Successfully Modernizing Our **Quality Management System** (QMS) w/ Aras Innovator

FUJIFILM
Value from Innovation

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About FUJIFILM

Breadth of Healthcare Products

Medical Systems : Diagnosis

X-ray imaging diagnostic systems
（FCR・D R・X-ray film）

Medical image informatics systems

Endoscope

Ultrasound

IVD
(In-vitro diagnosis)

Life Science : Prevention

Functional cosmetics

Nutritional supplement products

Medicine : Treatment

Pharmaceuticals

Bio CDMO: Treatment

Biopharmaceuticals

Regenerative medicine: Treatment

Autologous cultured epidermis

Autologous cultured cartilage

Agenda

- Project Motivation and Requirements
- Project Scope Definition
- Challenges & Solutions
- Business Benefits
- Future Vision

Project Motivation and Requirements

Identifying Requirements for New QMS

Our QMS & IT Needs	Translated to System Needs
Update Enterprise IT Infrastructure • Attempts made with several systems • None satisfied med device QMS requirements	**New, Dedicated QMS IT System**
Improve Product Quality & Operational Efficiency • Consistent methods for quality activities and documentation • Reduce databases, eliminate mix of paper and electronic documents	**Centralized database**
Easier Compliance and Audit • Compliance with changing medical device regulations • Present one document in different sites for multi-site audits	**Easy to modify** **Access & present on local PCs**

Our Reason for choosing Aras

Product Functionality

- Basic functions for PLM, Scalability, Connectivity
- Support level of medical device QMS requirements in native Aras.

Customize Capability

- Ability to inherit legacy system functions
- Easy customization for new requirements

