

# Global Q, Inc.



## Background - a quick history

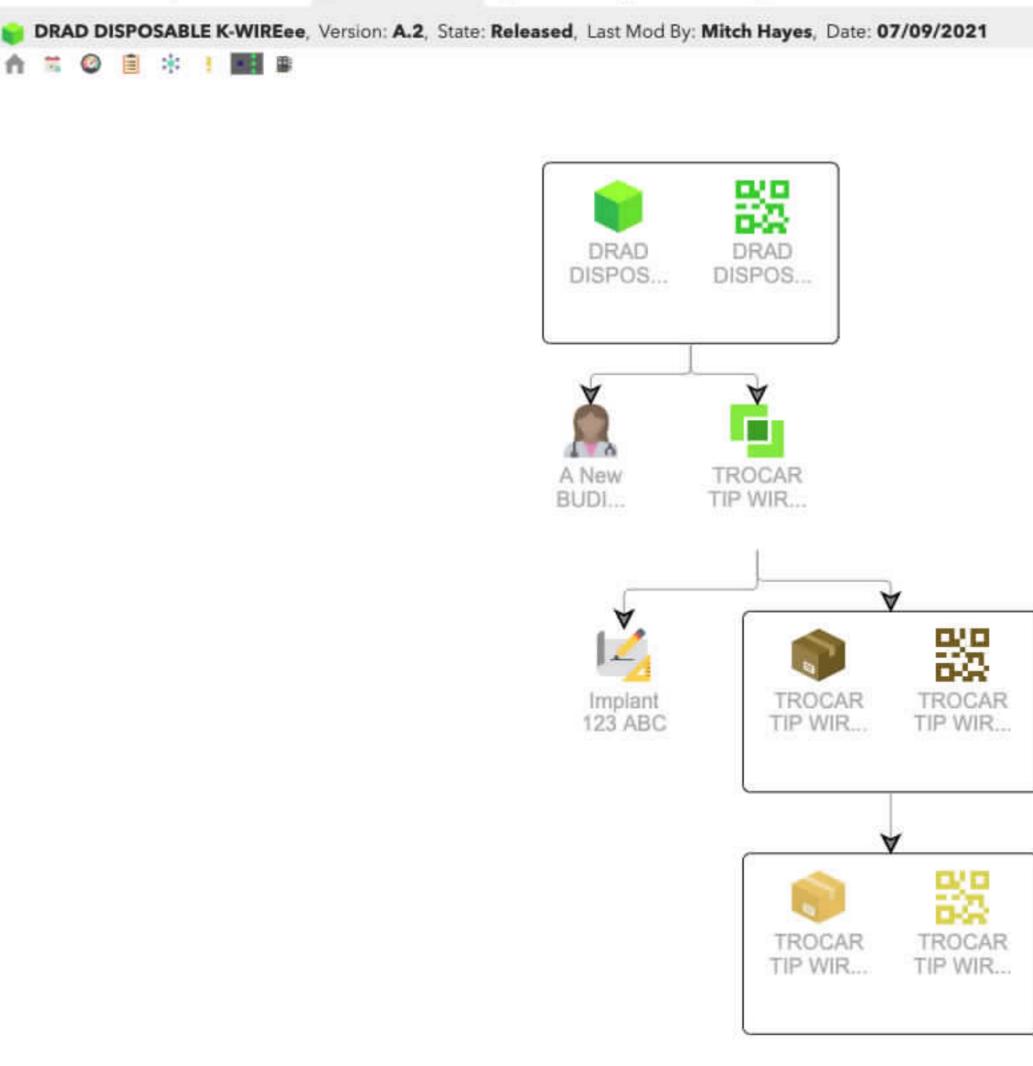
The learning objective of this TOPIC is discuss the following KEY POINTS:

