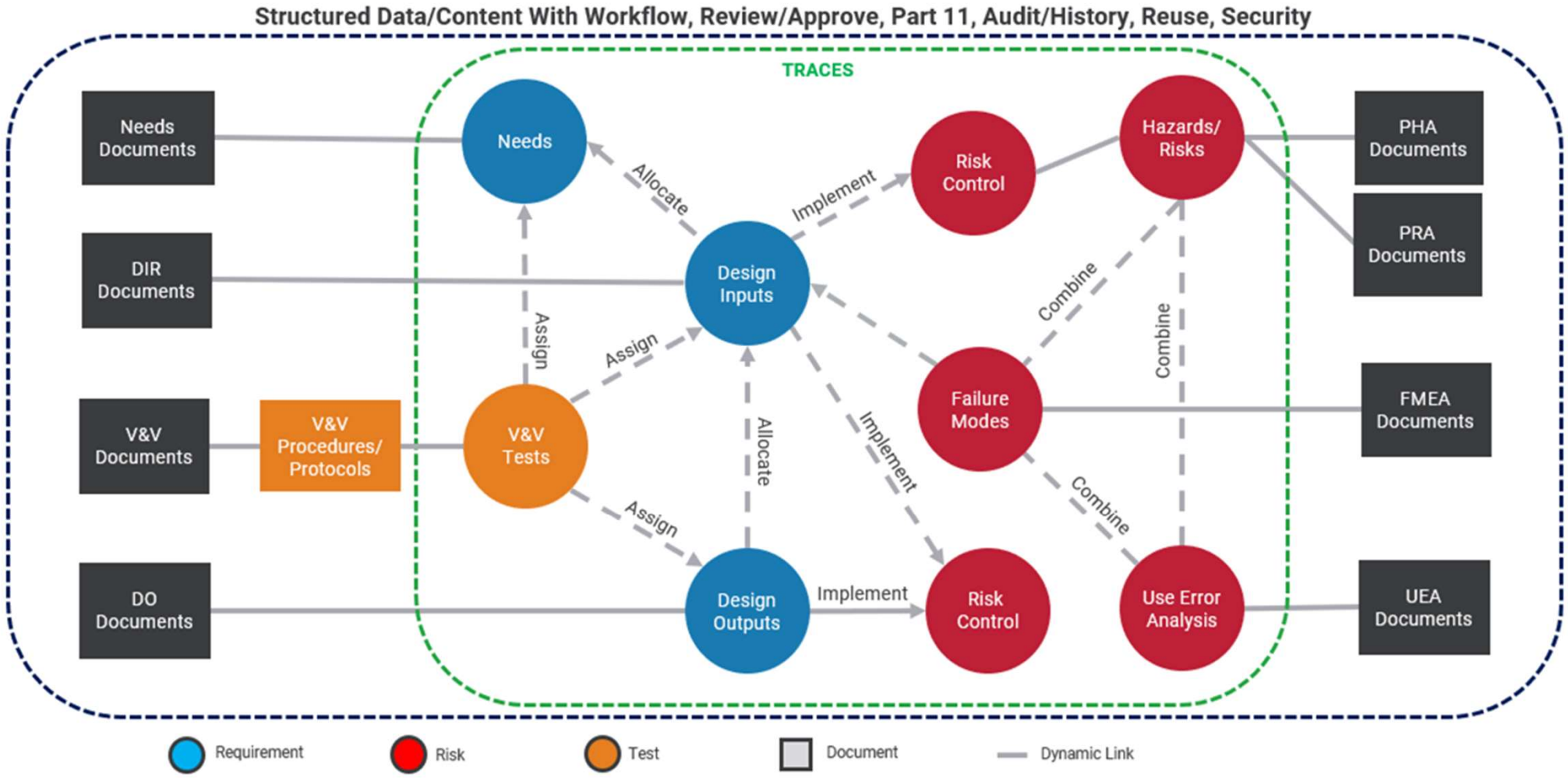
Tracing of Outputs Meeting Inputs

	Series of Word documents or Excel spreadsheets that are drafted, reviewed, approved, edited, controlled in DMS	Exact phrasing matters! Must be unambiguous, not conflicting, and complete
	Design user needs document	• List of user needs with criteria that can be validated
	Design input/requirement document	• Copy list of user needs • Create list of requirements that match users needs that can be verified
	Verification test protocol (is there more than one test, are there any line extensions with more testing?)	• Copy list of design inputs to show that outputs are verified to inputs • Reference sub-protocols that may also copy design input text, multiple studies, time points, etc.
	Validation test protocol	• Copy list of user needs to show that production-equivalent products are validated to intended use/user needs
	Risk management	• Copy/reference requirements at any level to link to controls/mitigations/evidence
	Trace matrix	• Trace matrix
	**What happens if one item changes???**	**Can you find all the references instantly? Do you know where everything may be tied over time to determine what documents are updated, which are obsoleted and replaced, where new documents, requirements, risks, tests are required?**

