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LIVEWORX

A NEW ERA IN PRODUCT LIFECYCLE INNOVATION

SESSION ID: PL1074B

DIGITAL TRANSFORMATION: A JOURNEY NOT A DESTINATION

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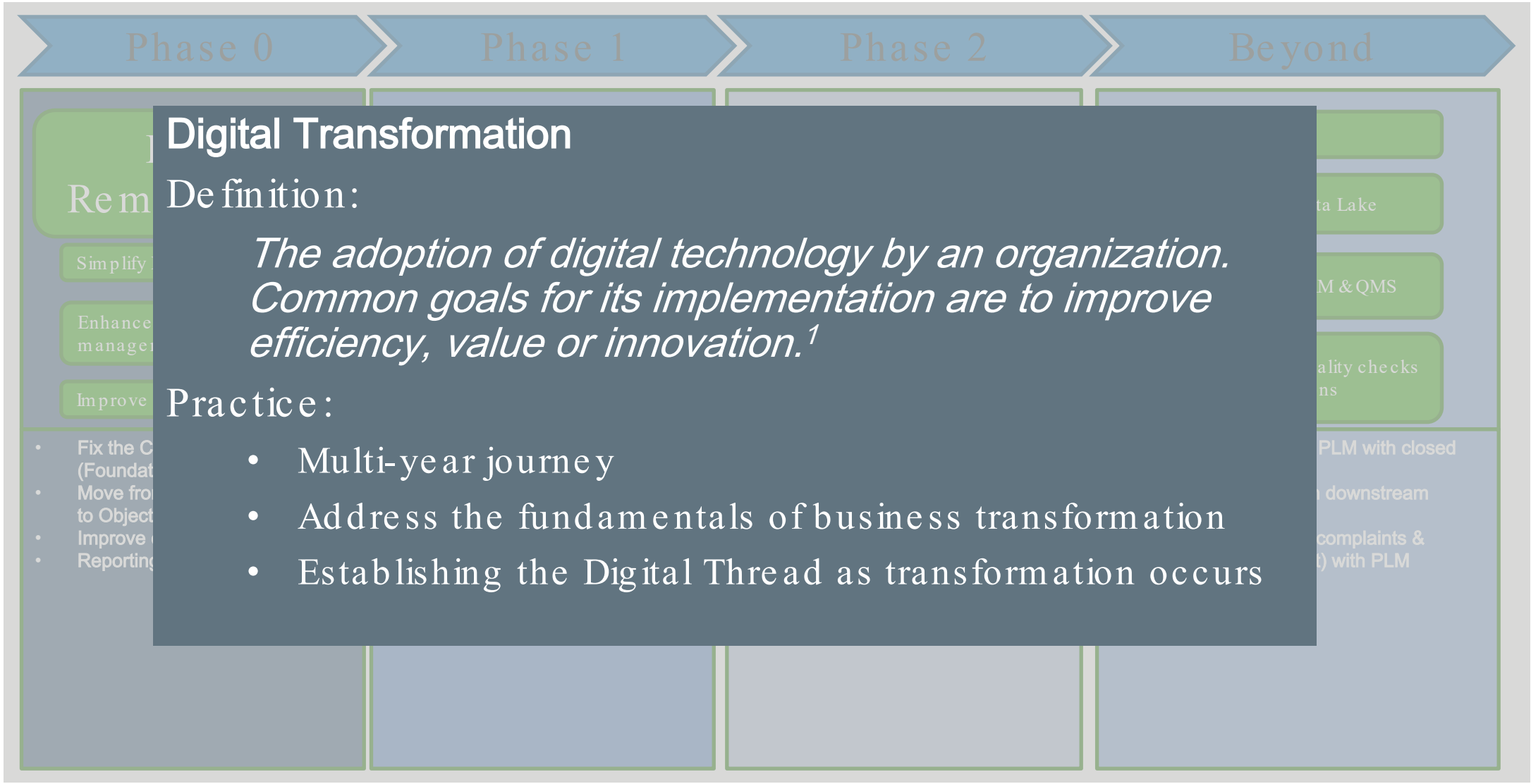
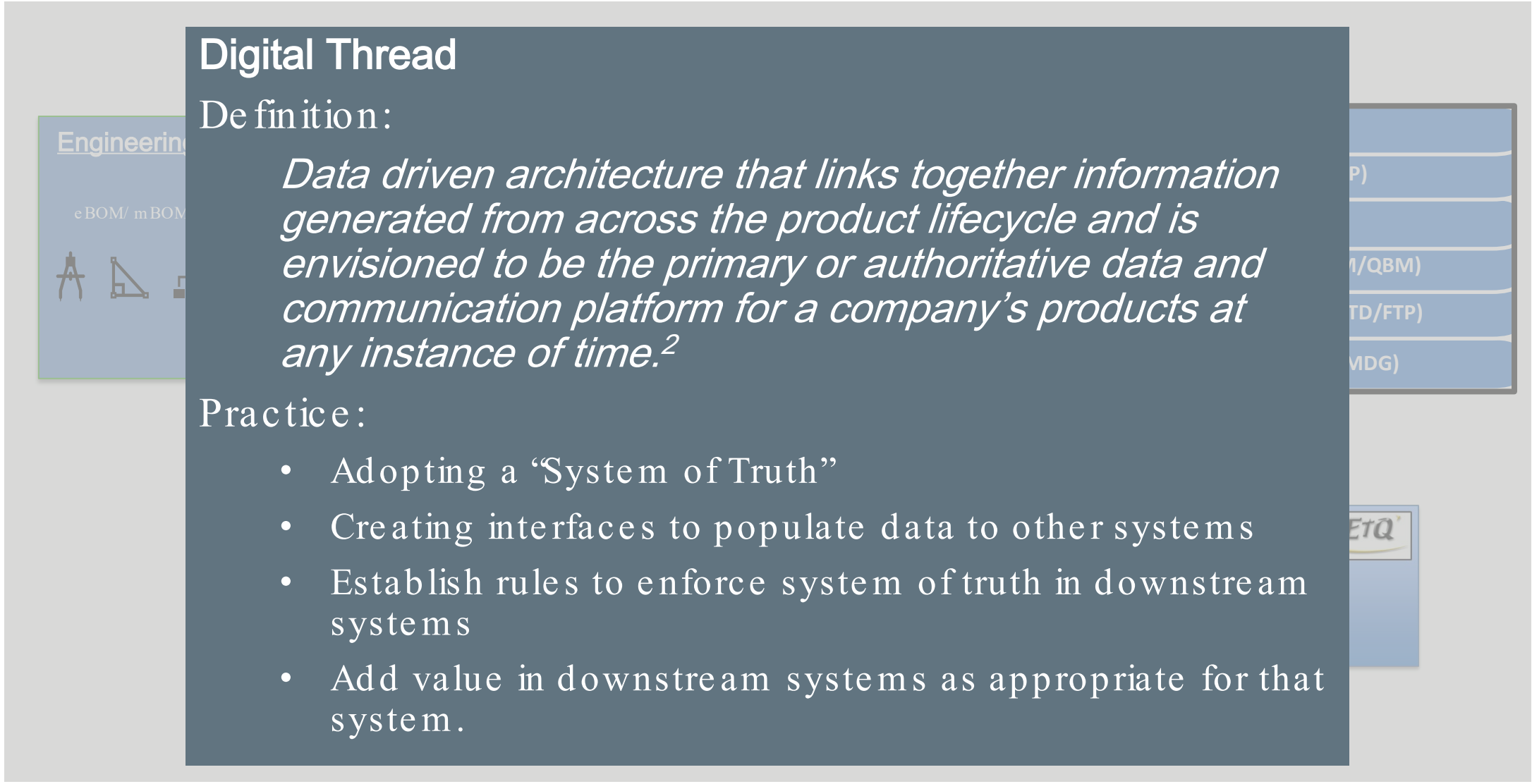
IT Enterprise Architect - MicroVention

DIGITAL TRANSFORMATION



1: Wikipedia.org

DIGITAL THREAD



2: Signh, Victor. "Engineering with a Digital Thread" Aerospace Resource Central, 9/30/2021

AGENDA

- About MicroVention
- Digital Transformation History
- Steps Taken
- Digital Thread
- Roadmap
- Call to Action

MicroVention is highly integrated to lead efforts in advancing neuroendovascular medicine.

