FLUKE®
Reliability

Complying with Changes to Regulatory Standards

Agenda

About us

Regulation Changes in the Industry & Drivers of Change

What is 21 CFR Part 11 and EudraLex

System Validation, Audit Trail, Electronic Signature Sign Off

KPIs and Metrics to support compliance

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Speaker Introductions

Tara Acree

Tara Acree is an enterprise account executive for the life sciences and automotive industries at eMaint, a Fluke Reliability company. She specializes in SaaS-based solutions and hardware tools across enterprise platforms, focused on a best practices approach.

Roy Rothwell

Roy Rothwell is the director of customer success, EMEA, for eMaint and Fluke Reliability. His customer services team provides unrivaled support in implementation, consulting, training, customer success management and helpdesk support.

About Us

- Subsidiary of Fortive, a diversified industrial technology conglomerate
  - **Part of Fluke Corporation** #1 in the world Industrial Precision Measurement
    - **eMaint CMMS** 35 Years on the market, Serving maintenance & reliability leaders **70,000** customers
      - Dedicated Life Sciences Team

Introduction

We will discuss changes, challenges, and industry trends along with best practices on how Life Science companies can:

- Comply with regulatory requirements
- Mitigate risk and provide world class metrics
- Automate digital processes to reduce manual methods

Includes an overview of proven steps to comply with FDA, GMP, and other regulatory practices while enhancing maintenance strategies to improve efficiency and visibility.

Audience Poll

What are you currently using to manage the maintenance on your equipment?

