

Beyond Compliance to Collaboration with Modern Safety Content Management Solutions



veeva



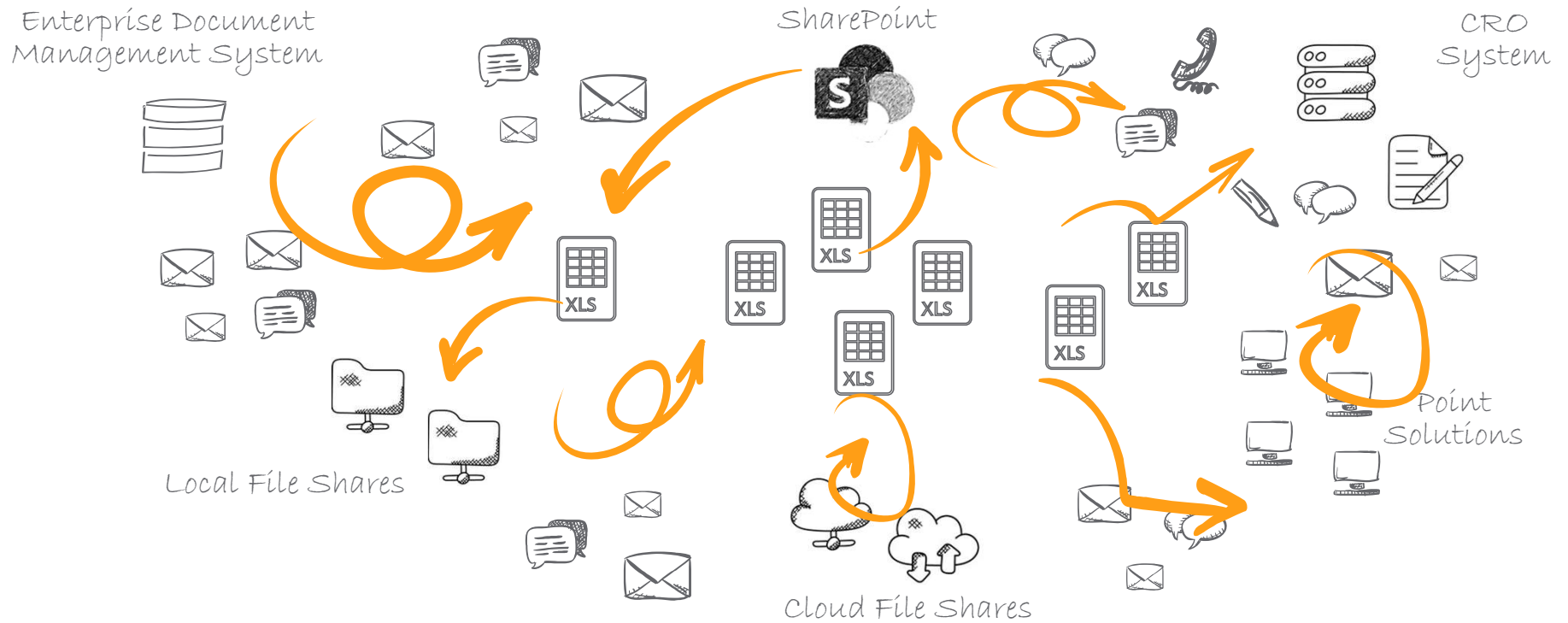
Question

Which of these content areas do you manage today?

- PV System Master File (PSMF)
- PV Agreements / SDEA's
- Periodic Report
- Literature
- Risk Management Plans
- Safety Management Tracking



Complex and Manual PV Content-related Processes



Keeping Up with Global Regulations

Authority Requirements

- European Union
- United Kingdom
- Eurasian Economic Union (EAEU)
- Latin America
- League of Arab States
- China
- Australia
- Iran
- African Countries
- India
- Indonesia
- Macedonia
- Montenegro
- Serbia
- Turkey
- Uzbekistan





Question

What are your challenges in managing and / or sharing PV content?

