# Data Lifecycle

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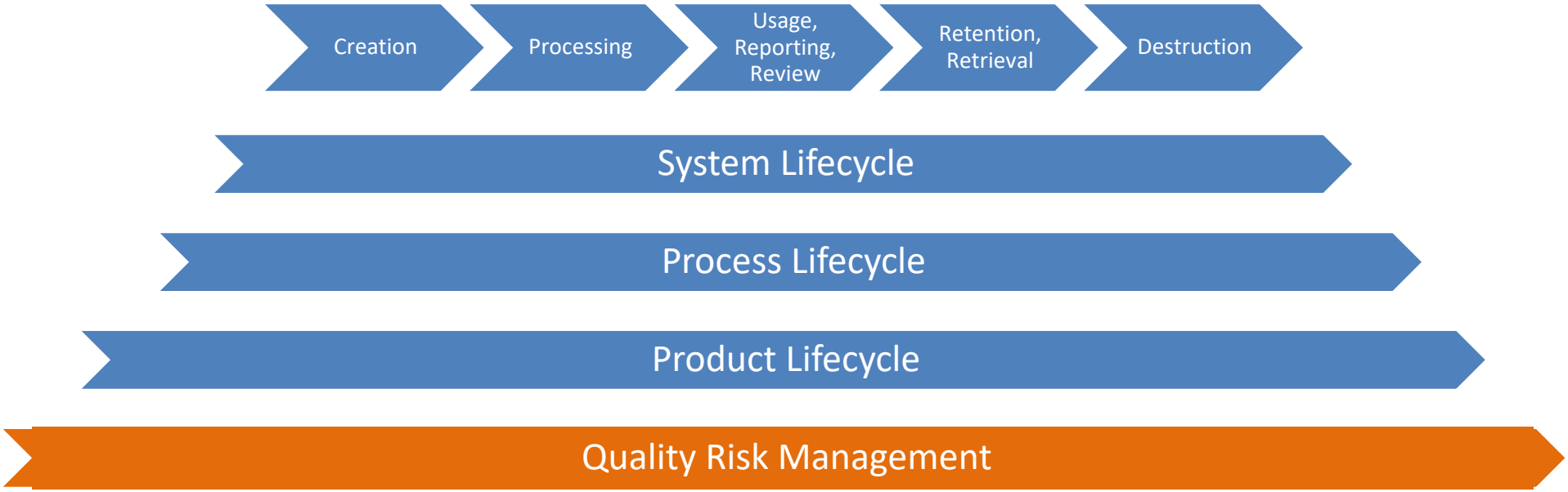
# Content Presentation Data Lifecycle

- Data Lifecycle: Why another Lifecycle Approach?
- Data Creation
- Data Processing
- Data Review, Report and Use
- Data Retention, Retrieval
- Data Destruction
- Understanding Data Flow over the Lifecycle
- Visualisation of Data Flow in the context of the Process
- Questions?

General Data Lifecycle:

Why another Lifecycle Management?




=> GxP is about not to forget anything, assure completeness

# Data Creation

Creation of Data:

- Appropriate **accuracy, completeness**, content, meaning, excluded data?
- If not reliable, data integrity makes no sense
- Stored in a **defined format** and location
- **Correct time** reference
- Manually captured:
  - At time of activity
  - Verification (e.g. by 2nd person or barcode system)
- Automatically captured:
  - Maintenance of instrument
  - calibration of instrument: correct range and accuracy
  - Define primary record in case of concurrent recordings

# Data Processing to Desired Format

Processing of Data:

- **Transform / calculate** data to the desired format
- Approved procedures / qualified systems
- Risk-based verification (e.g. by 2nd person, logging)
- **Prevent** original data from deletion or overwriting
- Prevent excluded data from deletion
- Limit processing to **authorised persons**
- Assure traceability to processing parameters / user parameters
- Evaluate user influence to processing results

Data Review:

- Defined procedure of review and approval of review
- Integrate **QA oversight**
- Should confirm predefined specs for data
- Review by 2nd person (e.g. IPK)
- Include **meta data**
- Review data at all different locations
- Justify excluded data
- **Detect data risks** (e.g. data amendments, orphan data)
- Handling of errors, omissions etc.