A. Nothing

B. Paper

C. Homegrown system

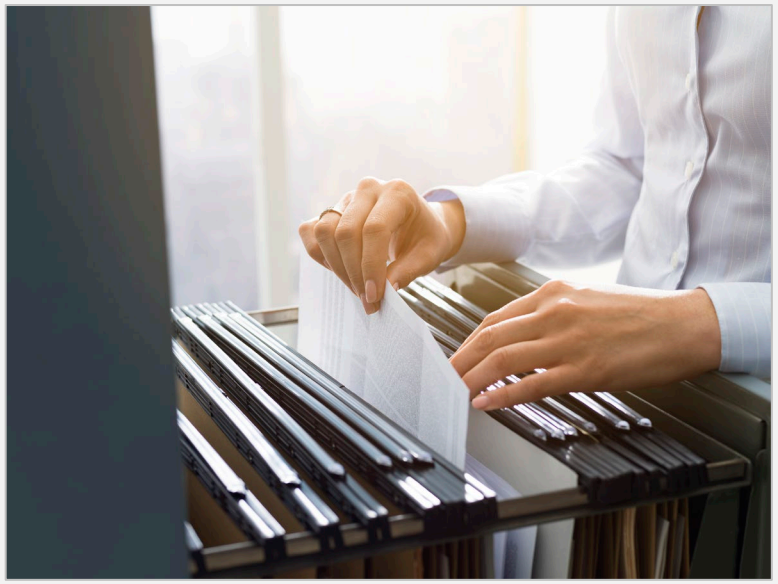
D. CMMS

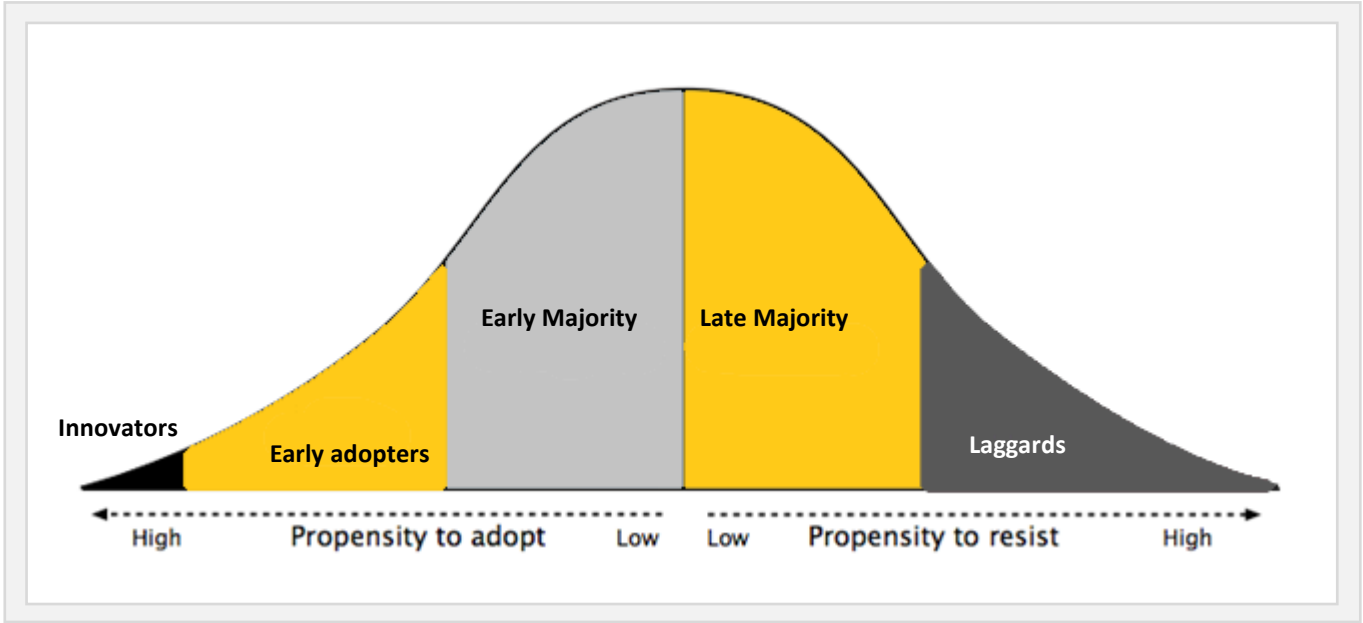
E. Validated CMMS

Traditional Life Sciences and New Technologies

Traditionally Manual Methods: Paper & Excel

- Costly to implement new processes
- Data Integrity
- Cyber Security
- Training & Skills Sets





Reasons for Change

1990
Pharma industry requests guidelines from the FDA for **electronic records and signatures**

1991
The FDA creates **Task Force on Electronic Identification / Signatures** to develop a uniform approach by which the FDA could accept electronic records and signatures for **all regulated activities**

1992
(February) Working group recommends publication of **ANPRM** to obtain public comment

(July) FDA publishes ANPRM and receives **53 comments**

1994
FDA publishes proposed rile in the **Federal Register** and receives **49 comments**

1997
(March) FDA publishes **21 CFR Part 11 Final Rule**