Aneurysm Therapy Solutions for ruptured and unruptured aneurysms. MicroVention has two distinct coil lines—Hydrogel Coils and Platinum Coils—both used with the V-Trak™ Delivery System. Additional products include our WEB™ aneurysm embolization system, LVIS™ coil-assist stent, and FRED™ flow diverter stent.*

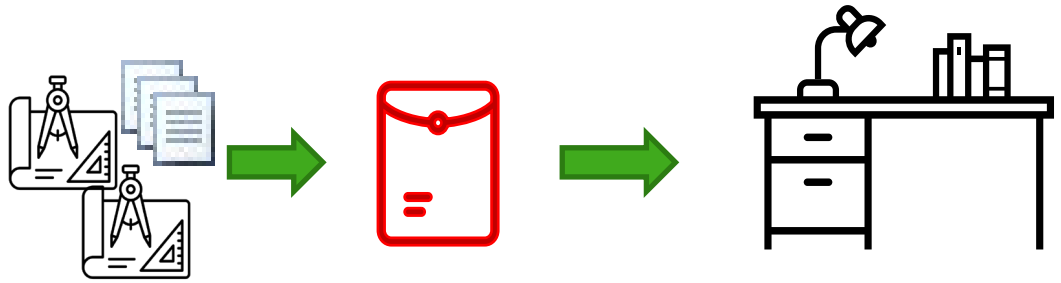
Ischemic Stroke and Carotid Artery Disease Solutions provide options for stenting and mechanical thrombectomy. This portfolio includes CASPER™ carotid stent, SOFIA™ aspiration catheters, ERIC™ stentriever, BOBBY™ balloon guide catheter, and other stroke accessories.* At MicroVention, we continue to make a significant investment into the design and innovation of our stroke technology platform.

Neurovascular Malformation Solutions has PHIL™ liquid embolic* for the treatment of Dural Arteriovenous Fistulae (DAVF), Arteriovenous Malformation (AVM), and Tumors.* Our Headway™ Duo microcatheter and SCEPTER™ compliant dual-lumen balloons complement this category to maximize each patient's treatment options.

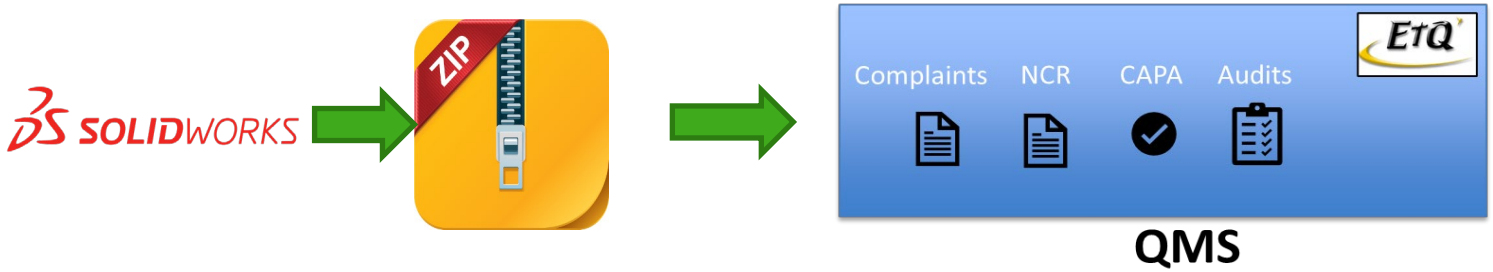
Access Product Solutions guide catheters, intermediate catheters, microcatheters, balloon microcatheters, and guidewires are specifically designed to work interchangeably across each of our product lines. In addition, we provide multiple-access product configurations that include a variety of choices for length, flexibility, shape, inner and outer diameter, design, and material.