Audit Trail Review:

- Establish defined and documented **routine process**
- Should be supported by validated system reports
- Needs **process understanding**
- Quality **risk based need** and scope
- Verify changes by authorised users
- Detect data integrity issues

# Data Usage for Informed Decisions

Data Reporting:

- Defined procedure
- Which data in which layout?
- Source of data (e.g. system, user)
- Define use of reports for GxP decisions
- Summary reports need additional verification with respect to complete raw data

# Data Usage for Informed Decisions

Data Distribution:

- Defined procedures
- By and to authorised individuals or systems
- Interfaces clearly defined, designed, verified
- Define need for confirmation of data reception
- Document control

# Data Retention and Retrieval

Retention Period, Retrieval of Data:

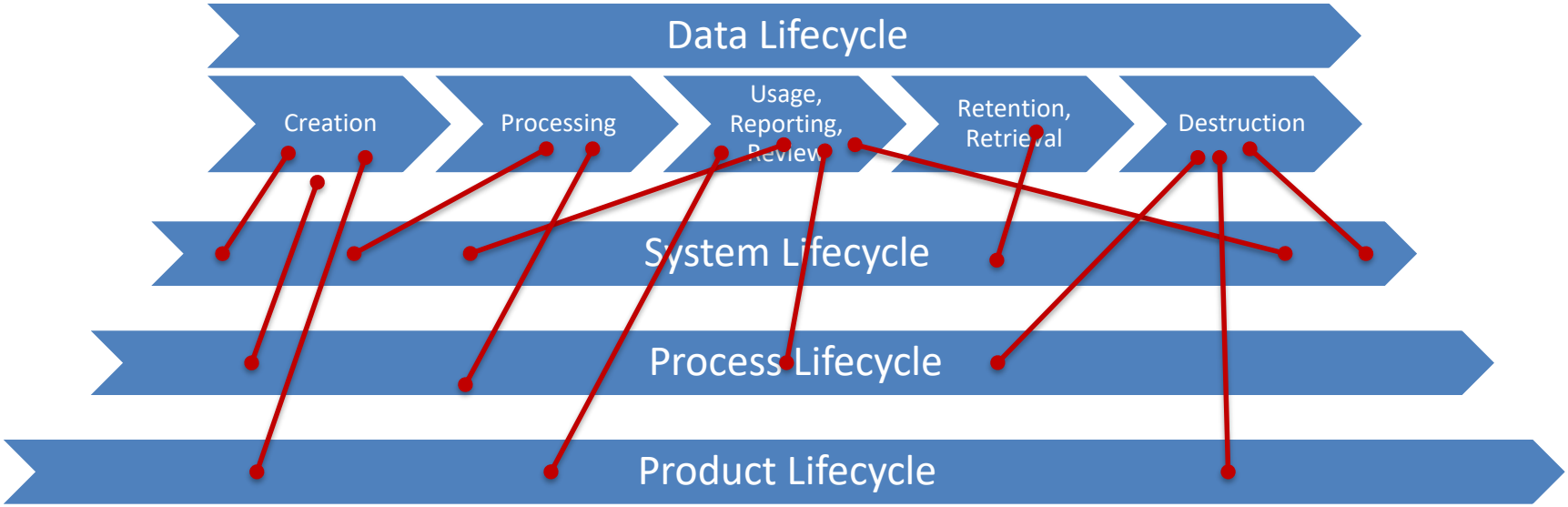
- Defined procedures
- **Accessible and readable** through retention period
- Consider all regulatory or internal requirements
  (e.g. retention period of 30 years for blood products in Europe)
- Covers original **raw data and meta data**, preserve content and meaning
- Paper records may be transferred to an electronic system (True Copy) preserving content and meaning
- Retention period may last longer than corresponding system lifecycle
- Backup / restore acc. to a defined procedure (incl. per. checks)
- Archiving acc. to a defined procedure (incl. per. checks)

# Data Destruction

Destruction of Data:

- Defined procedure
- Respect **retention requirements**
- Method to prevent from accidental destruction, verify if data is currently in use by a business process (e.g. complaints, periodic review)
- **Limit access** to a restricted number of individuals
- Systematic approach to cover all physical and logical locations
- Define **methods** for logical and physical destruction