(August 20th) Part 11 **goes into effect**

1999
FDA publishes a **Compliance Policy Guide** (CPG) and drafts **five guidance docs**

2002
FDA announces modernization initiative, ***Pharmaceutical cGMPs for the 21st Century – A risk-Based Approach***

2003
(February) The FDA **Revokes CPG 7153.17**, the enforcement policy and the **Part 11 guidance documents**

(August) FDA publishes new Guidance for Industry – ***Part 11, Electronic Records, Electronic Signatures – Scope and Application***

2010
FDA announces intent to conduct inspections focusing on 21 CFR 11 requirements relating to **human drugs**

Why do we do this?

- Goal of regulators is to ensure the safety and quality of products for the consumer.
- Audits and inspections are meant as a safeguard for the overall public health

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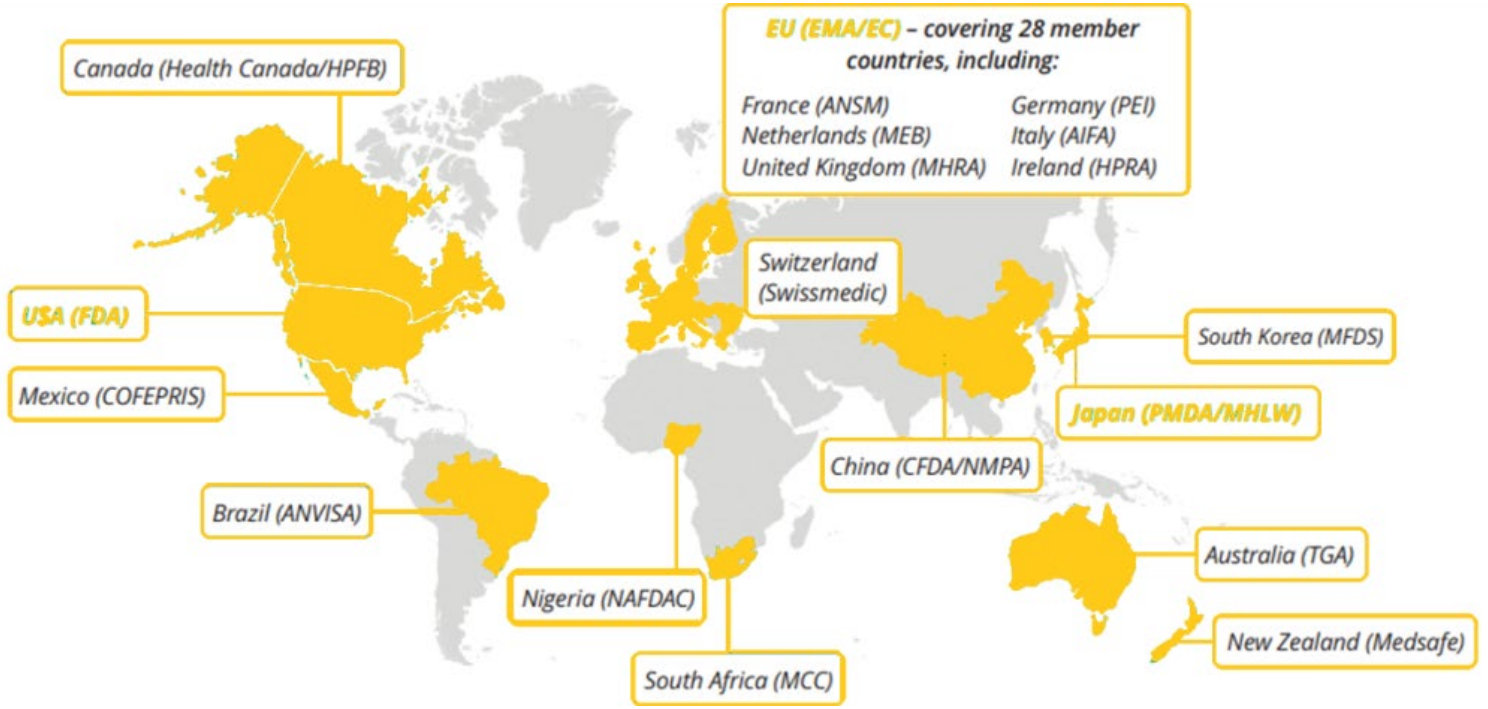
What are the Challenges?