- EUDAMED
- Dr. ZEUS
- EU MDR





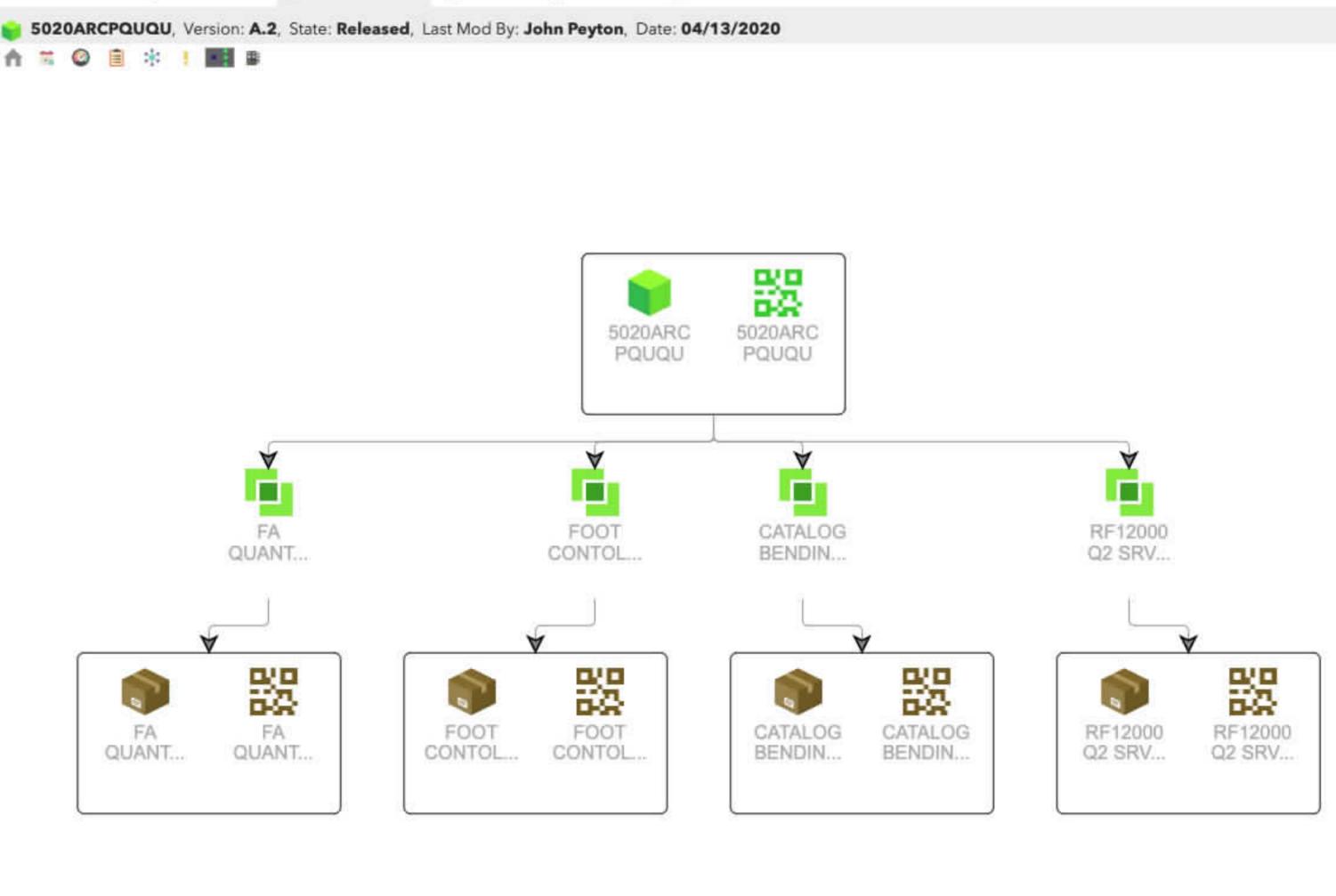