TRANSFORMATION HISTORY

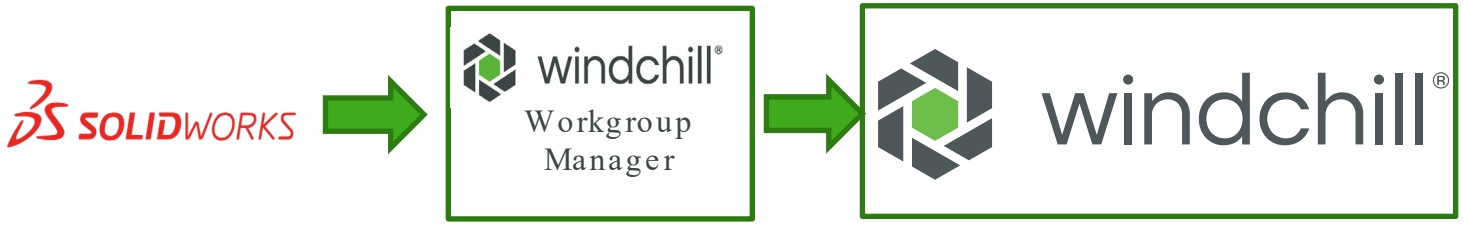
Paper Centric Process



Document Centric Process with CAD



Document Centric with PDM control of CAD for production data



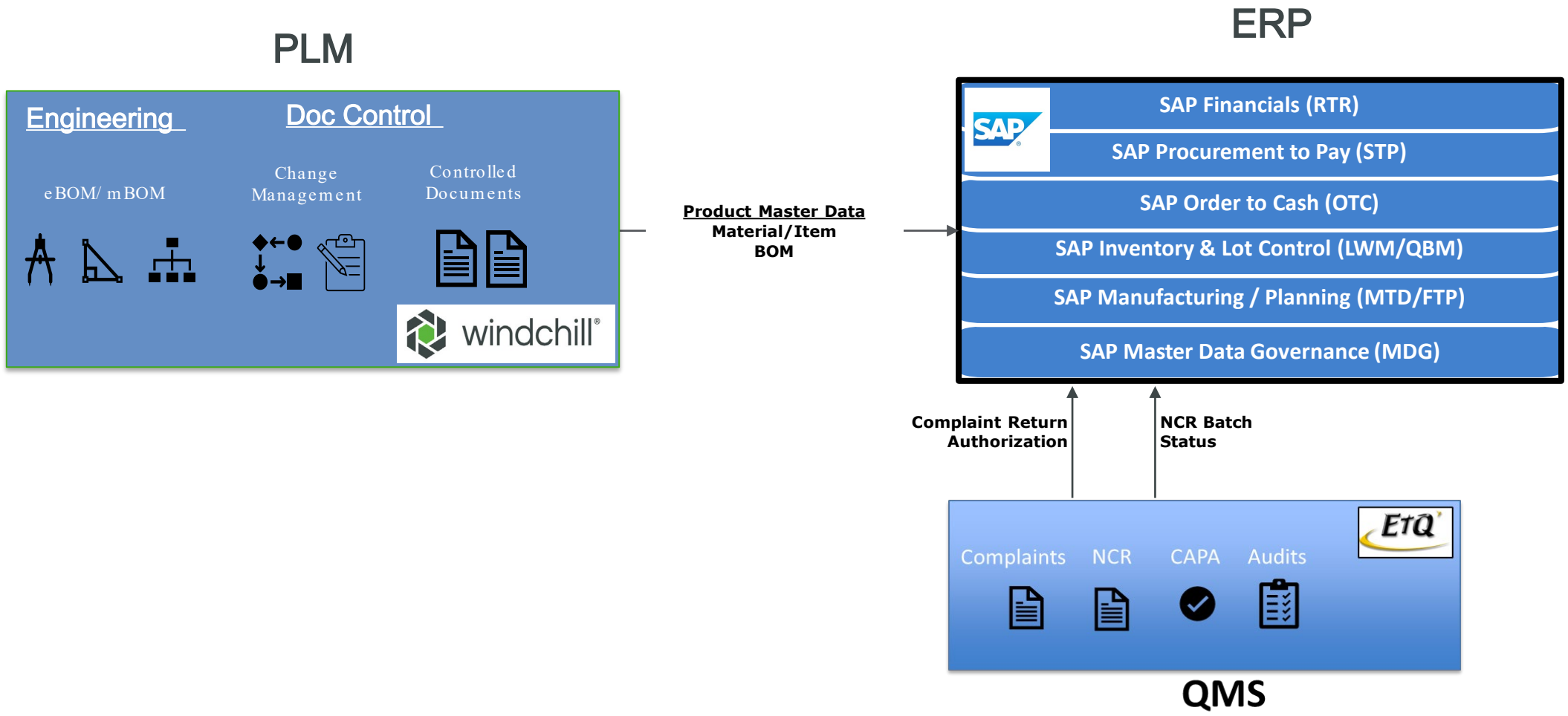
STEP 1

- Put in System for CAD Data Management
  - SolidworksCAD

STEP 2– SCOPE ADDED

- Establish System of Record for:
  - Materials and BOM
  - Manufacturing Process Documentation
  - End-to-end Change management
  - Document Control
  - Integration with SAP

DIGITAL THREAD- CURRENT

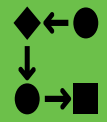


STEP 3- REMEDIATION

- Address Inefficiencies