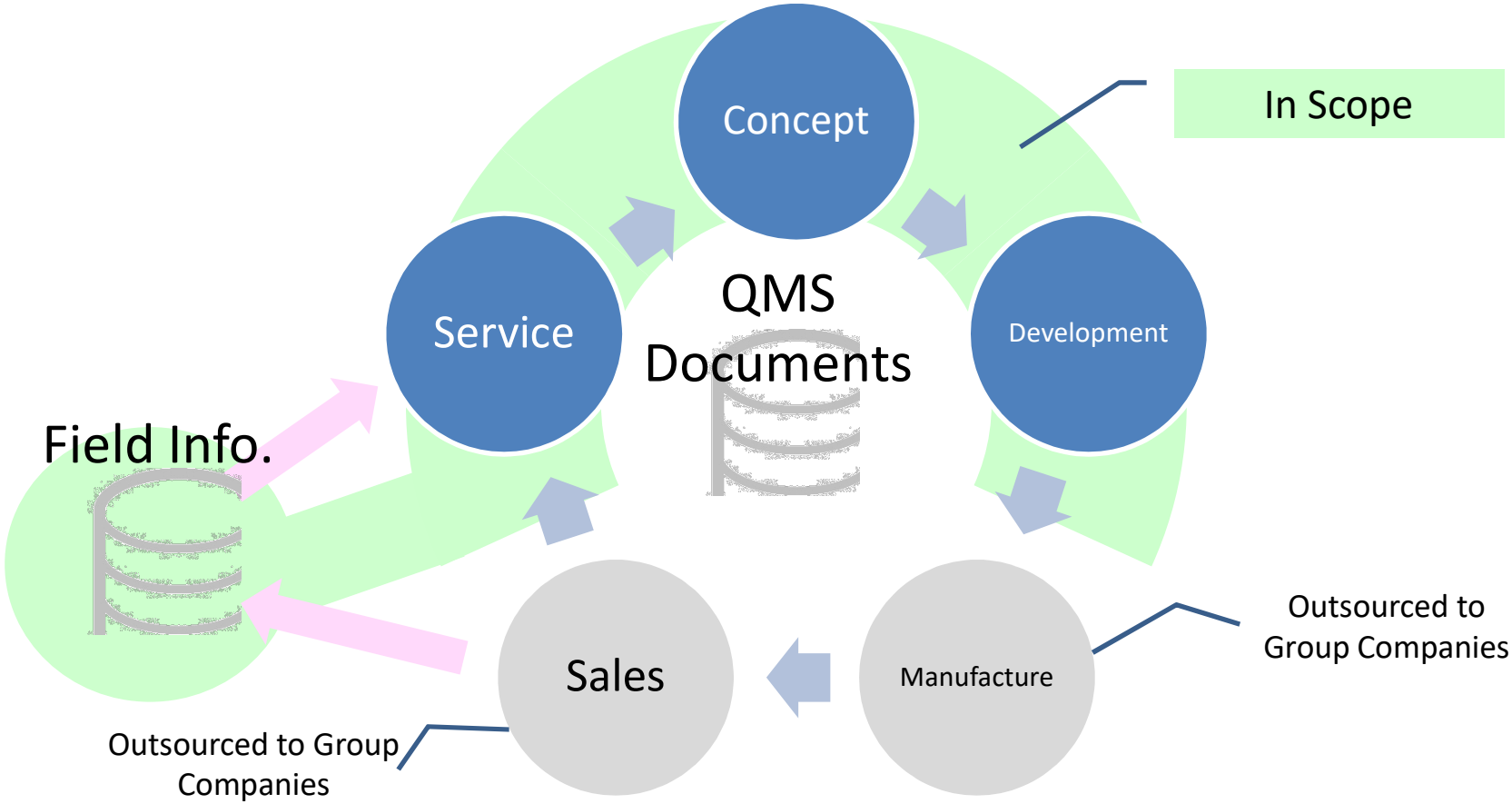
System Lifecycle Cost

- License fee, Maintenance fee or Subscription fee
- Development cost for customization
- Operating cost

