Validation of a commerical software

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Agenda and Learning Objectives

- **Definition of commerical software**
    - Understand what is meant by commerical software

- **Data Integrity By Design and related validation**
    - Learn how to build in data integrity into the design and how to validate

- **Data Migration**
    - Understood a basic data migration approach and related problems

- **Part 11 and Annex 11**
    - Understand the key differences between Part 11 and Annex 11

Definition of commerical software

- **Commercial software**, or seldom **payware**, is computer software that is produced for sale or that serves commercial purposes.
  Commercial software can be proprietary software or free and open source software (*Wikipedia*).

  - **Hardware related:**
    - Operating systems
    - Firmware

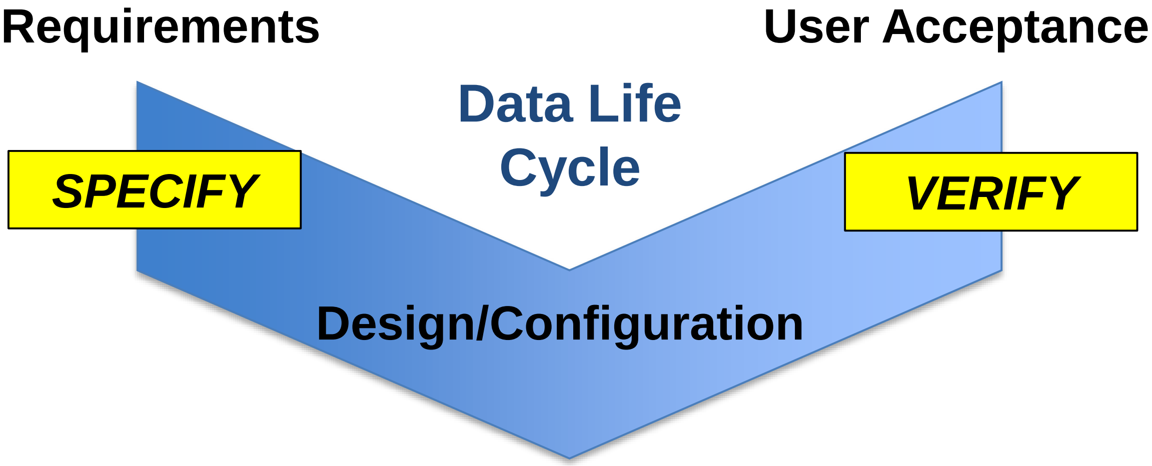
  - **Software related:**
    - Configured Software
    - Customized Software

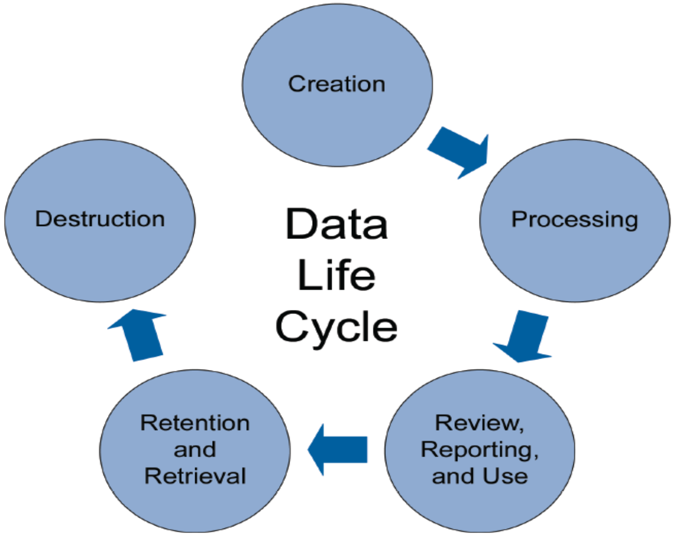
```
return a.split(" "); } $("#unique").
var a = array_from_string($("#fin").
").val(), c = use_unique(array_from
").val())); if (c < 2 * b - 1) {
c), this.trigger("click"); }
!= a[b] && " " != a[b] || a.
logged").val(); c = array_from
c.length;b++) { -1 != a.indexOf(
for (b = 0;b
```

Data Integrity By Design and related validation

Validation Approach

- **Define data integrity requirements** along the data life cycle and build them into process and system design
- **Verification of** implemented data integrity controls to provide sufficient documented evidence of the compliance of systems and processes