1. System is not purpose built for Safety teams
2. System does not easily support the evolving regulation landscape
3. System has poor sharing / collaboration capabilities
4. Limited oversight and manual processes
5. All of the above





Customer Case Study



Challenges Managing PSMF



High overhead for
collaboration



Limited global
content oversight



Time consuming to
generate PSMF file




Difficult to keep up
with regulations




Customer Evaluation Criteria

Collaborate




Easily collaborate with all stakeholders

Trusted Global Content



Unified, accessible / visible internally and externally

Easy to Use



User friendly interface with intuitive workflows



Approaches to Managing PSMF

Traditional Decentralized



Manage all PSMF content locally to meet regional requirements

Modern Modular



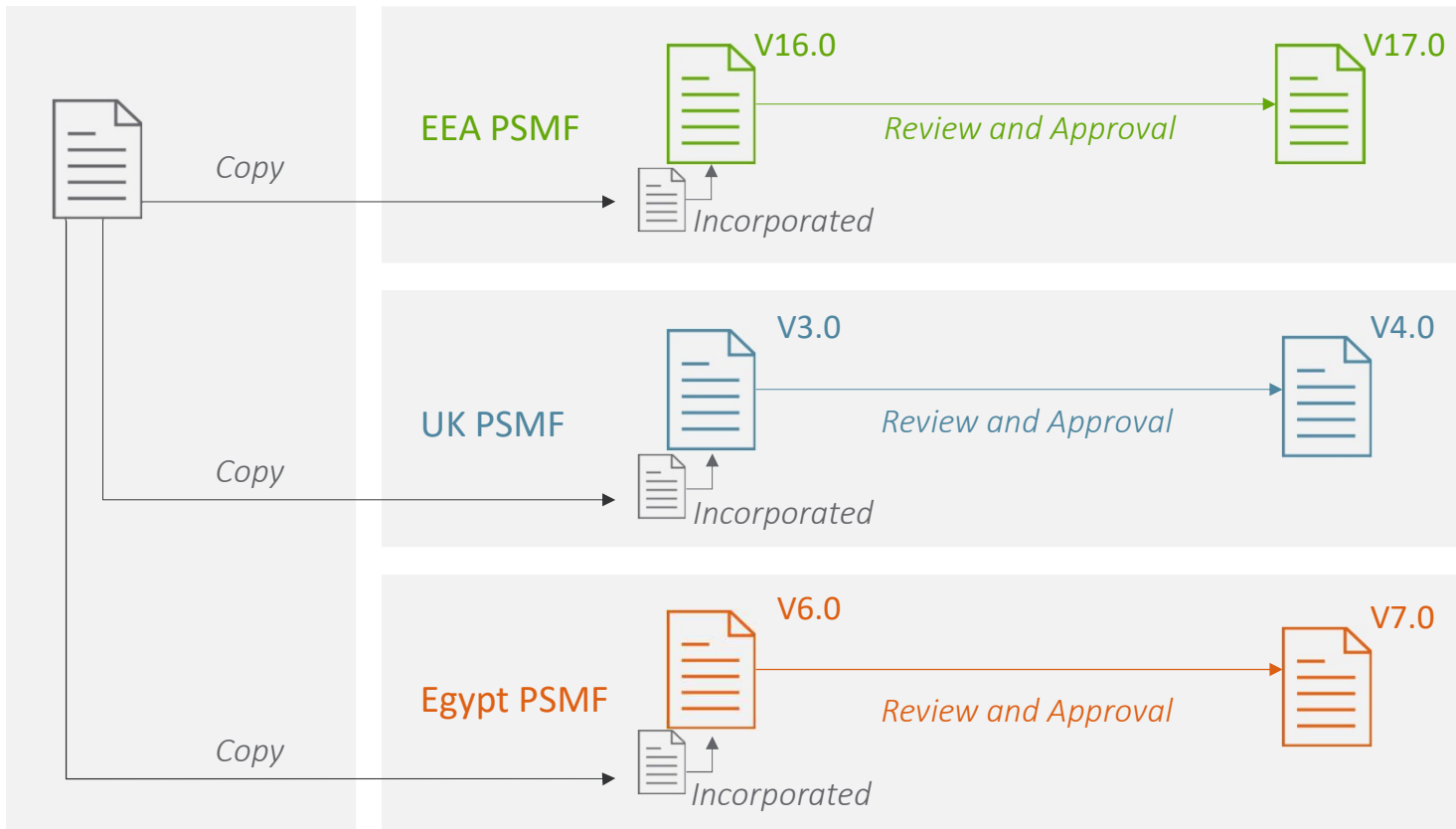
Centrally manage global content and regionally manage local variations