- Variance in regulatory Standards - Different standards around the world
- Increase demand for Digital Documentation
  - Early 1990s introduction to 21 CFR Part 11 Compliance1991-Electronic Records and Signatures
  - 2002 publication ***Pharmaceutical cGMPs for the 21st Century – A Risk-Based Approach***, was created to encourage adoption of new technological advances and implement risk-based approaches
  - 2018 Canada and United states use a Common electronic submission gateway to ensure inspection schedules on equipment and labs

Regulatory Organizations Worldwide



United States (FDA) Food and Drug Administration	**European Union (EMA and EC**) European Medicines Agency / European Commission	**United Kingdom (MHRA)** Medicines and Healthcare products Regulatory Agency
Brazil (ANVISA) Agência Nacional de Vigilância Sanitária	**Ireland (HPRA)** Health Products Regulatory Authority	**New Zealand (Medsafe)** New Zealand Medicines and Medical Devices Safety Authority
Canada (Health Canada/HPFB) Health Canada/ Health Products and Food Branch	**Italy (AIFA)** Agenzia Italiana del Farmaco	**Nigeria (NAFDAC)** National Agency for Food and Drug Administration and Control
China (CFDA/NMPA) China Food and Drug Administration / National Medical Products Administration	**Japan (PMDA/MHLW)** Pharmaceuticals and Medical Devices Agency / Ministry of Health, Labour and Welfare	**South Africa** (MCC) Medicines Control Council Switzerland (Swissmedic) Swiss Agency for Therapeutic Products
Germany (PEI) Paul Ehrlich Institute	**South Korea (MFDS)** Ministry of Food and Drug Safety	**Switzerland (Swissmedic)** Swiss Agency for Therapeutic Products
France (ANSM) Agence Nationale de Sécurité du Médicament et does Produits de Santé	**Mexico (COFEPRIS)** Comisión Federal para la Protección contra Riesgos Sanitarios	**Netherlands (MEB)** Medicines Evaluation Board
		Australia (TGA) Therapeutic Goods Administration

What is 21 CFR Part 11 & Eudralex

21 CFR Part 11 and EudraLex Annex 11 compliance focus on five critical areas:

Impact of regulations on the client's computer systems, including Quality Management Systems

1

Identification of the client's computer systems and operating environment

2

Review and consideration of client procedures

3

Analysis of procedural documentation, validation, and audit data

4

Regulatory significance of the computer systems

5

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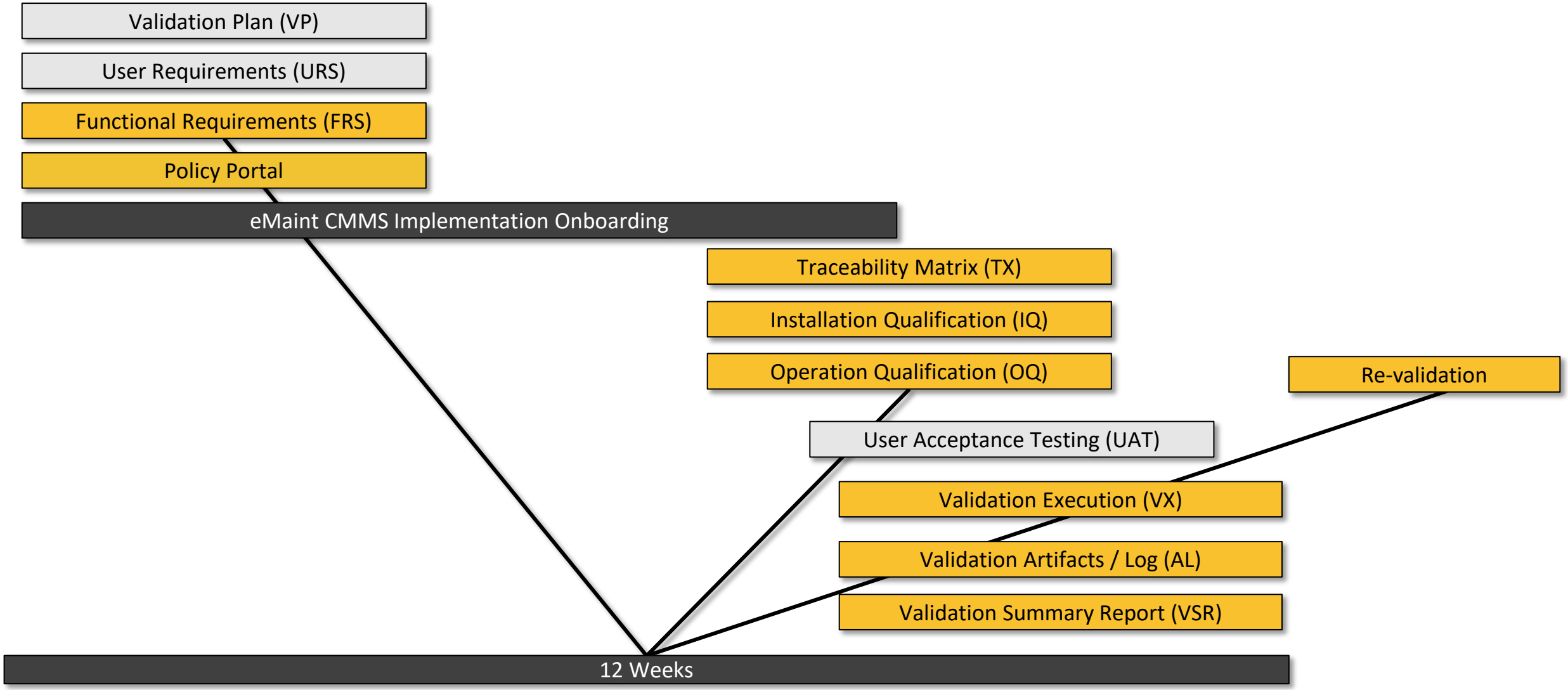
Compliance - Buzzword Bingo!