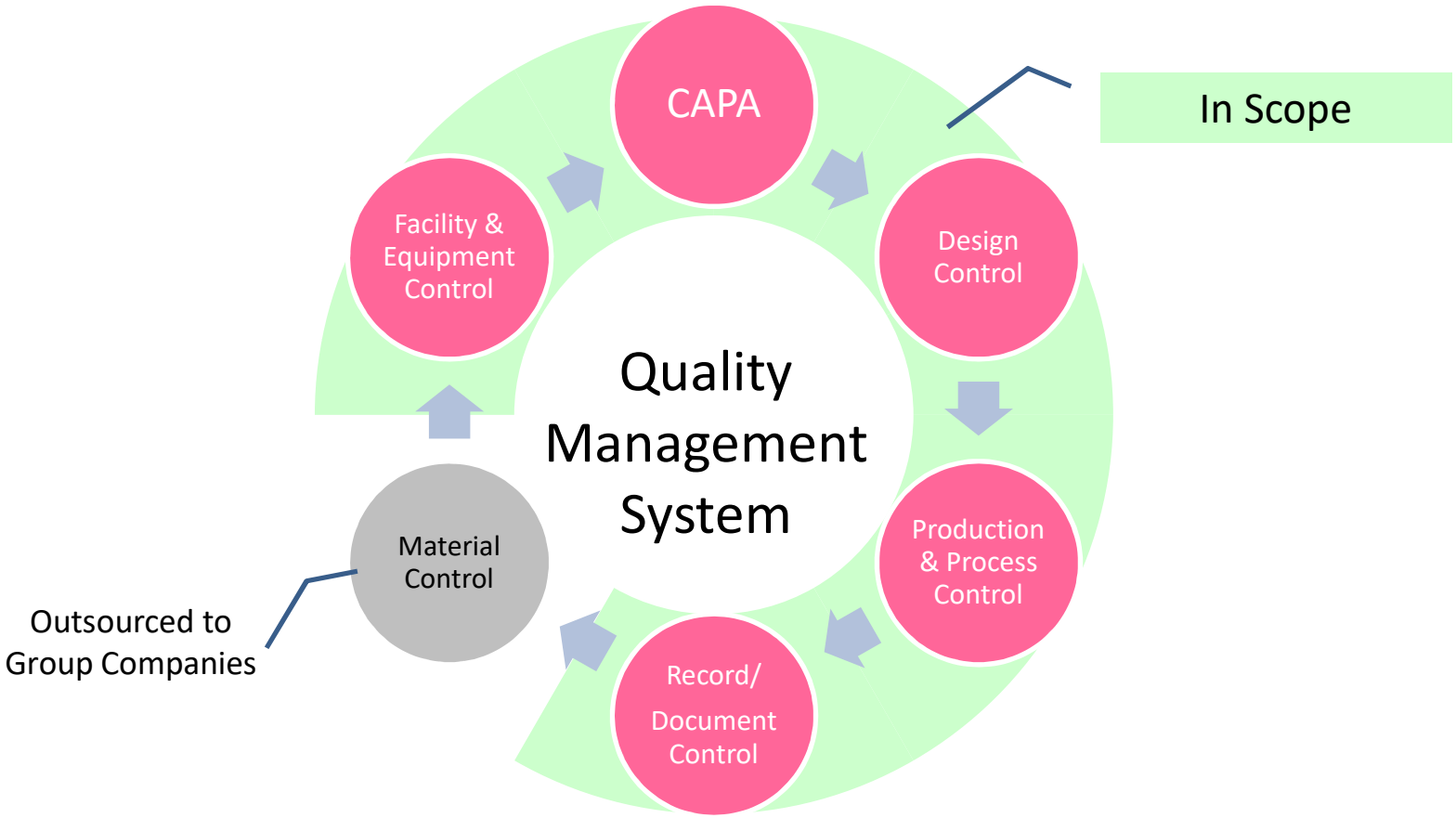
Project Scope Definition

- Lifecycle Scope
- QMS Scope
- Project Timeline

Lifecycle Scope

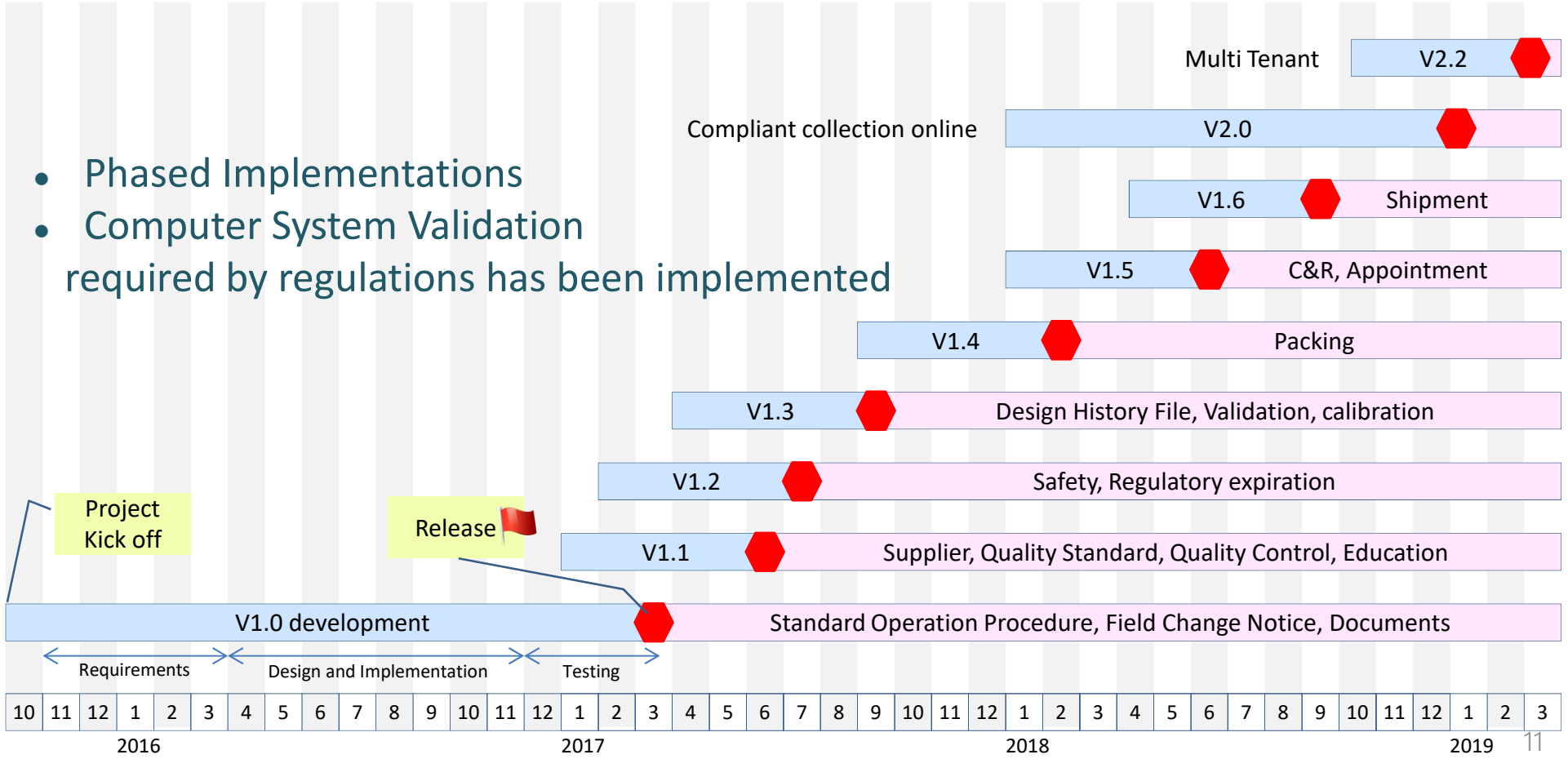


QMS Scope


CAPA
In Scope
Facility & Equipment Control
Design Control
Quality Management System
Material Control
Production & Process Control
Outsourced to Group Companies
Record/ Document Control

Project Timeline

- Phased Implementations
- Computer System Validation required by regulations has been implemented



Challenges & Solutions

- Medical Device Regulations
- QMS Issues
- IT Issues

Medical Device Regulations

Pre-marketing: Product safety
Providing safe and effective products

510(k)/PMA, MDD CE Marking/MDR, etc.