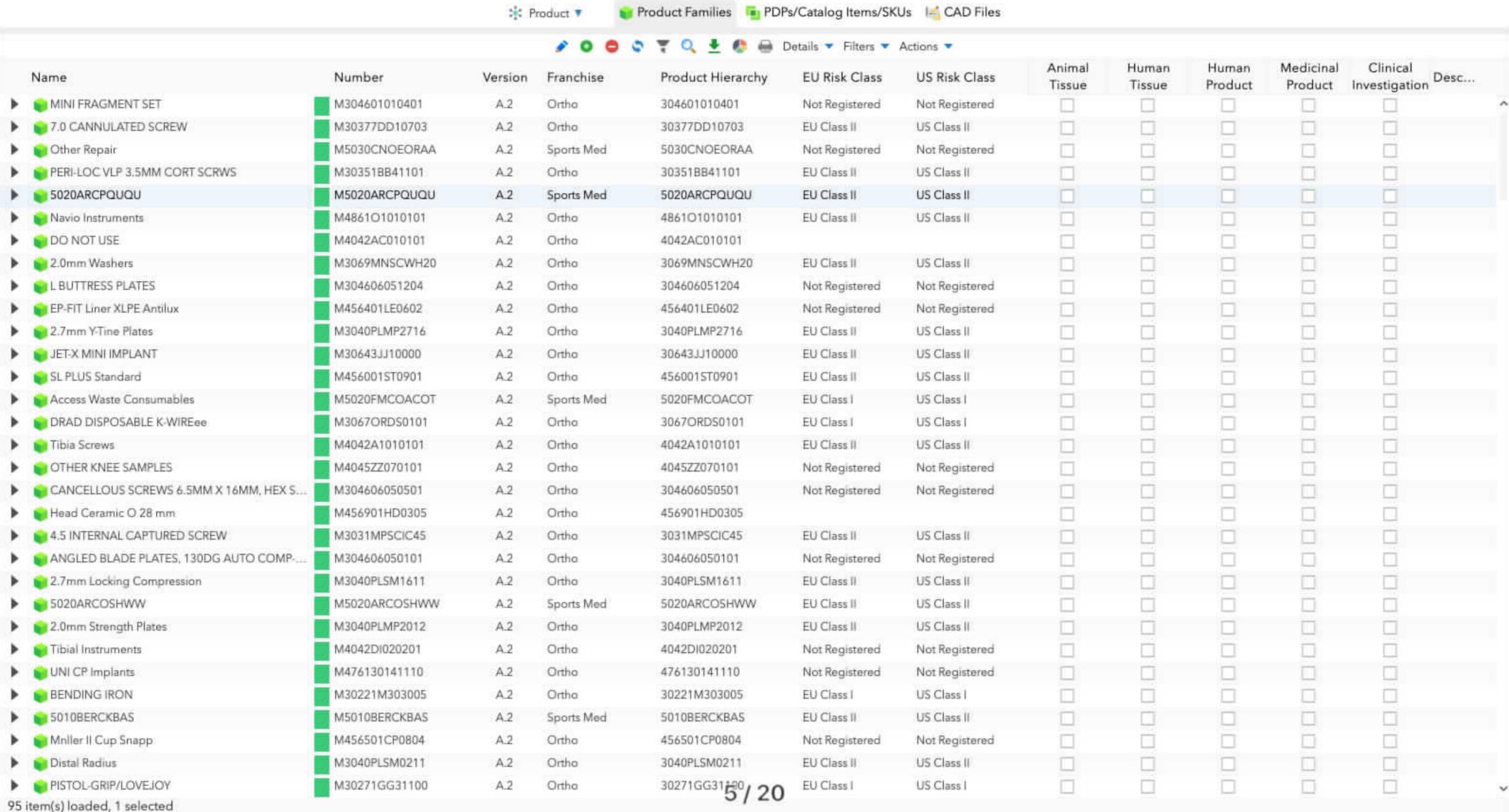


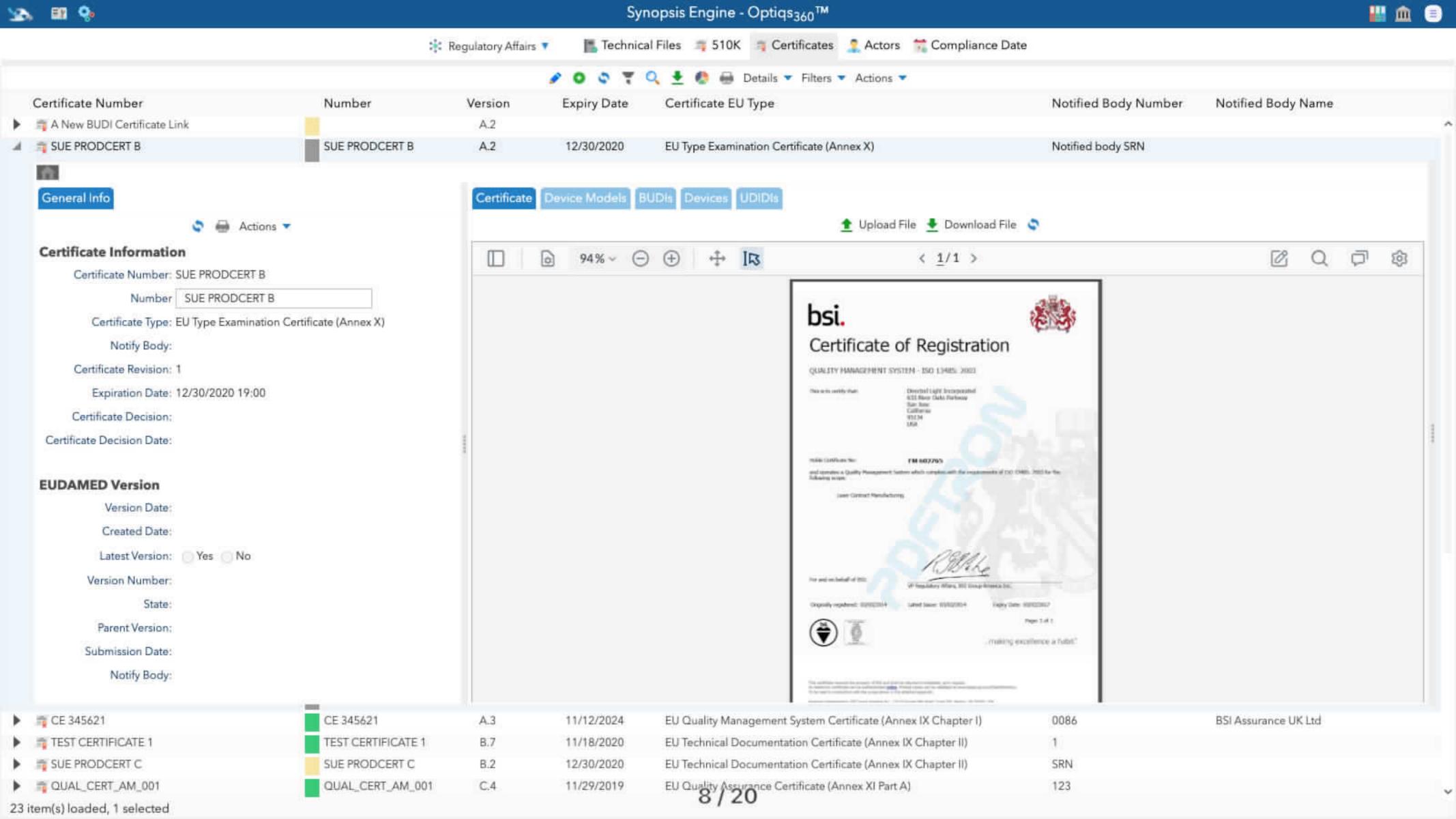