Traditional Global PSMF Management

Common Content

Each PSMF is a single document and managed regionally



High Manual Overhead

Redundant Content

Common content copied and edited within each PSMF

Documents Out of Sync

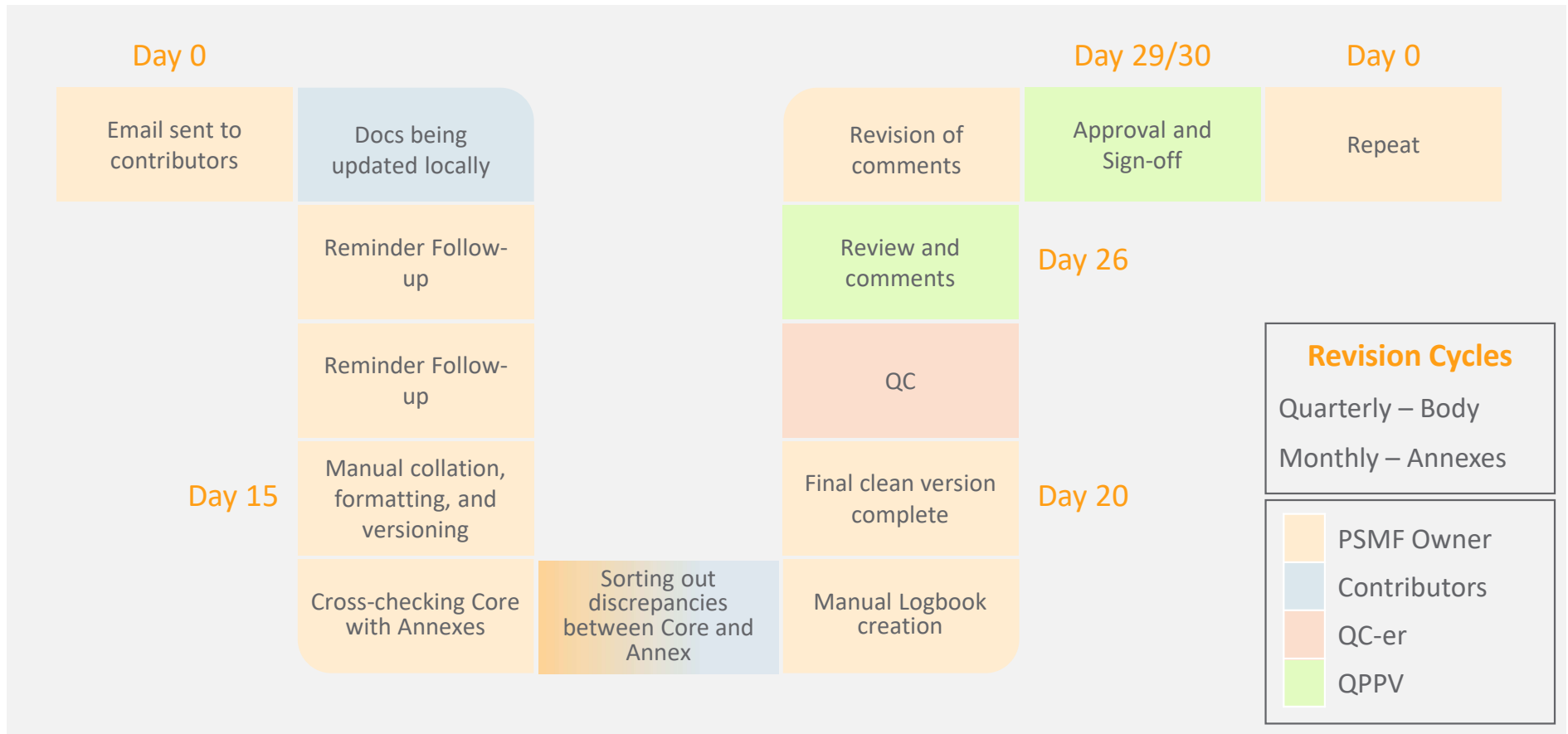
Difficult keeping copied content in sync with original