Post-marketing: Incident report, recall (post-marketing vigilance)
Reacting to issues when they occur
MDR, C&R, Vigilance System, etc.

QMS Issues

Quality Management System

Continuously supplying stable products

IT Issues

IT System

Ensuring data reliability: CSR Part11, GAMP5, etc.

QMS Issues

Quality Improvement

A. Different processes depending on product group

B. Linkage errors/missing documents due to manual linkage of different systems

Efficiency Improvement

C. Paper document management beyond our workload limit

D. Confusion in document control due to mixture of paper/electronic systems

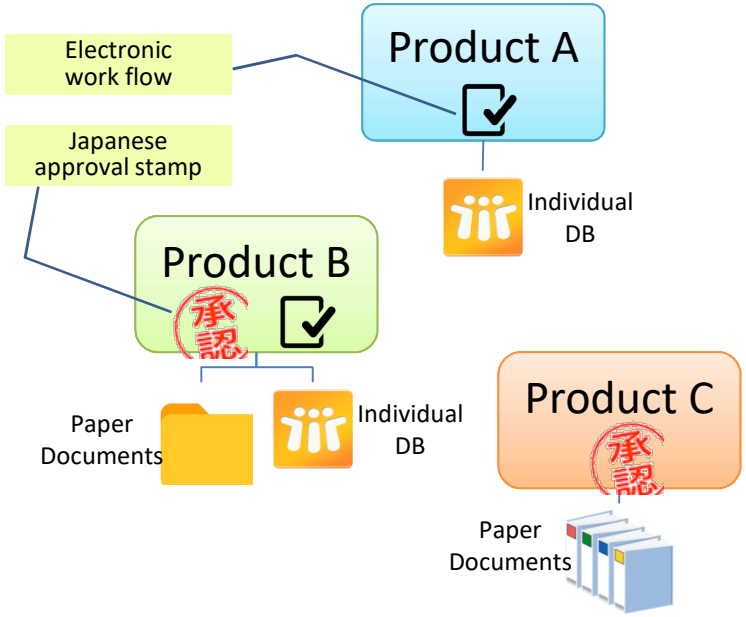
E. Time-consuming audit preparation especially for multi-sight audit