Source: ISPE GAMP Records and Data Integrity Guide, Figure 4.1

Data Integrity By Design and related validation

Examples of Data Integrity requirements

ALCOA Principle	Data Integrity Requirements
Attributable (Who performed the action and when)	Use of individual user name, password and secured date-time stamps
Legible (Data must be readable throughout the entire data life cycle)	Data must be securely stored and data changes must be traceable
Contemporaneous (Must be documented at the time of the activity)	Systems are configured to support sequencing of steps (e.g. workflow-based systems)
Original (Original data are the first or source capture of data)	Complete original data including meta-data (e.g. audit trails) are maintained and reviewed
Accurate (All data must be correct and without errors)	Systems are validated based on intended use and meet all aspects of the ALCOA principle

Data Integrity By Design and related validation
Challenges

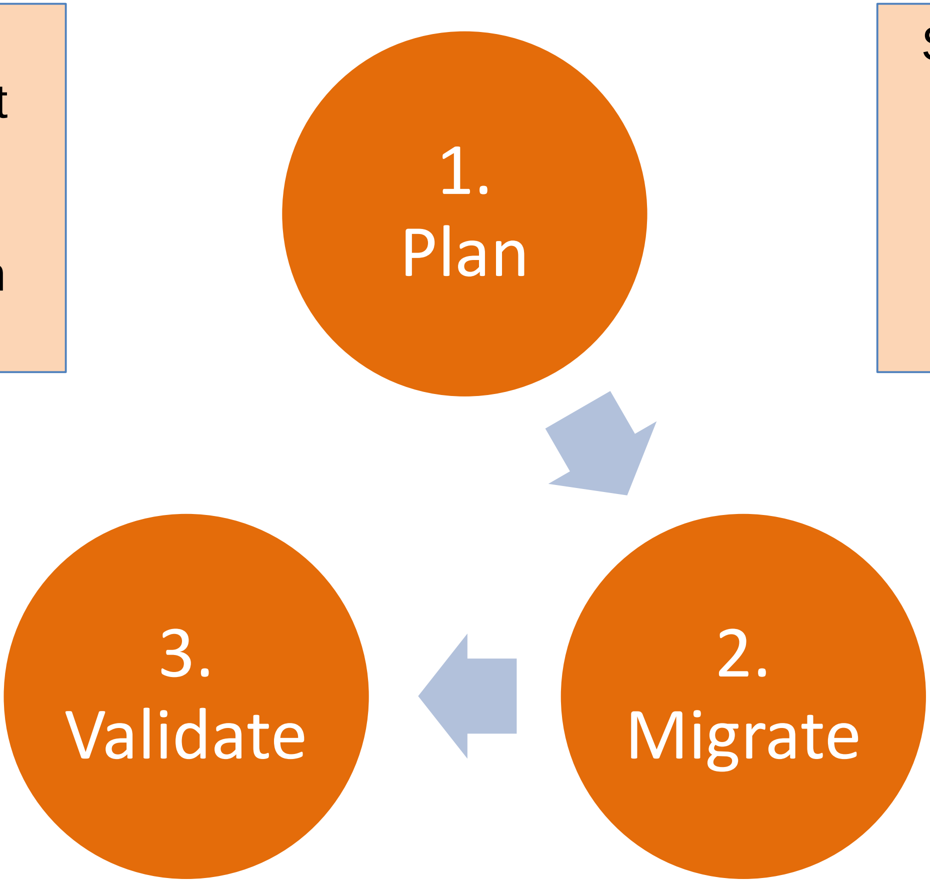
- Expectations from health authorities related to data integrity are based on draft guidances (except: MHRA)
- Software vendors have very often limited understanding of data integrity
- Consequently software products have Data Integrity weaknesses (e.g. no automated saving, insufficient audit trails)
- The user company is responsible for mitigating these weaknesses by means of appropriate controls (e.g. procedural measures) to ensure the system is validated for intended use and meeting compliance expectations

Data Migration
Methodology

Electronics Records must be retained according to GxP retention requirements

Systems get outdated (new releases)