FDA 21 CFR	EudraLex Volume 4 Annex 11
FDA 21 CFR Part 11 1. Controls for Closed Systems 2. Controls for Open Systems (Not Applicable) 3. Signature Manifestation 4. Signature/Record Linking 5. Electronic Signatures – General 6. Electronic Signatures – Non-Biometric 7. Controls for Identification Codes and Passwords	1. Risk Management 2. Personnel 3. Suppliers and Service Providers 4. Validation 5. Data 6. Accuracy Checks 7. Data Storage 8. Printouts 9. Audit Trails 10. Change and Configuration Management 11. Periodic evaluation 12. Security 13. Incident Management 14. Electronic Signature 15. Batch Release 16. Business Continuity 17. Archiving
FDA 21 CFR Part 820 1. FDA 21 Part 820 Quality System Regulation 2. FDA 21 Part 820.50 Quality - Purchasing controls 3. FDA 21 Part 820.70(i) Production and process controls 4. FDA 21 Part 820.75 Process validation	

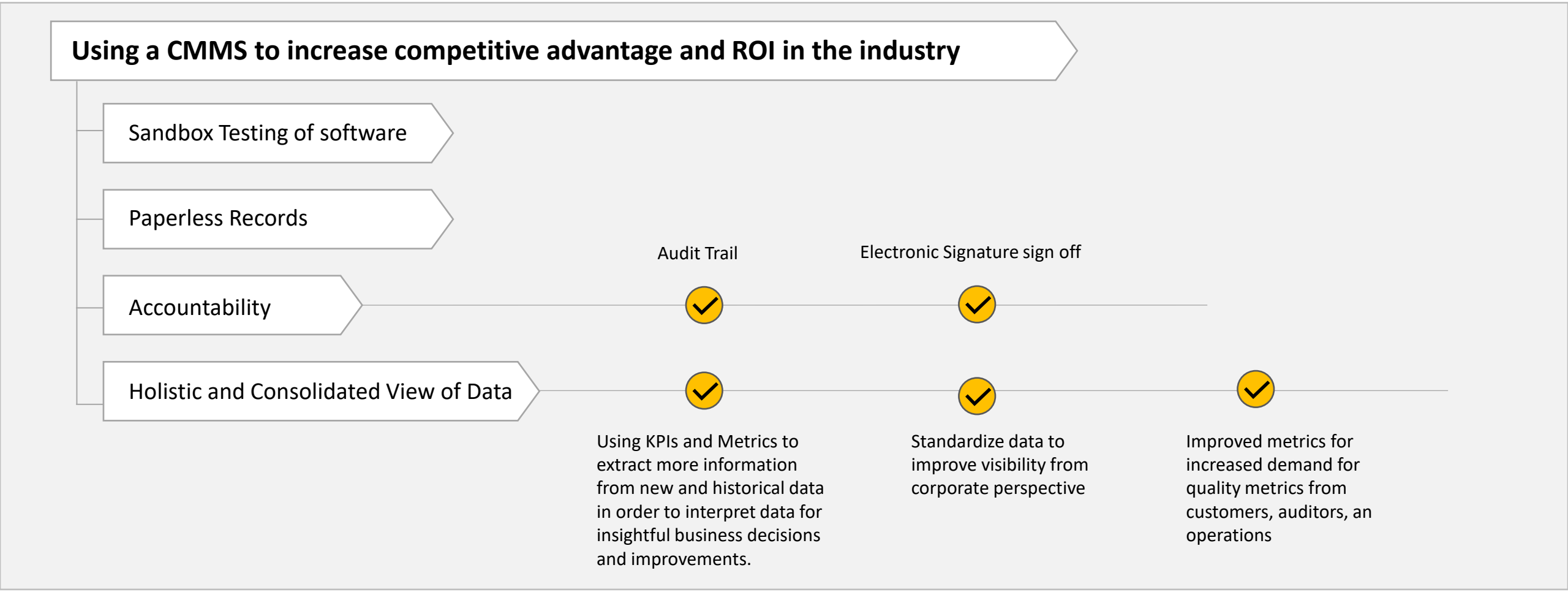
Compliance - Stakeholder landscape

Client	Pre- Sales / Sales	Governance, Risk, Compliance, Quality, Information Security	Product eMaint CMMS	Implementation & Validation	Support	Re-Validation
GxP 21 CFR Part 11 EudraLex Annex 11	User Requirements Functional Requirements Non-Functional Requirements Vendor Audit	Quality QMS GDP Non-Functional Requirements Policies SOPs Technical Responses	Electronic Records Electronic Signatures	Implementation & Computer System Validation	Release Management	Periodic Review Computer System Re-validation
Resources / Components / Deliverables						
		NDA Policy Portal	Release Notes	Validation Environment Functional Requirements Specification Traceability Matrix Installation Qualification Operational Qualification Artifacts Log On-site CSV Execution	Release Notes	Re-validation Environment Digital Re-validation report