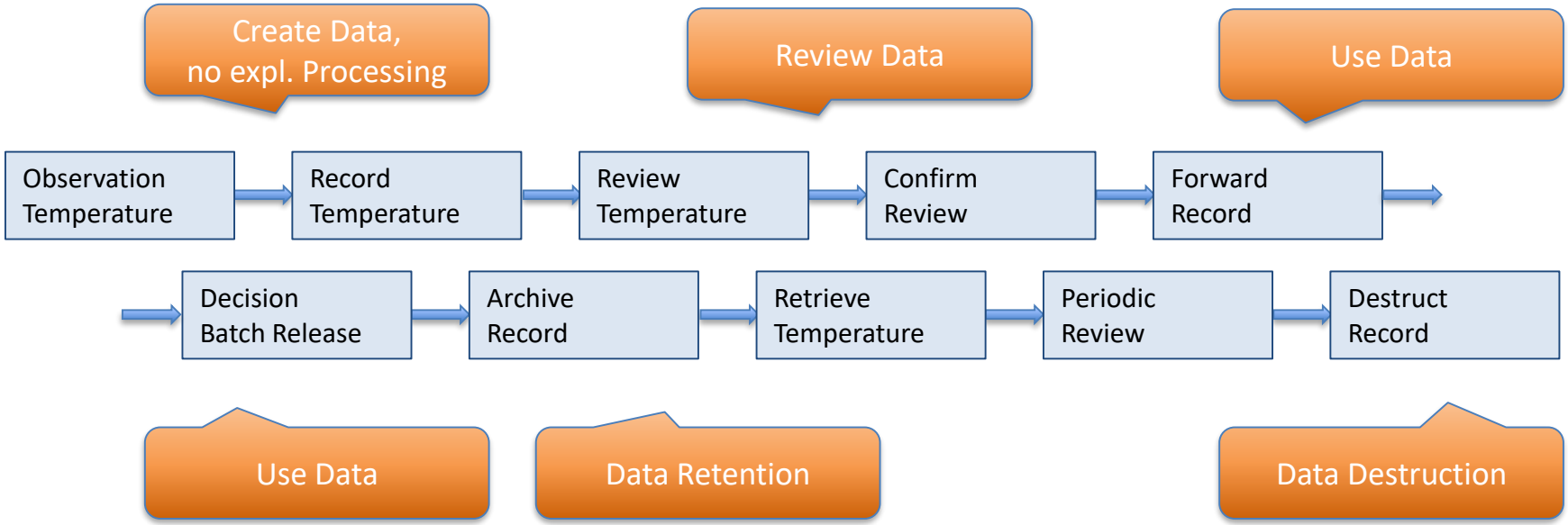
## Data Lifecycle in Context with System, Process and Product Lifecycle



# Data Flow

Analysis of Data Flow:

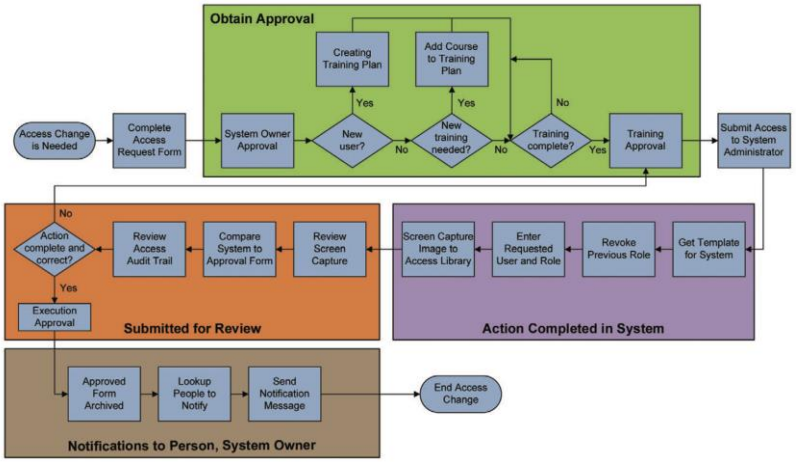
- In **context** of system, process (targeting product quality!!)
- Over **lifecycle** of data
- Risk based look through **ALCOA-glasses**