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Relationships: Data and Usage



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EXAMPLE DATA TRACE



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Benefits of Real-Time Data Trace with Cognition



Improved efficiency and faster time to market

Eliminates need to create the trace as final and tedious step.

Efficiency gains when managing changes: change once, change everywhere.

More efficient data management, continual list of inputs and reporting.



Enhanced accuracy and safety

One Source of Truth: trace is always accurate.

In manual process, it can be easy to miss one edit in one document.



Streamlined audit responses and report creation

Audits often ask for traces to see that the outputs meet the inputs and vice versa.

All data organized, linked, and controlled means less likely to have errors.

Easy to accommodate data and report requests: exports or data management.



Finding the right partner

Platform specifically designed for medical device development.

Partner to support on journey to transition.

Reference: https://blog.cognition.us/medical-device-companies-real-time-traceability

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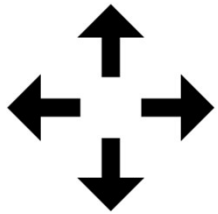
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EXAMPLE TRACE DOCUMENT

User Needs	Design Inputs	Design Outputs	Ver. Test Method	Ver. Protocol	Ver. Report	Val. Test Method	Val. Protocol	Val. Report	Risk
R UNS11006: Product must be supplied undamaged R UNS11009: Product must be supplied Sterile	R SSR10998: Ship Test	D DO10999: Tyvek Pouch D DO11001: Pouch Label D DO11002: Shelf Box Label D DO11004: DWG#1234 Finished Good assembly with packaging D DO11000: Shelf Box	T TC2994: Ship Test for Generic Packaging	TP1207	TR00542	T TC2993: Post Ship Test Inspection T TC2996: Sterilization Validation Test	TP0024,TP7748	TR00152,TR00786	D DFMEA2863 F UFMEA2864
R UNS11009: Product must be supplied Sterile	R SSR11007: Aging	D DO10999: Tyvek Pouch D DO11000: Shelf Box D DO11001: Pouch Label D DO11002: Shelf Box Label D DO11004: DWG#1234 Finished Good assembly with packaging	T TC2995: ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	TP0428	TR00328	T TC2996: Sterilization Validation Test	TP7748	TR00786	D DFMEA2865

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Change History Trace



Why is history important?

The who, what, when, where, and why

Official change history: redlines and change justification

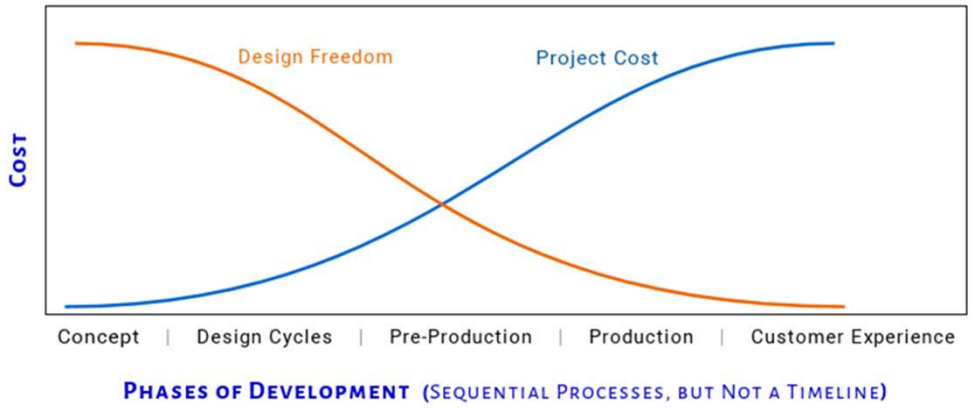
- Controlled change pre- or post-market release
- Documented rationale for change with rationale or testing on released products
- Verifies change and all related impacts

Unofficial change history: who modified, when

- Can you see who made the change down to the individual object?
- Can you track the rate of change in a document?
- Can you see who made suggested changes or comments in a review?
- Are there rationales and conversations about the change that may give perspective in the future?