Solving QMS Issues : Process and System

Problem

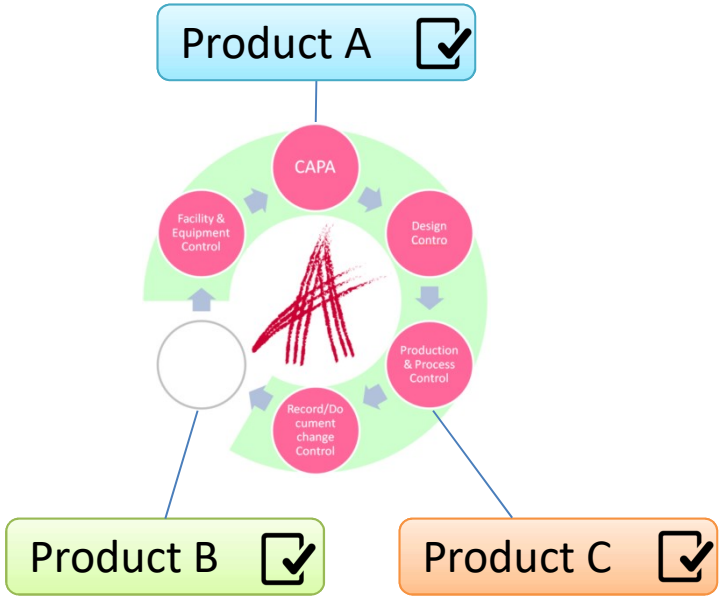
A. Different process depending on product group