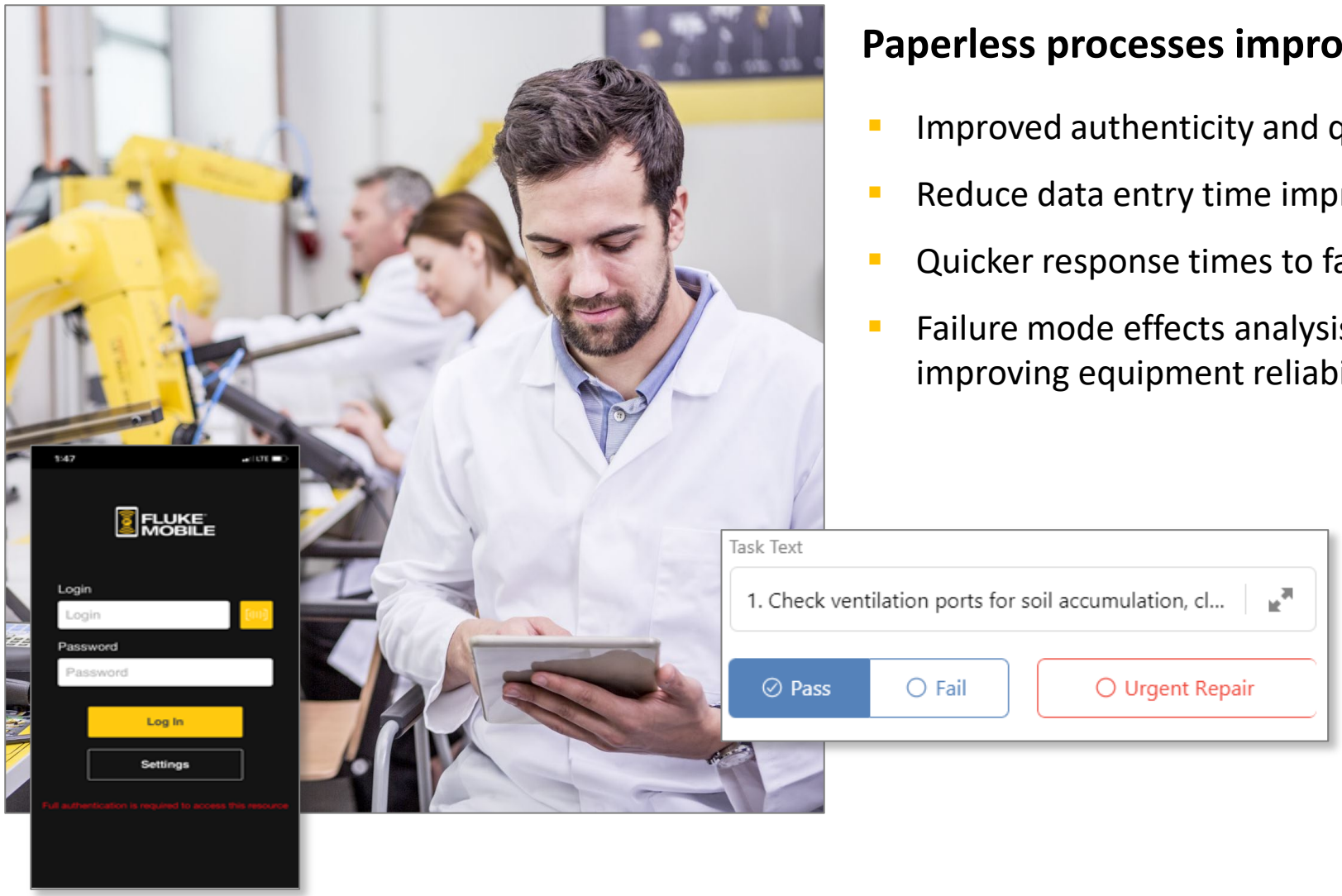
Compliance - CSV Approach & "V" Model



Ways Technology Can Help



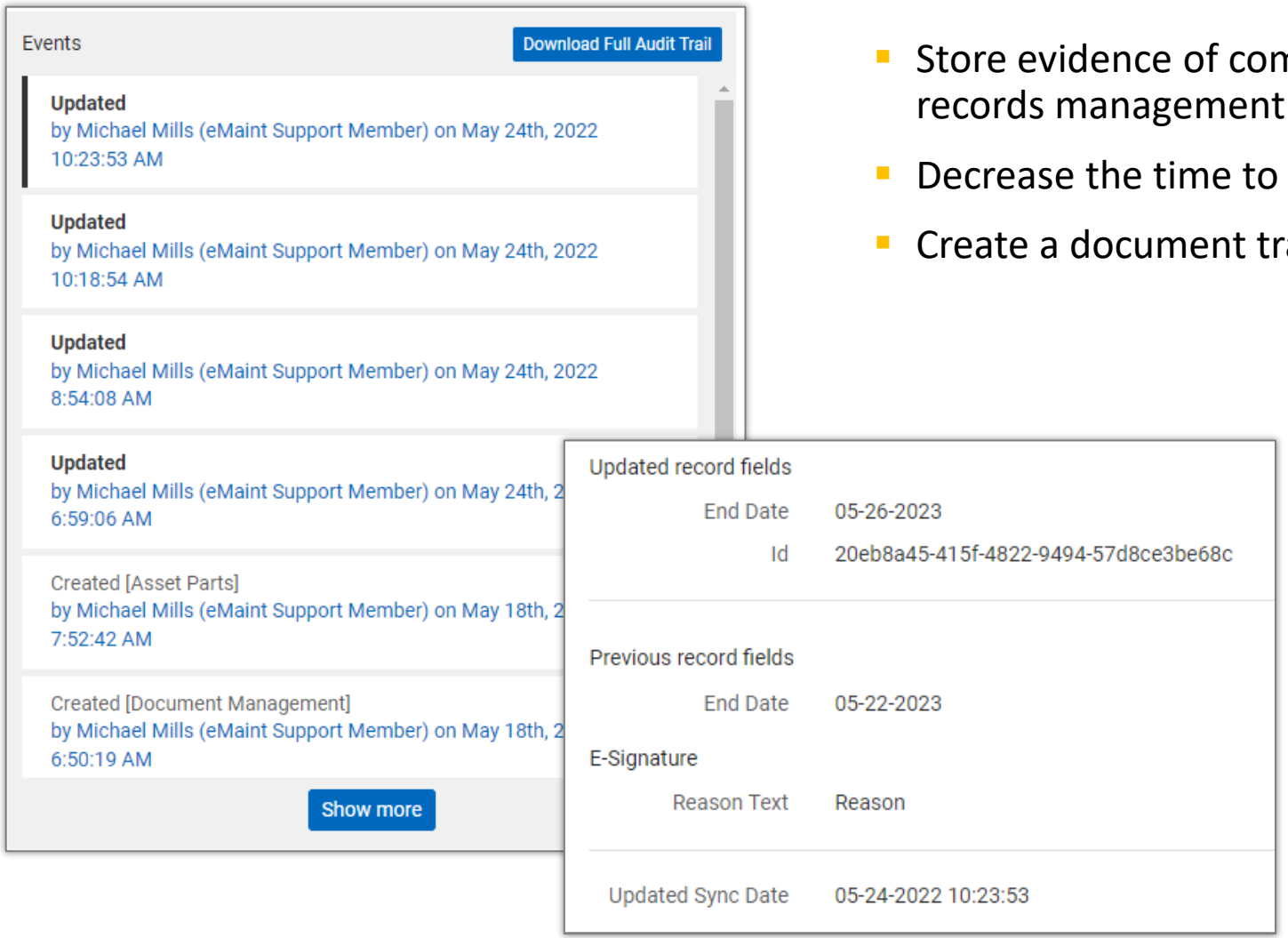
Paperless Records



Paperless processes improve competitive advantage by:

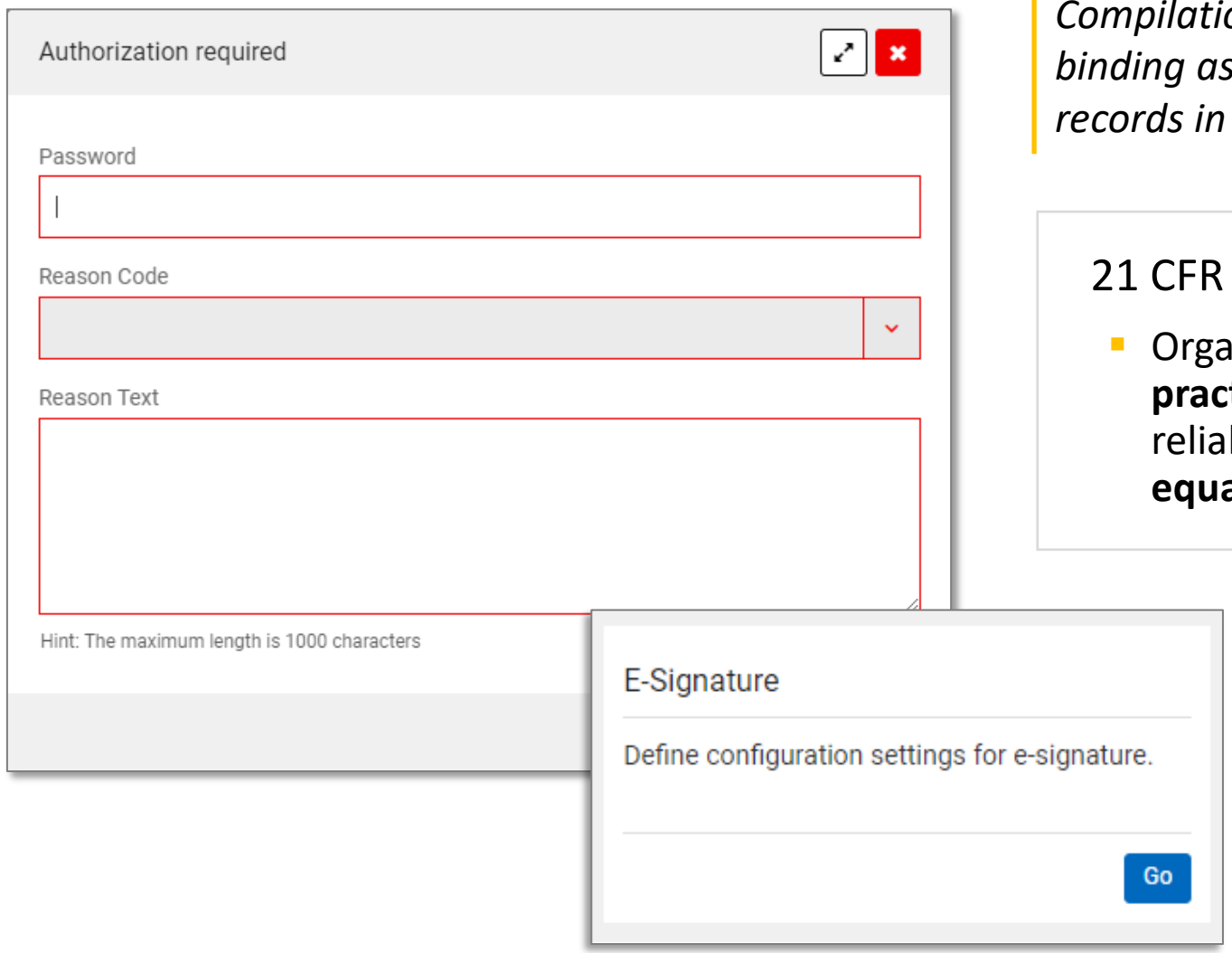
- Improved authenticity and quality of data
- Reduce data entry time improving efficiency of staff and production
- Quicker response times to failures and quality reviews
- Failure mode effects analysis for predicting future issues and improving equipment reliability

Accountability: The Audit Trail



- Store evidence of compliance and demonstrate your records management
- Decrease the time to prepare and complete an audit
- Create a document trail for future audits