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4TH DIMENSION IN DATA

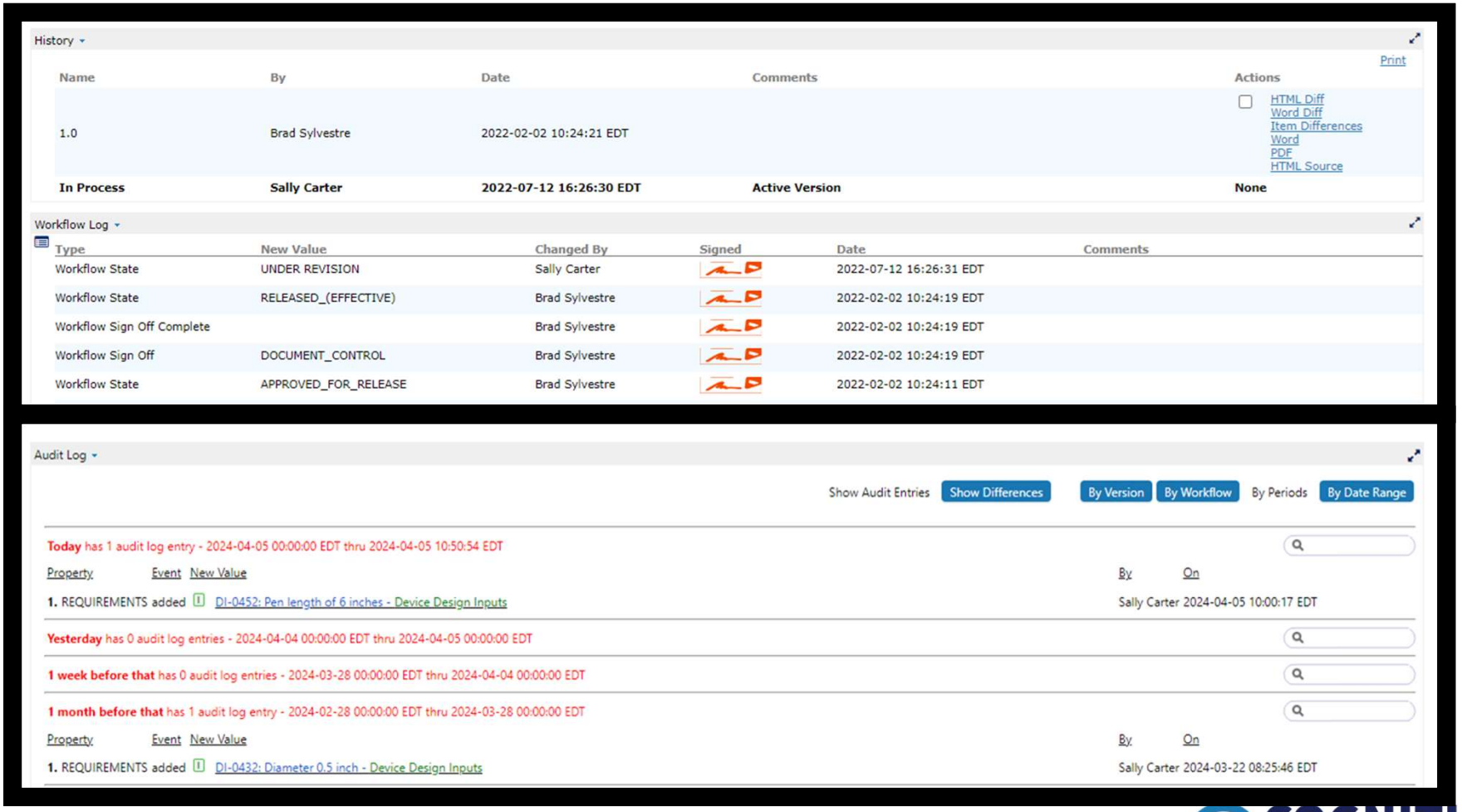


- Visualize dimensions as:
  - Requirement cascade: up/down (2D) to
  - Extending to risks and test data (3D) to
  - Changes over time (4D)
- Iterative process
- Smart data utilizes information and actionable context to drive decisions
- Design history transparency critical
  - Changes made when, by whom, why, etc.
- Clear history audit trail: can go beyond formal change control to specific changes made in the tool in the early design process
- Manage all data items from requirement to documents, risk library to risk definitions, test methods to verification trace
- Build information around changes and connections—risk, test, requirements—evolution over time
- Manual tools are limiting and linear, no data relationships or instant reuse
- Database foundation to managing complex dynamic data sets