D. Confusion in document control due to mixture of paper/electronic systems



Aras Solution

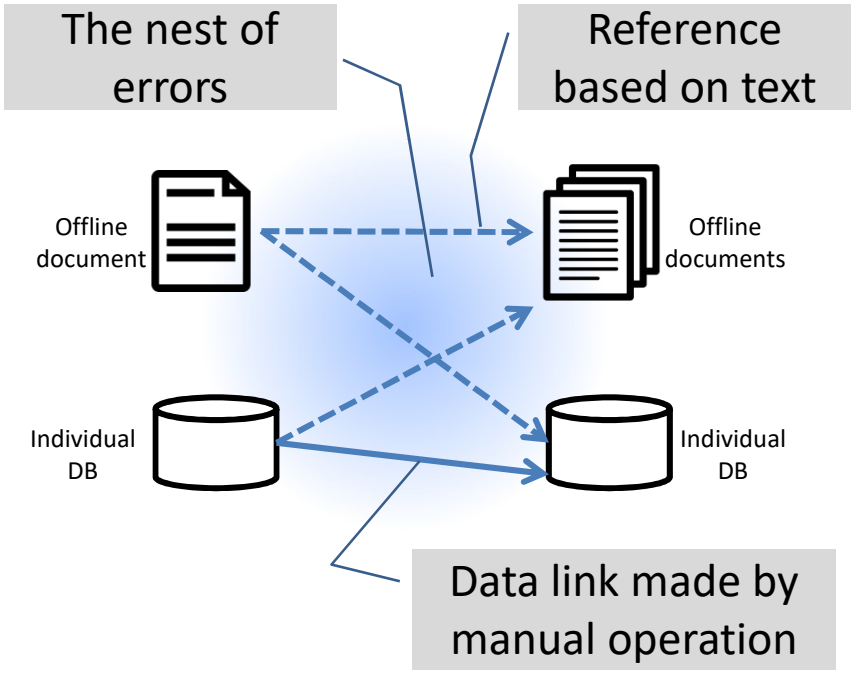
Unified Process with One Database



Solving QMS Issues : Data Discontinuity

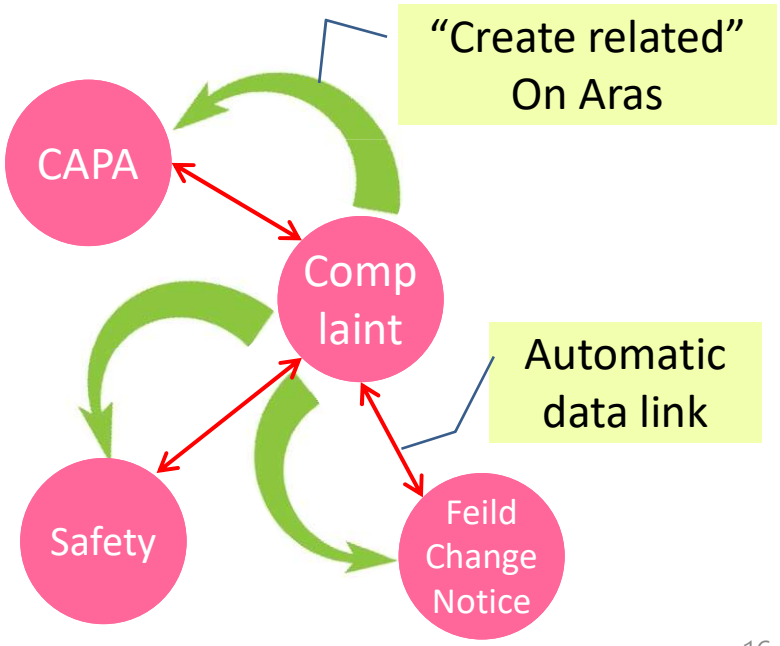
Problem

B. Linkage errors/missing documents due to manual linkage of different systems



Aras Solution

Full E-system and automatic data link



Solving QMS Issues : Full E-data and WF

Problem

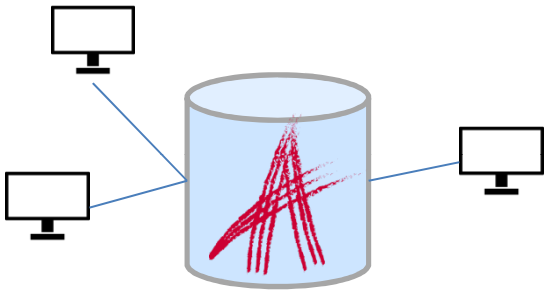
C. Paper document management beyond the workload limit

E. Massive audit preparation especially for multi-sight audit

Since documents for medical devices must be retained until the end of product life cycle, huge amount of paper documents are stored in warehouses. They must be transferred to the office for audits, and copies be made for multi-site audits.

Aras Solution

Full electronic document and softcopy system



Significant reduction in workload by full computerization

- Printing documents
- Preparing paper folders
- Storing and managing folders
- Making copies
- Searching documents

IT Issues

Data Reliability

A. Information and data should never be lost

B. Revision history should always be retained

C. Approved data should not change

D. A full set of documents should be stored at every design process gating

E. Access permission should be accurately set up according to organizations and roles

F. A consolidated data copy should be provided when requested

G. A full-text search, including search of legacy system, should be available

Solving IT Issues : Data freeze after approval

No Special data guard after approval

Click, Select and make the link

Approver Title

QA Manager ...

T.Hoshino, QA Manager

User Master File

When the master file was updated after the item approval,

Approver Title

RA Manager ...

T.Hoshino, RA Manager

Updated User Master File

Linked data was updated according the master file

Customized: Data freeze after approval

Approver Title

QA Manager ...