- Overcome Training Hurdles
- Process Bottlenecks

1 People

- **Steep learning curves** results in poor user adoption, frequent rework and low user satisfaction
- Centralized team to create data in PLM – Longer cycle time

2  Process

- **Complex workflow** and **customizations can** drive unpredictable results
- **Process bottlenecks** and **centralized functions** result in non-scalable, inefficient processes

3 Technology

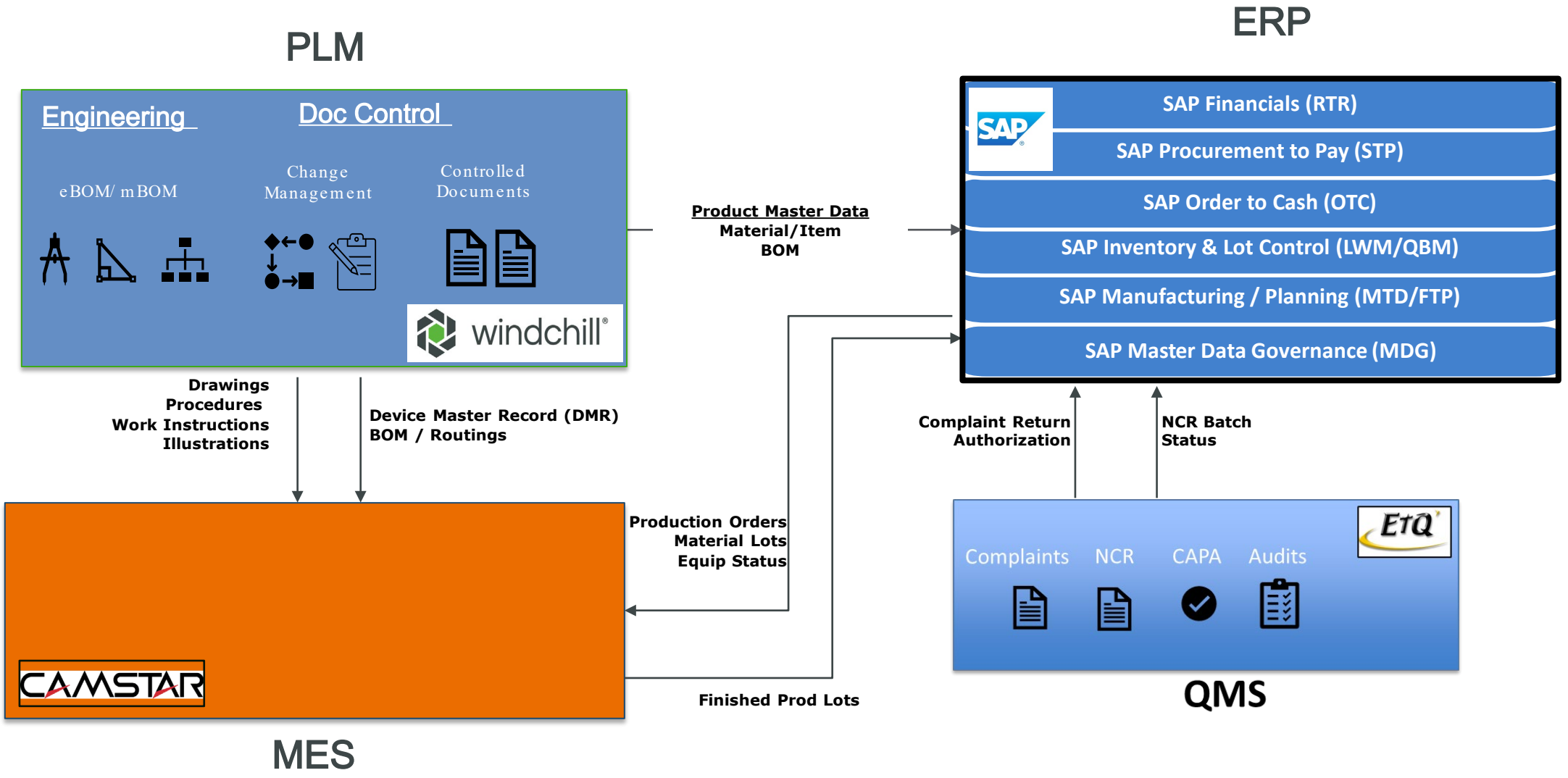
- **Data integrity issues** with legacy data
- System design based on legacy MVI **paper -based** processes
- Object Model doesn't support OOTB Windchill Processes