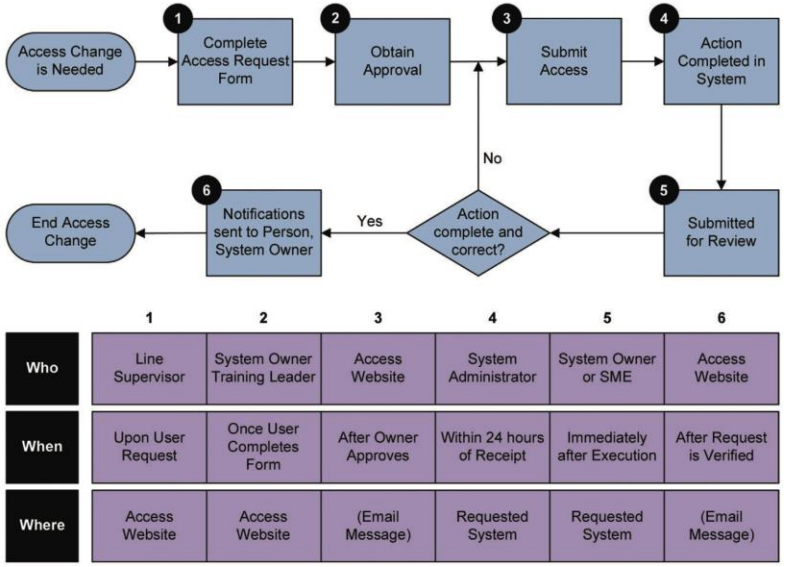


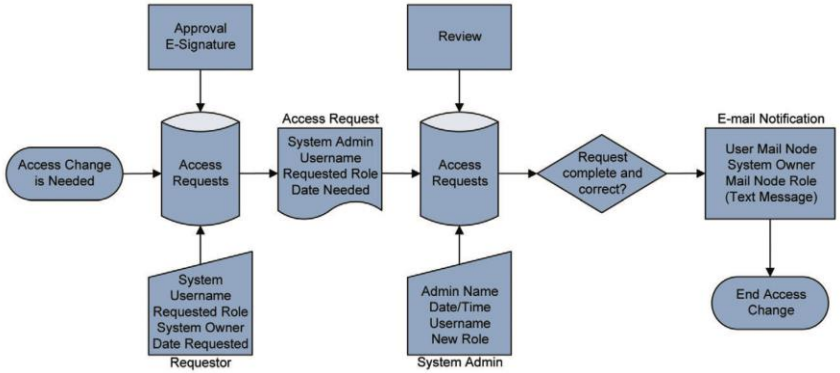
# Data Flow

Visualisation of Data Flow:

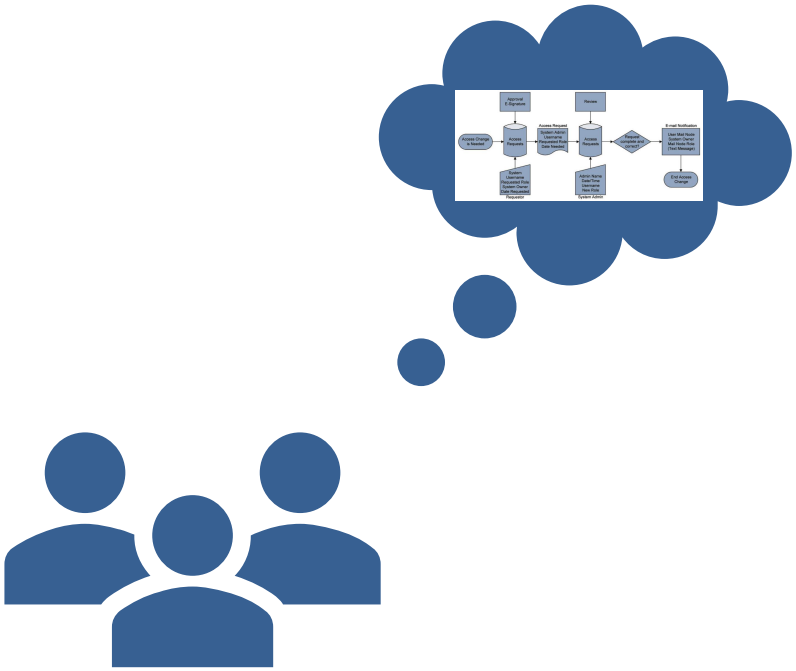
- Implicit with process flow chart
- Separate flow chart
- eEPC Diagrams
- Samples (GAMP5 [1]):



# Questions



# Acknowledgements

## References

(1) **ISPE:** “ISPE GAMP Guide: Good Automated Manufacturing Practices (GAMP5)“