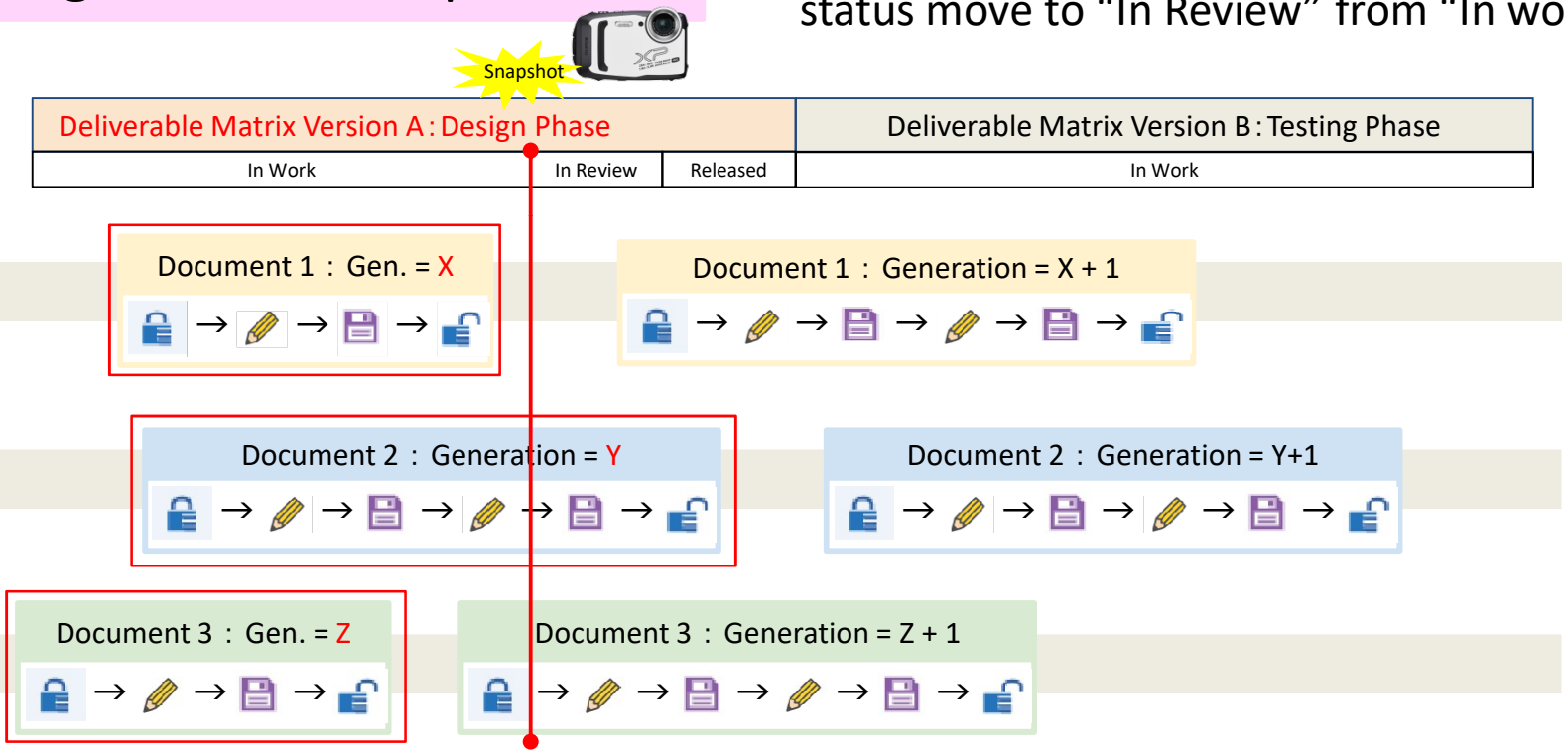
The look and operation feel are the same as Aras standard, but the text area is not a link but a data copy of the master.

Therefore, after the approval of the item its text is not changed.

Solving IT Issues : Full document set snapshot by gate

DHF document control using Minerva Template

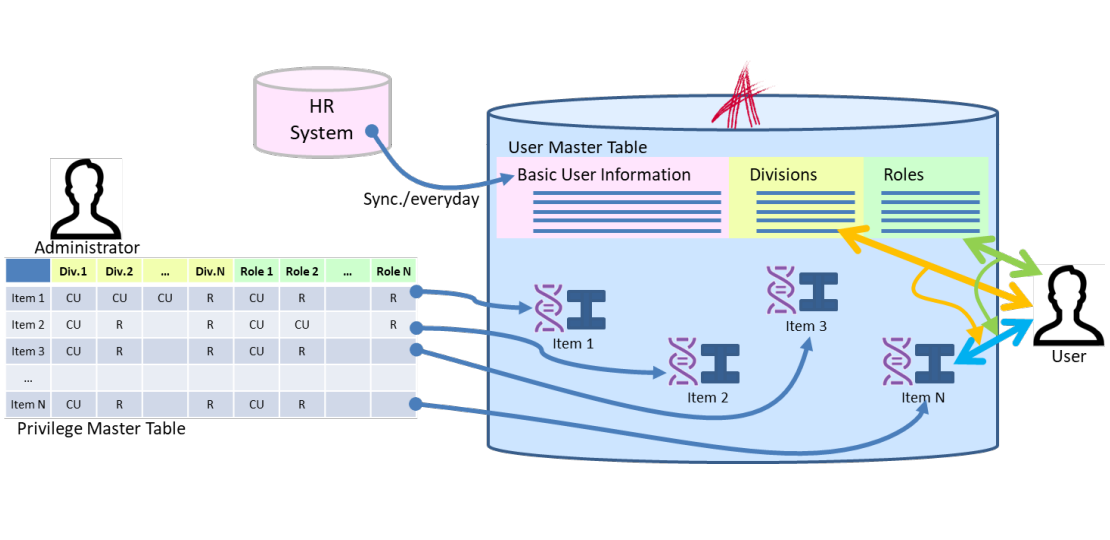
The snapshot including all of valid generation documents is made when Deliverable Matrix status move to “In Review” from “In work”.