STEP 4– LONG TERM VISION

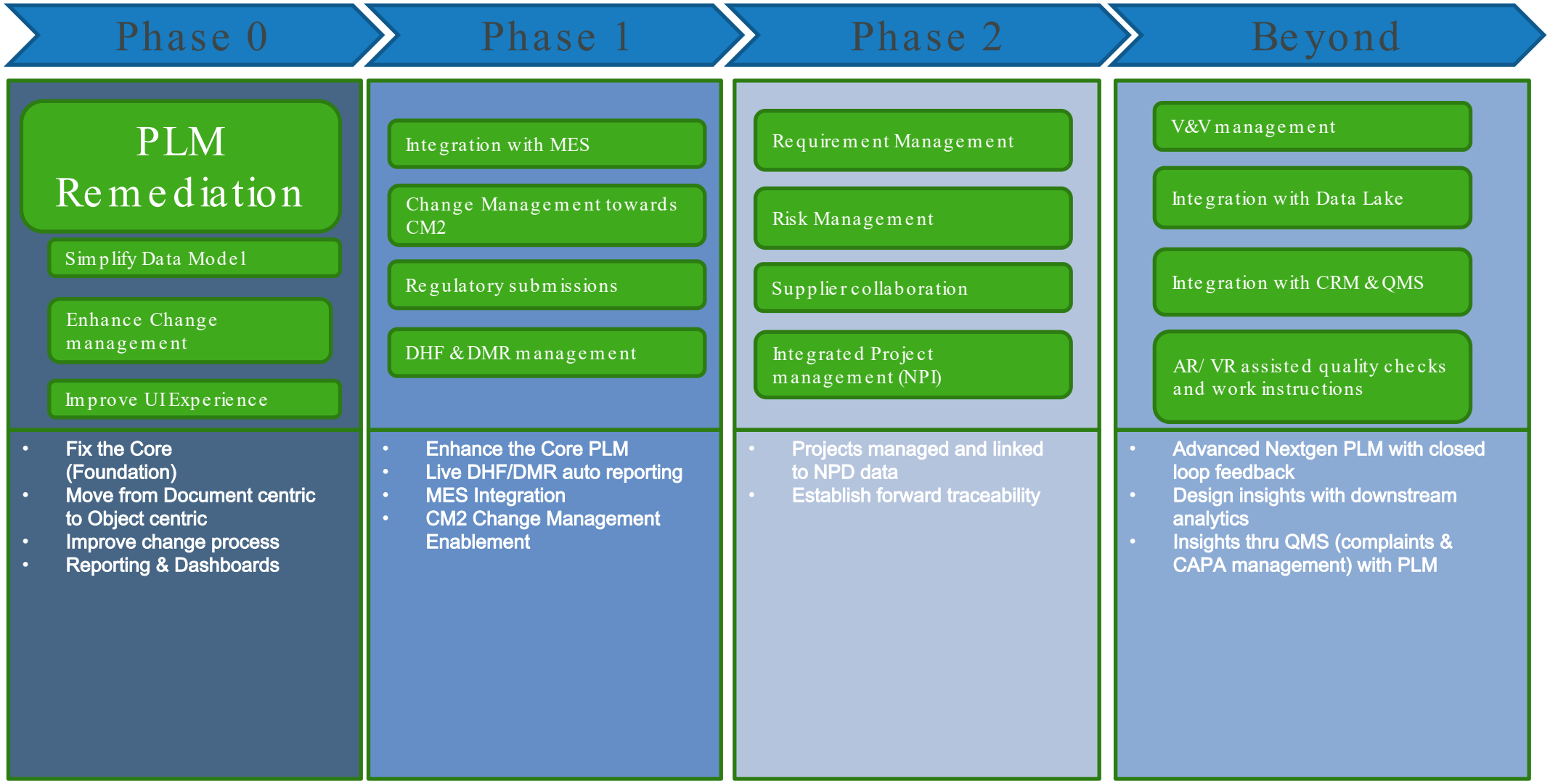
- Communicate
- Educate
- Strategy
- Growth