Accountability: Electronic Signature

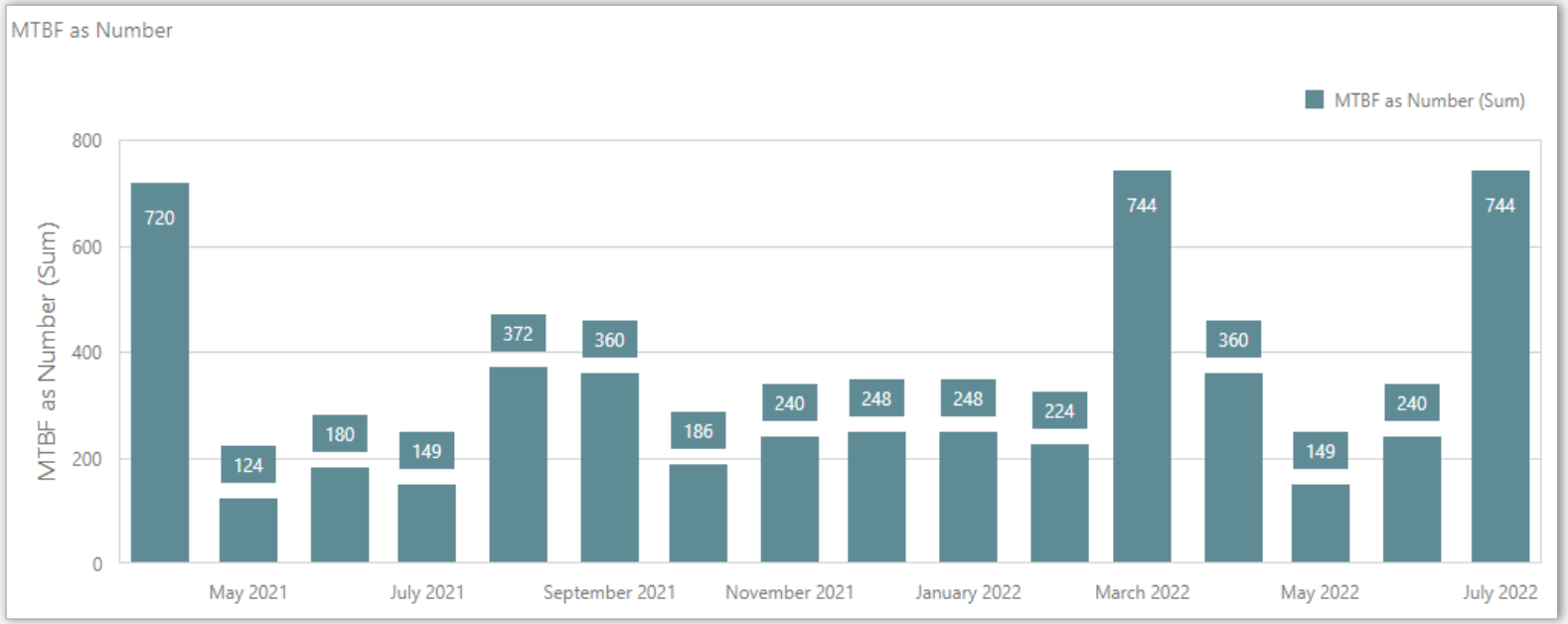


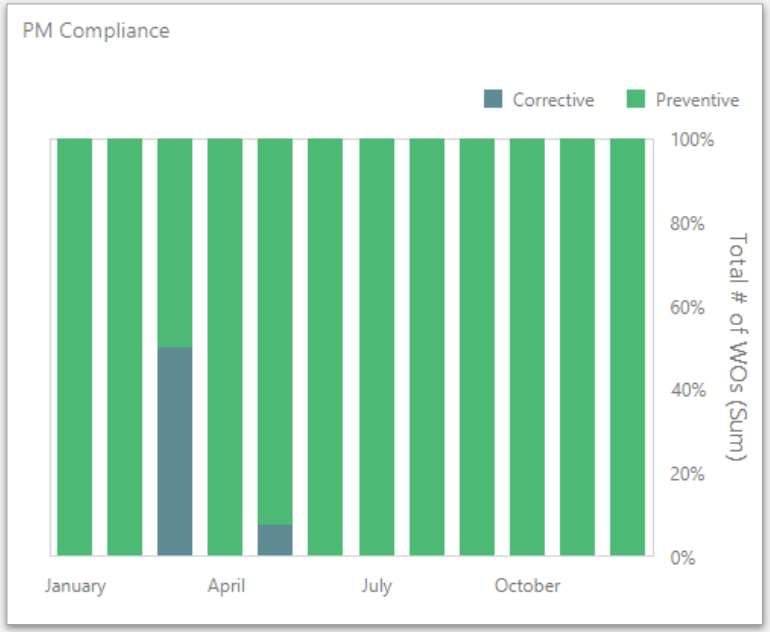
Compilation of electronic data that is as unique and legally binding as a handwritten signature but is used to sign records in a computer system.

21 CFR Part 11 on electronic signatures:

- Organizations must **adopt sound business practices** by ensuring signatures to be accurate, reliable, confidential, authentic, trustworthy, and **equal to paper and handwritten signatures.**

Using a CMMS to increase competitive advantage and ROI in the industry





Holistic and Consolidated View of Data

- The ability to interpret data for insightful business decisions and improvements based on new & historic trends
- Standardize data to improve visibility from corporate perspective
- Provide historical analysis to satisfy increased demand for quality from customers, auditors, and operations

Audience Poll

Which *element?* of CMMS that increases competitive advantage and ROI would you perceive as most *helpful? relevant?* for your organization?

A. Sandbox Testing of software

B. Paperless Records

C. Accountability (Audit trail, e-signature sign off)

D. Holistic and Consolidated View of Data

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In Summary

Changes in regulatory standards and increased demand around the world have caused strict demands from companies on:

- Digital Documentation
- Accountability & Quality reviews
- Paperless record keeping
- World Class Metrics

21 CFR Part 11 allows companies guiding regulations ensure the safety and quality of products for the consumer via:

- Audit Trail
- Electronic Signature Sign Off
- System Validation
- Maintaining the validated state

Let us know if you would like us to follow up with you.

A. Please call me- I'd like to learn more!

B. Please send me educational materials via email

C. This was great, but I don’t need any more information at this time.

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Up Next

- **Webinar 2:** Using a CMMS to Help Solve the Worker Shortage

- **Webinar 3:** Innovations in Maintenance, from AI to IIoT Sensors and AR/VR
  - Technology enabled approach

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THANK YOU!

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