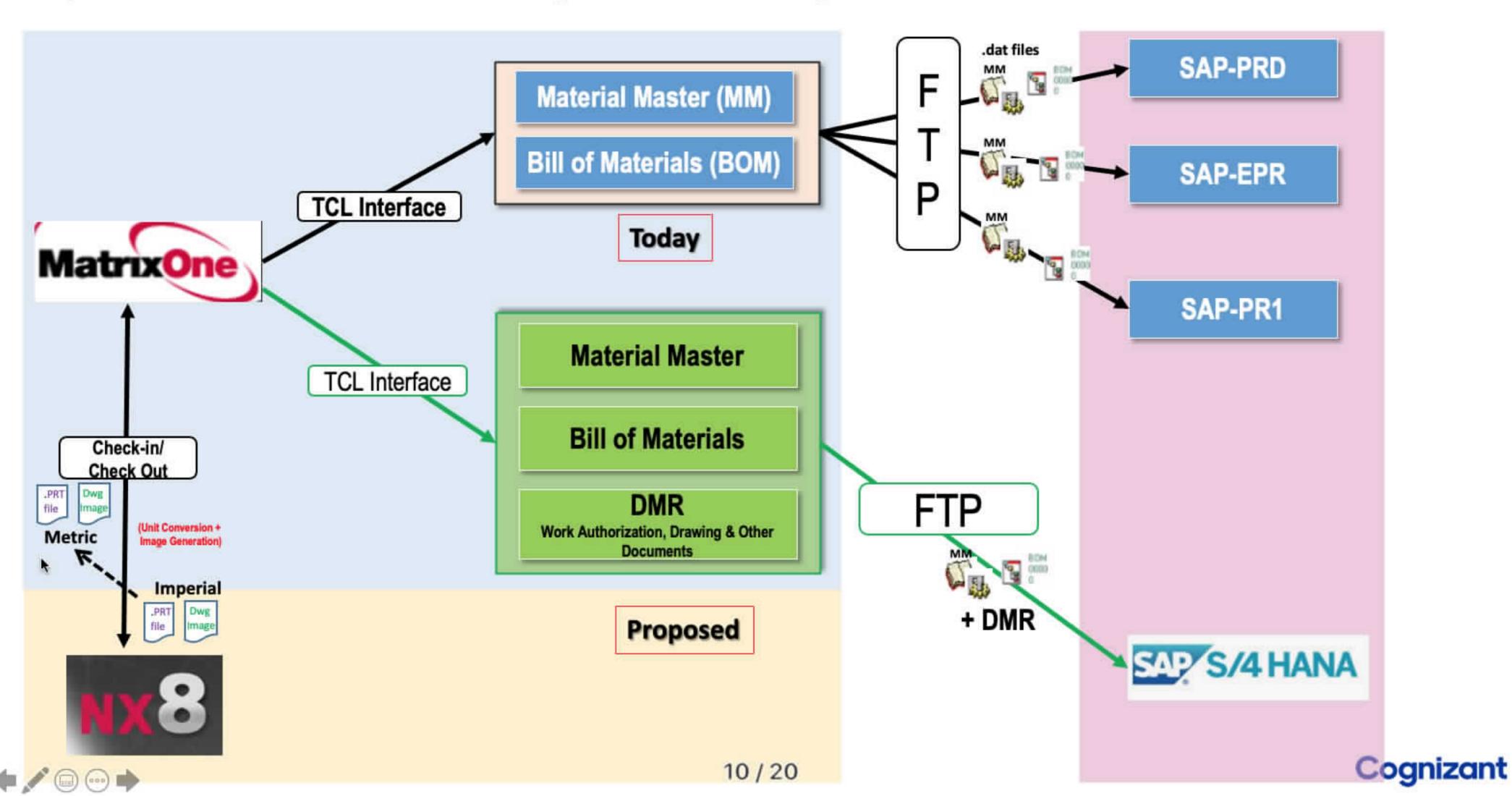
## Project Zeus: Integration Options w/Pros & Cons