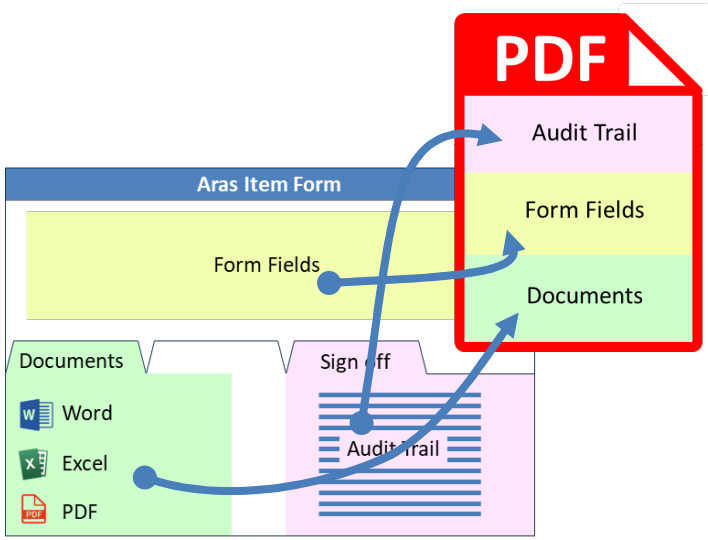
Solving Other IT Issues

Access permissions to all items, fully controlled, linked to HR system

One consolidated PDF is created with live data upon request for audit trail purposes



	Div.1	Div.2	...	Div.N	Role 1	Role 2	...	Role N
Item 1	CU	CU	CU	R	CU	R		R
Item 2	CU	R		R	CU	CU		R
Item 3	CU	R		R	CU	R		
...								
Item N	CU	R		R	CU	R		



Full-text search, including legacy system data.

Business benefits

- Positioned Fujifilm as an ‘Audit Ready’ company in the global Medical System market
- Established enterprise-wide quality management system for highly regulated products
- Implemented a system for faster response to in-field product issues
- Huge savings in operating costs

Future Vision

- Future plan
- Future Roadmap with Aras

IMMUNO AG2

Future Plan

Enhancement of system linkage

- Linkage to other systems within Fujifilm: SAP, SalesForce, etc.
- Enhanced linkage between inside and outside documents/data (group companies).
- Dissemination of information to outside the Fujifilm group companies.
- Documents shared with outside via PORTER function

Extension of applicable scope

- Centralized control of information from product planning to installation at customers.

Utilizing data

- Use of BI to meet regulatory requirement for data analysis

Future Roadmap with Aras

1 Computerization in medical device industry is expected to further accelerate. We would like to have the functions required by regulations for development of medical devices as standard functions.

For instance:

a. Creating snapshots of review and approval audit trail.
b. Flexible WF (which can be controlled by settings)
c. Output function (Generation of a complete copy of a document and its approval information)

2 Improvement of communication functions as discussion panel

Special thanks

I would like to express my gratitude once again to people from Aras and SIer Hitachi Systems who were committed and studiously worked with us to develop this new system.

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