Reconciliation Overhead

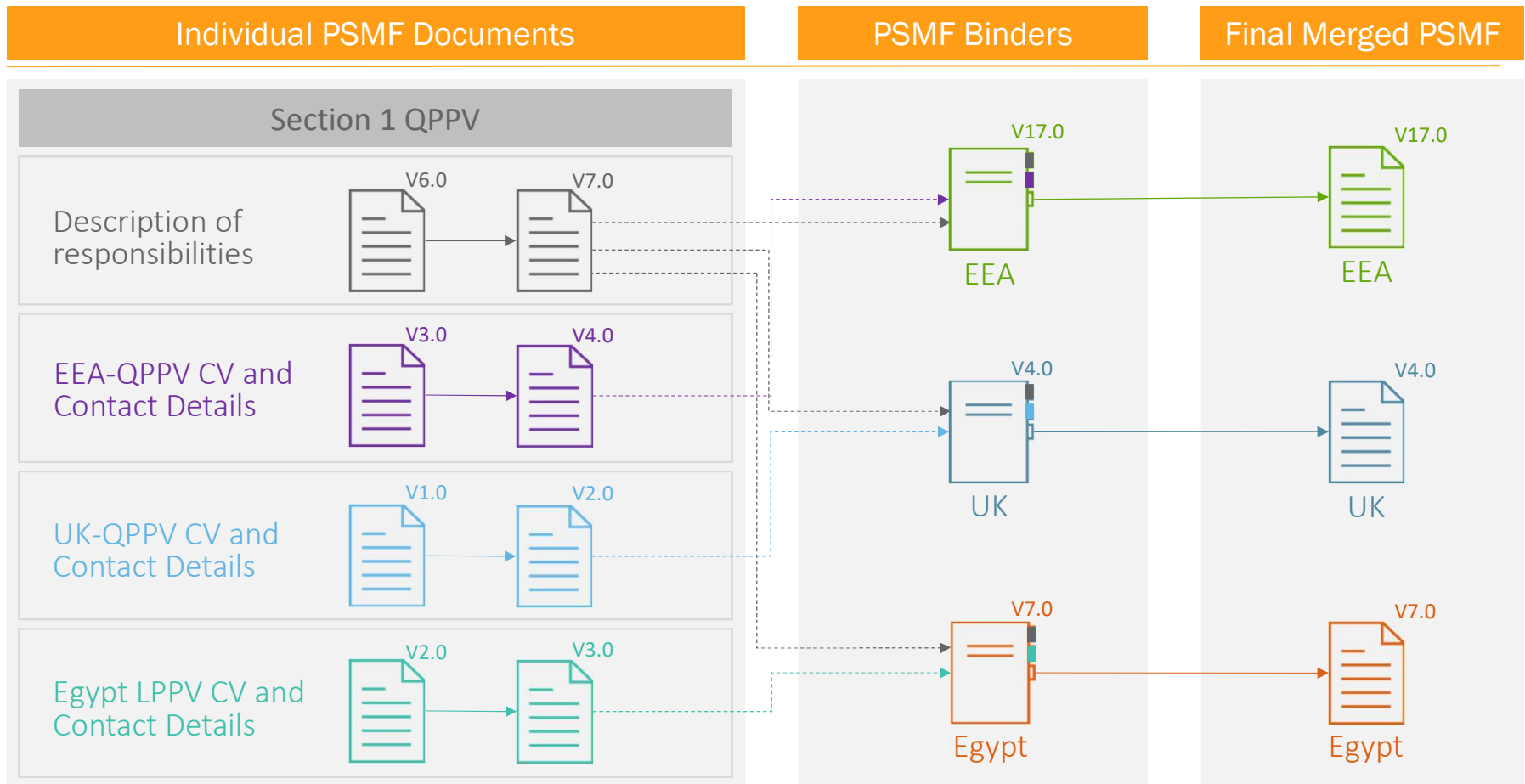
Regularly need to reconcile local PSMF with common content



Traditional Global PSMF Management Challenges



Modular PSMF Management Approach Deployed



Modular PSMF Benefits Achieved



Visibility and Oversight

- Global / regional visibility
- 60+ markets with PSMF or equivalent requirement



Governance & Control

- Governance framework
- Global / regional alignment
- Single global process



Operational Efficiency

- Efficiently content collection & mgmt.
- Improved global collaboration
- Effort reduced by 2 weeks
- Improved Quality



Compliance

- Timeliness of reporting
- Easier to support and demonstrate compliance
- Submission tracking

- Providing oversight while delegating document ownership to specific team members to keep current
- Content publishing that goes through approval of the final PDF document electronically
- PSMF electronic approval and final content stored in the same system



Core Focus Areas of Safety Content Management

Vault SafetyDocs



PSMF



PV Agreements



Periodic Reports



Literature



Risk Management



Safety Team Mgmt

Vault Safety

Efficient case processing, management, and submissions

Vault Signal *future*

Earlier detection and proactive risk management

One Unified Solution

Vault Connections

CLINICAL
DATA

CLINICAL
OPERATIONS

REGULATORY

QUALITY

MEDCOMMS

 Vault Platform



Unified Platform - PSMF Data Exchange



Contact Information



Questions



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Thank you