Reference: https://blog.cognition.us/space-and-time.-are-you-considering-the-4th-dimension-for-product-development

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EXAMPLE HISTORY TRACE



History

Print

Name	By	Date	Comments	Actions
1.0	Brad Sylvestre	2022-02-02 10:24:21 EDT		HTML Diff Word Diff Item Differences Word PDF HTML Source
In Process	**Sally Carter**	**2022-07-12 16:26:30 EDT**	**Active Version**	**None**

Workflow Log

Type	New Value	Changed By	Signed	Date	Comments
Workflow State	UNDER REVISION	Sally Carter		2022-07-12 16:26:31 EDT	
Workflow State	RELEASED_(EFFECTIVE)	Brad Sylvestre		2022-02-02 10:24:19 EDT	
Workflow Sign Off Complete		Brad Sylvestre		2022-02-02 10:24:19 EDT	
Workflow Sign Off	DOCUMENT_CONTROL	Brad Sylvestre		2022-02-02 10:24:19 EDT	
Workflow State	APPROVED_FOR_RELEASE	Brad Sylvestre		2022-02-02 10:24:11 EDT	

Audit Log

Show Audit Entries | Show Differences | By Version | By Workflow | By Periods | By Date Range

Today has 1 audit log entry - 2024-04-05 00:00:00 EDT thru 2024-04-05 10:50:54 EDT

Property	Event	New Value	By	On
1. REQUIREMENTS	added	DI-0452: Pen length of 6 inches - Device Design Inputs	Sally Carter	2024-04-05 10:00:17 EDT

Yesterday has 0 audit log entries - 2024-04-04 00:00:00 EDT thru 2024-04-05 00:00:00 EDT

1 week before that has 0 audit log entries - 2024-03-28 00:00:00 EDT thru 2024-04-04 00:00:00 EDT

1 month before that has 1 audit log entry - 2024-02-28 00:00:00 EDT thru 2024-03-28 00:00:00 EDT

Property	Event	New Value	By	On
1. REQUIREMENTS	added	DI-0432: Diameter 0.5 inch - Device Design Inputs	Sally Carter	2024-03-22 08:25:46 EDT

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Impact Analysis of Change



- Example: Suture anchor fillet
  - Sudden reports in field of anchor head failure during surgery
  - Change to a machined anchor vendor
  - Root cause determined to be lack of fillet
  - How to determine what needs to change in paper DHF
    - Risk analysis: was failure of anchor head assessed, was missing fillet?
    - Testing: what is measured at incoming inspection, during design verification, for release
    - Design requirement—strength—was this tested during design or during supplier change?
    - Design output: was fillet defined? NO
    - What needs to be done if drawing changed to verify the root cause was found and fixed?
      - What documents need to be updated and what justifications need to be done to verify change?
        - No change to ship testing or aging, for example (Titanium anchor)
  - In paper system, difficult to locate all the references quickly

How quickly can you find everything in all the documents related to anchor strength?

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LEVERAGE TRACE FOR IMPACT ANALYSIS



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Production/Manufacturing Traceability

Why is lot traceability important?

- Control of process
- Repeatability and reproducibility
- Root cause analysis if failure in the field
- Containment if any nonconformities in production

What gets traced?

- Product version (drawings, specs, “design”) and Device Master Record (DMR)
- Raw material, component lot numbers, subassemblies, packaging, finished goods
- Equipment calibration, installation, qualifications, maintenance
- Personnel records, training, qualifications, who tested, who manufactured
- Complete Device History Record of each product

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Cost Savings with Database Utilization

How long does it take to manually cut-paste and verify data?

- Multiple documents, multiple people, different states of document review and release

How long during an approval cycle does it take to confirm and cross-check?

- Human dependent process: varies due to natural detail orientation and distractions

How can a database help?

- Change once, update everywhere; same exact object used in multiple places
- Consistency is key: same phrasing for risk items, easier to find related assessments
- Less need to worry about manual errors and maintenance
- Ability to create complex traces spanning product lines
- Query data across organizations/business units, can create central libraries of common data (harms, hazards, standards, and more)
- Collaboration, improving communication, and breaking down silo walls to improve efficiency

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Conclusion



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ANY QUESTIONS?

FOR MORE INFORMATION

info@cognition.us

www.cognition.us

Presentation will be posted on our website under Resources

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