SmithNephew Cognizant

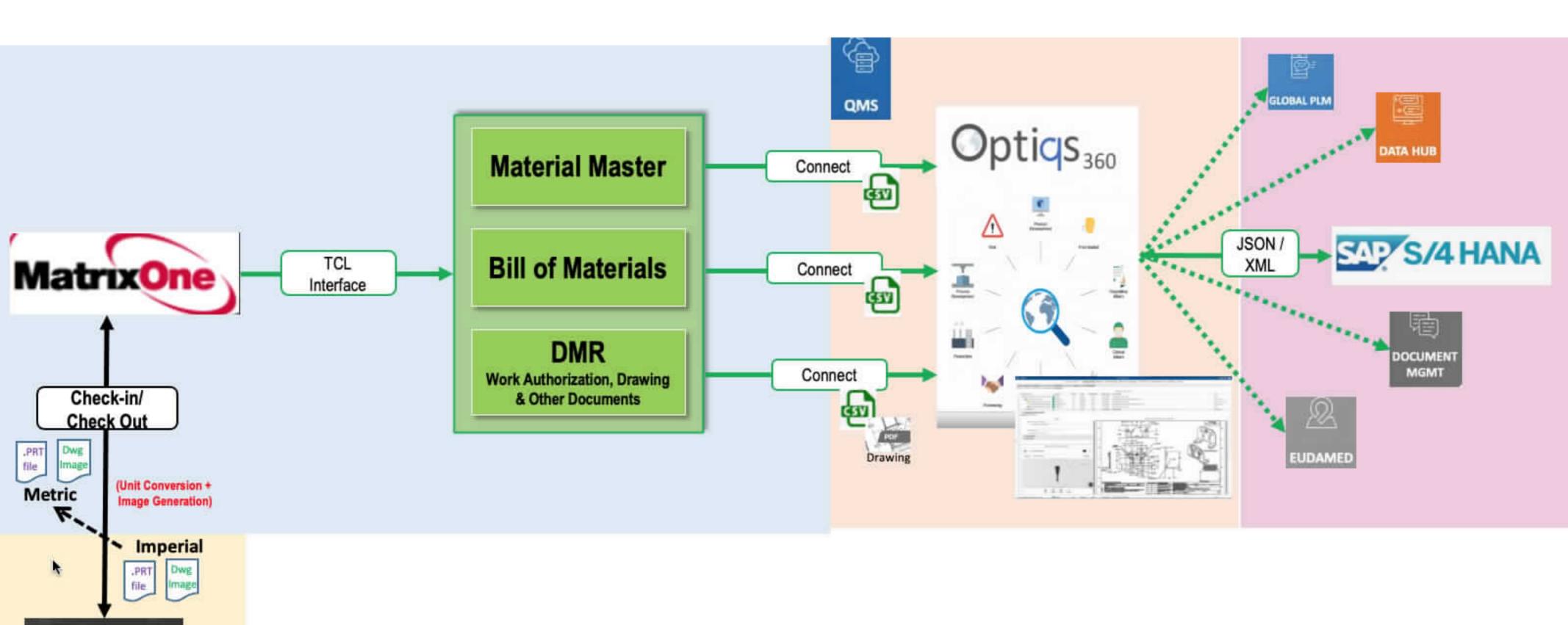




## Option 1: Point to Point (FTP Transfer)



## Option 2: Single-Connect, Multi-serve through 'Optiqs 360' QMS



## **Our Sponsors**





Guerdan, Melissa

Chief Quality and Regulatory Affairs Officer Smith & Nephew Executive



Huckle, James

Vice President, Portfolio Compliance Global Quality & Regulatory Affairs



Tupil, Sri VP IT Q/RA & R&D IT Leadership Team

## **Our Team**



Mines, Angie Sr. Manager, R&D / Quality MDR R&D QE - Global



Bhat, Ullas R+D Architect R&D Systems



McGonigle, Tammy

Director, Global Quality Systems and Training Global Quality Systems



Neyhard, Eric Program Director - PMPA



Mays, Patricia Staff Computer Science Engineer



Rubin de la Borbolla, lan R&D Surge Lead Operations





Enable global accelerated technical file remediation through processes & technology





Create a common user interface for the SN enterprise that is linked to site systems for reporting and monitoring quality & regulatory compliance. Be the BEST owner for the patients that use our products & the people in our organization.





## Solution Selected! Optiqs 360 Delivers!



- GxP Validated System
- Assimilation & Aggregation are core to integration
- 3. User visualization through Integration
  - Elimination of point to point connection to systems of record
  - b. View of information by cross functional group
- Privileges management of records and record types
- 5. Relationship between task and deliverables Task driven deliverable management

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- 6. Project Management capabilities with accountability to released records
- 7. Operational efficiency in day to day activities / tasks
- 8. High configurability through lifecycle management
- Medical Device domain specific
- 10.Low code and agile environment for configuration / development



## **Short Term Wins: Get Better Memphis**





## The user needs to retrieve & visualize the required Technical File records (40 checklist items) related to a SKU

### Weakness in current system

- New Matrix users commonly require 60

   90 days to be effective in search, retrieve, and contribute to technical file deliverables
- Data mining for existing users requires 2-12 hours per week in data mining to perform job tasks.