- Plan for multi -generational project
- Develop strategy for missing technology gaps
- Gaps to be developed along with business value drivers
- Key Business Processes
  - R&D
  - Operations/Manufacturing
  - Regulatory
  - Quality
  - Labeling

DIGITAL THREAD- FUTURE



ROADMAP


Phase 0
Phase 1
Phase 2
Beyond
PLM Remediation
Simplify Data Model
Enhance Change management
Improve UI Experience
Integration with MES
Change Management towards CM2
Regulatory submissions
DHF & DMR management
Requirement Management
Risk Management
Supplier collaboration
Integrated Project management (NPI)
V&V management
Integration with Data Lake
Integration with CRM & QMS
AR/ VR assisted quality checks and work instructions
• Fix the Core (Foundation)
• Move from Document centric to Object centric
• Improve change process
• Reporting & Dashboards
• Enhance the Core PLM
• Live DHF/DMR auto reporting
• MES Integration
• CM2 Change Management Enablement
• Projects managed and linked to NPD data
• Establish forward traceability
• Advanced Nextgen PLM with closed loop feedback
• Design insights with downstream analytics
• Insights thru QMS (complaints & CAPA management) with PLM

BREAKING IT DOWN

- Digital Transformation
  - Implementation of technology is easy
  - Evolving business process vital to adoption of technology
  - Manage the productivity dip of change
  - Communicate early and often
  - Choose the correct business partners
  - Change is given, be willing to learn and adapt
- Digital Thread
  - Avoid manual duplication/entry of data
  - Use appropriate technology based on process or system
    - Direct integration based on trigger event
    - Webservices for pull of information (REST/SOAP)
    - Tidal jobs
  - Process owners for data

ACTION

1. **Make a Roadmap**
   - Identify target areas by business value
   - Align with a timeline
2. **Get Executive Buy-In**
   - Educate to gain alignment
   - Priortize based upon business objectives
   - Mitigate organizational roadblocks
3. **Communicate**
   - Have plan to share with business stakeholders and users
   - Feedback sessions to gain alignment early
4. **Be Flexible**
   - Plans change – Roadmap is living document
   - Update as needed

QUESTIONS?