## Expected Benefits with OMNI through Optiqs

- 130,000 design control records available in an indexed library reduces onboarding obligations for training
- Expected data mining time reduced to less than 1 hour per week
- Expected training ramp up time reduced to 30 days



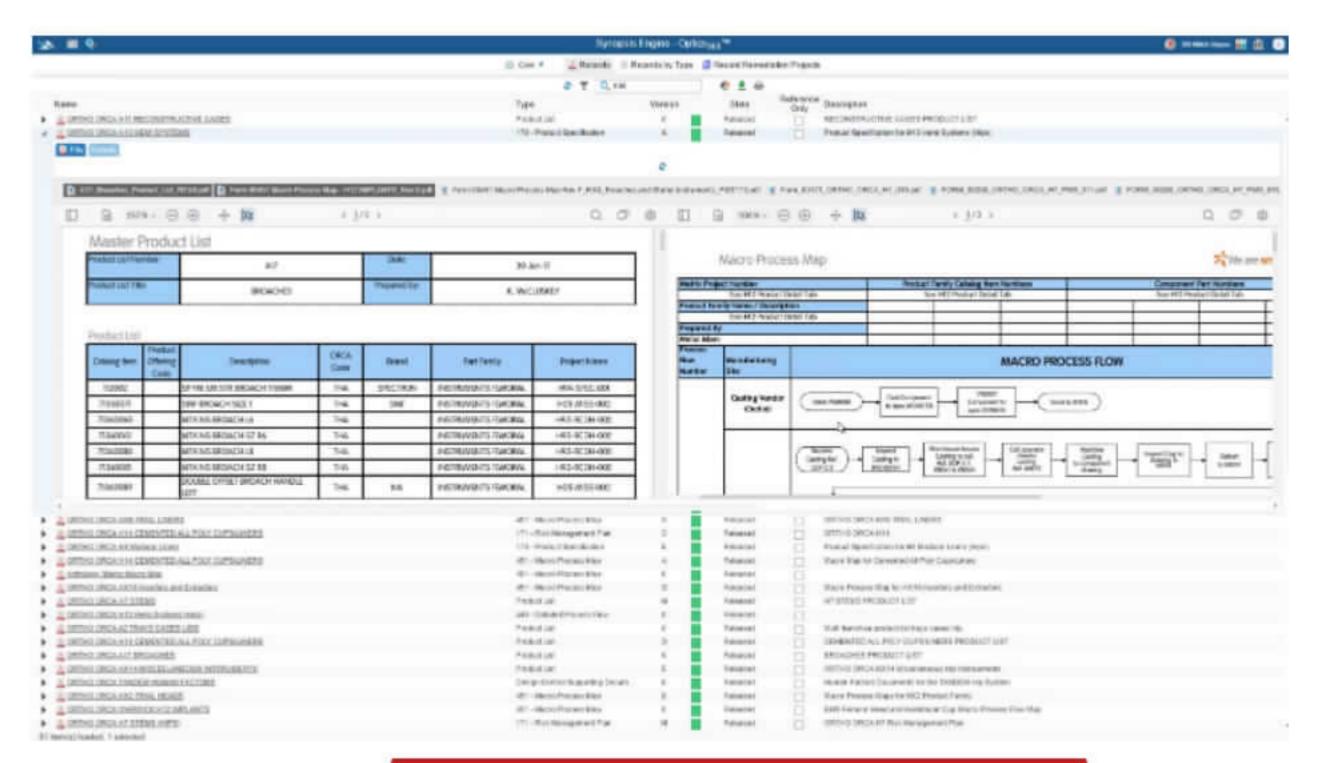
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## **Proof of Concept: Before & After**





10 Clicks
when you know where to go
100 Clicks
if you are an investigator
20 minutes - 2 hours
to view files retrieved



2 Clicks
when you know where to go
10 Clicks
if you are an investigator
2 minutes - 5 minutes
to view files retrieved

## Mid-Term Wins: Reconcile all records to one truth





## The user needs ability to add intelligent attribution across multiple records

### Weakness in current system

- Shared resource teams do not have transparency of DMR, DHR, DHF to perform assessments independently – Disparate systems
- SME's regularly reiterate similar work without being able to leverage prior efforts
- Information is repeated in several records increasing the chances for document errors in versions and risking inspection observations, nonconformities, findings

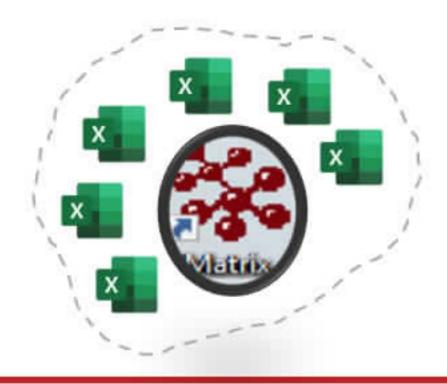
### Expected Benefits with OMNI through Optiqs

- Centralization of data to manage global processes (Hazardous substances, cleaning, packaging, sterilization, biological safety)
- Attribution data available for use during next review phases instead of repeating
- Expected reduction in resource allocations