Thank you! You can find me at:

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PROVIDE SESSION FEEDBACK

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Your feedback provides us with valuable information on how to shape future content strategy for the event!

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THANK YOU

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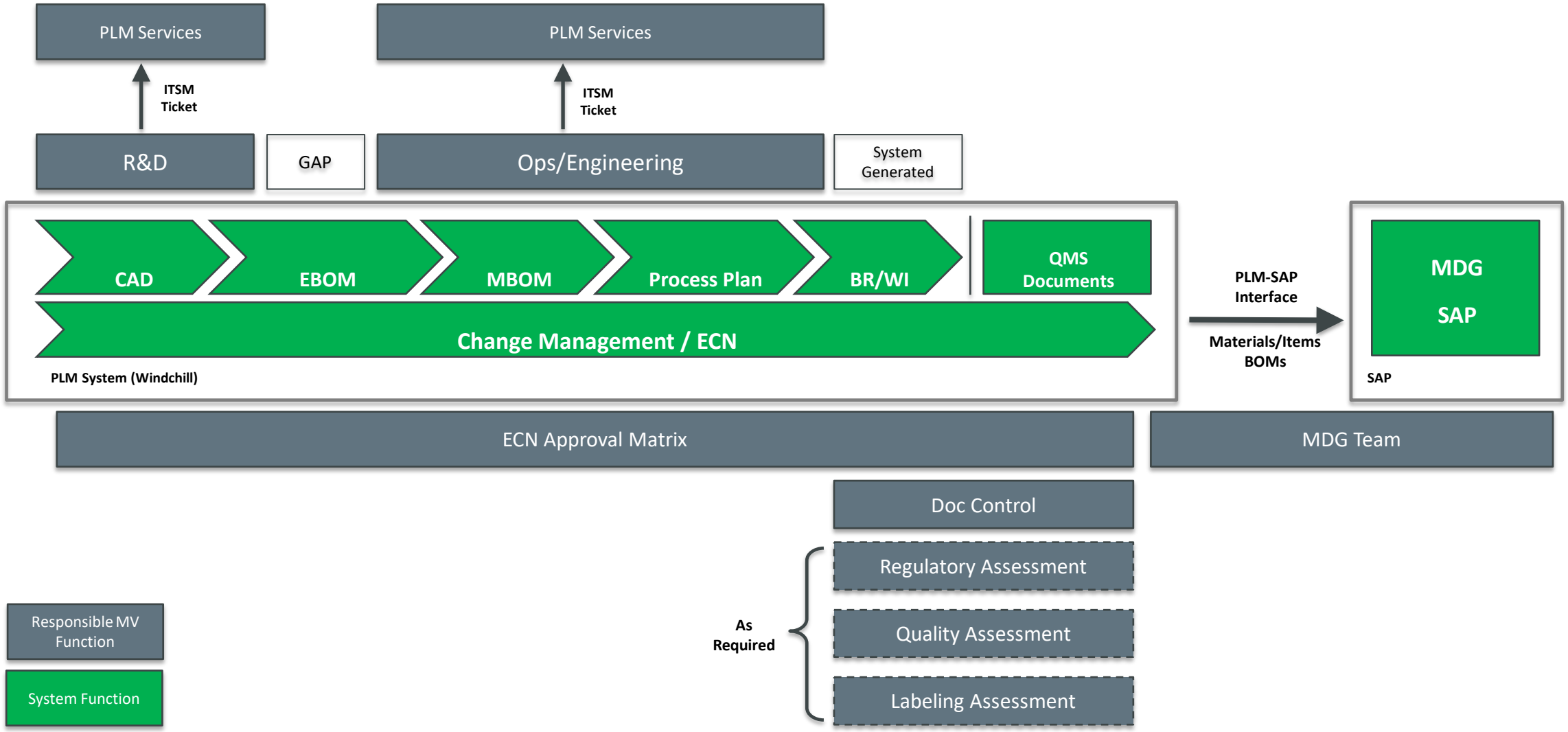
ORGANIZATIONAL CHALLENGES