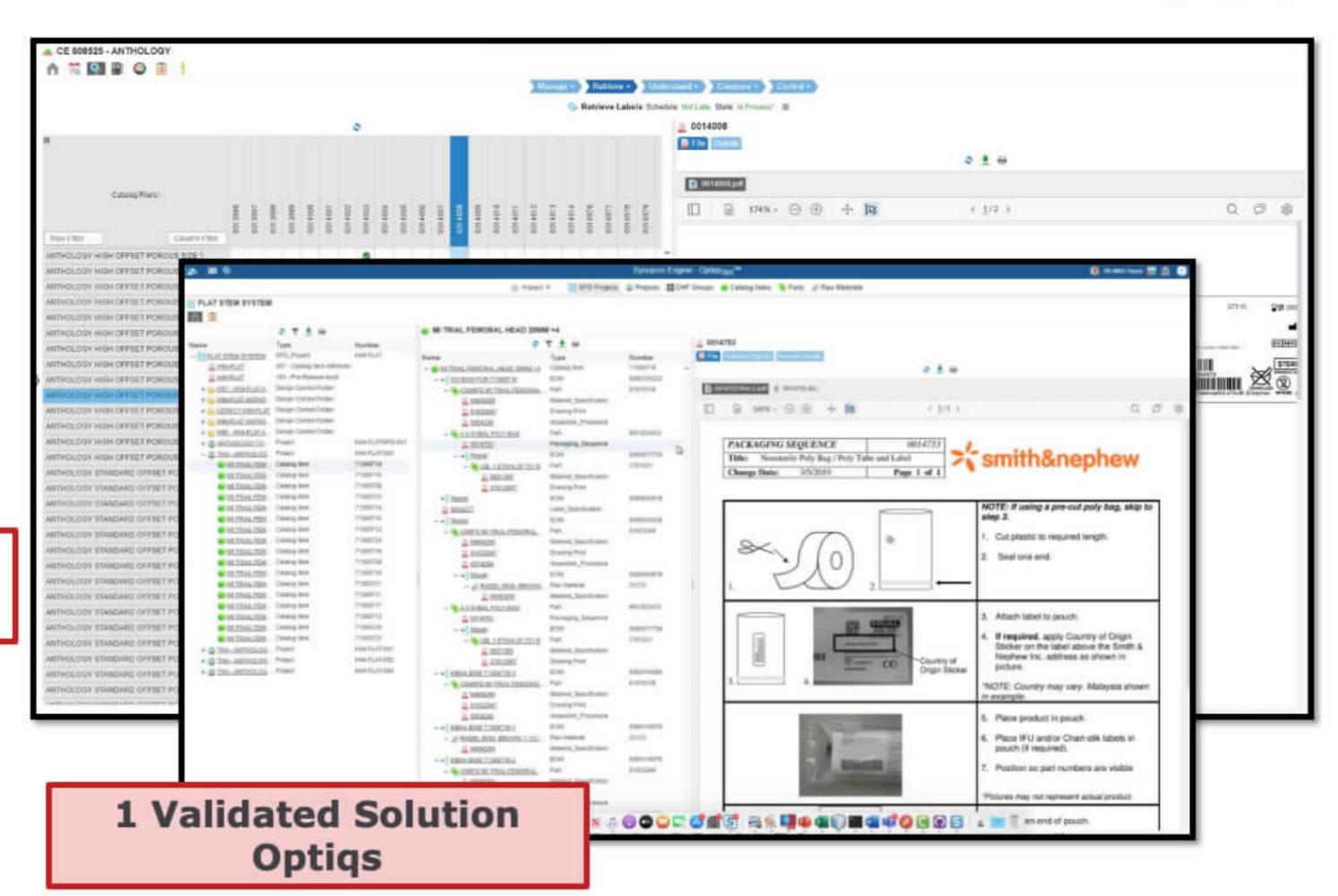
## Before & After (Phase II)





Accumulated Excel spreadsheets by person & department

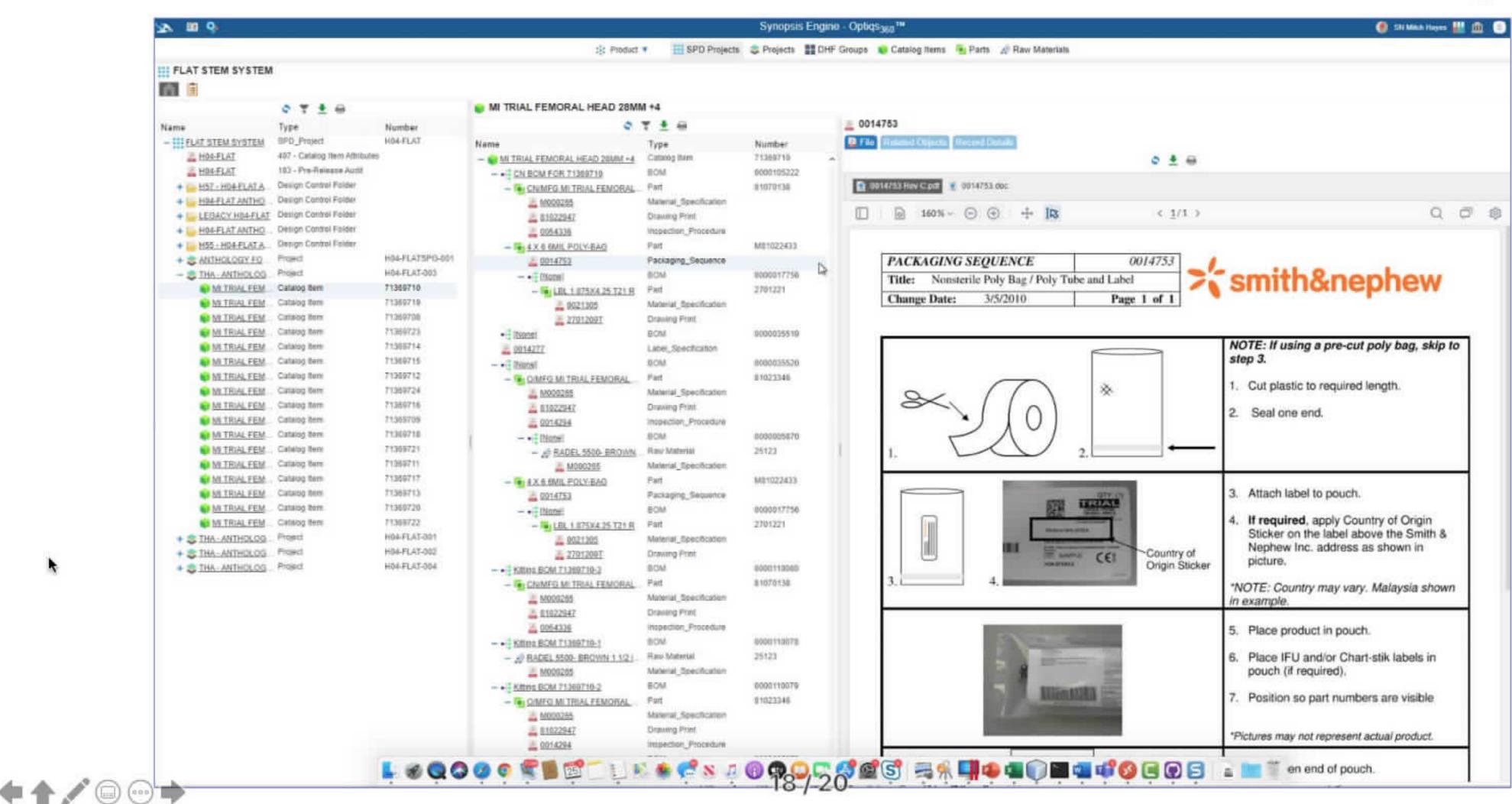
1 – 15 spreadsheets





## Proof of Concept: DHF | DMR | Record





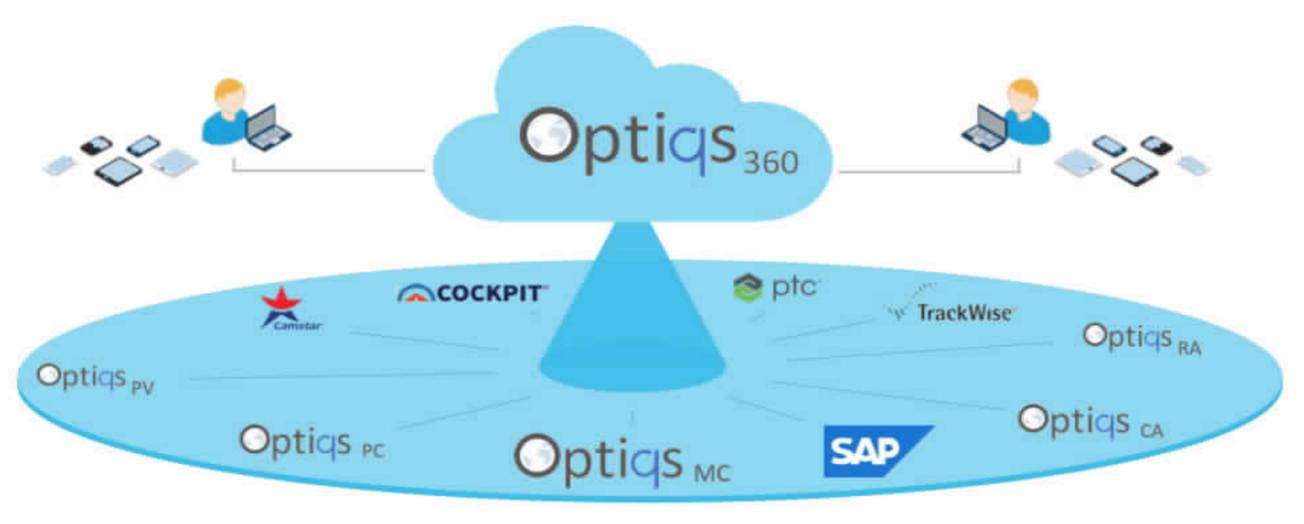
## **Long Term Wins:**



Retrieve Files – Understand - Compare - Control - Project Planning All in one place



Need an intuitive user interface for transforming and harmonizing the enterprise end to end design control process





## Before & After (Phase III)