Data migration or archiving becomes necessary



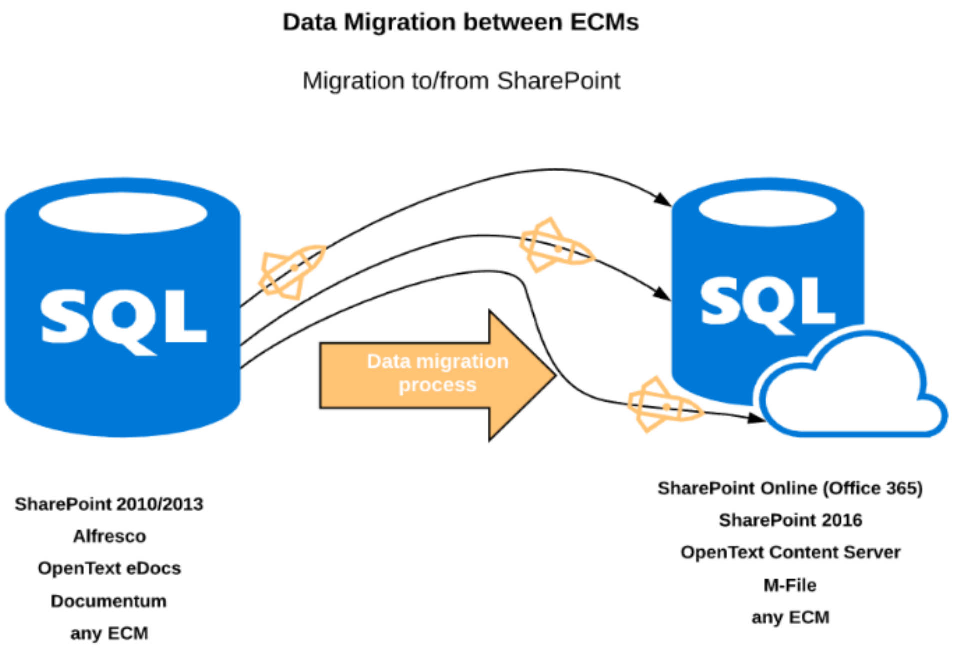
1. Plan

2. Migrate

3. Validate

Data Migration
Plan

- Determine migration requirements
- Identify current storage environment
- Create a migration plan
- Develop design requirements
- Create Migration Archtitecture
- Develop test plan



Data Migration between ECMs

Migration to/from SharePoint

SharePoint 2010/2013
Alfresco
OpenText eDocs
Documentum
any ECM

SharePoint Online (Office 365)
SharePoint 2016
OpenText Content Server
M-File
any ECM

Data Migration
Migrate

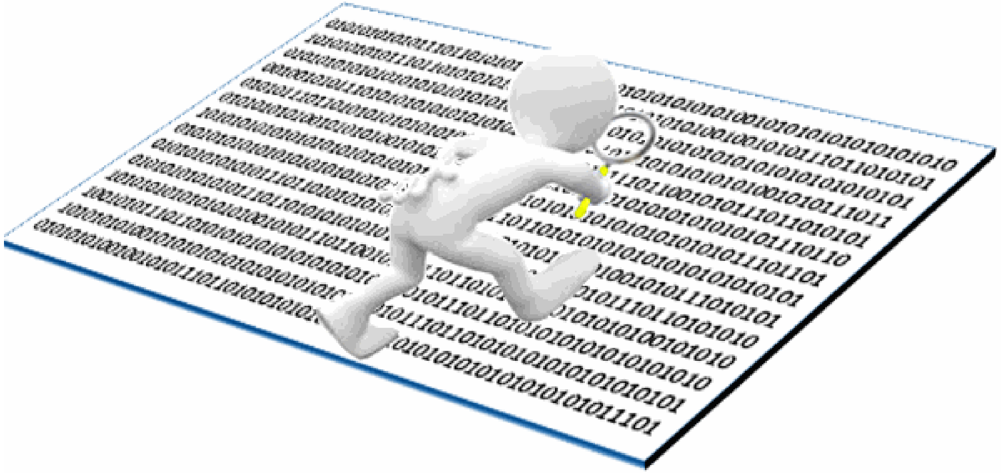
- Communicate deployment plan
- Validate HW and SW requirements
- Install and configure Data Migration software/tools
- Run pre-validation tests
- **Perform migration**
- Verify migration completion

Typical Problems:

- Extended or unexpected downtimes
- Data corruption, missing data or data loss
- Application performance issues
- Technical compatibility issues

Data Migration
Validate

- Run post-validation tests
- Finalize data migration report
- Communicate data migration completion



Part 11 and Annex 11

Regulatory Baselines - Comparison

	EMA - Annex 11	FDA – 21 CFR Part 11*
Scope/Principle	• Computerized systems as part of GMP regulated activities • Application should be validated • IT infrastructure should be qualified	• Electronic records and electronic signatures as used for all FDA regulated activities
Focus	• Risk-based quality management of computerized systems	• Using electronic records and signatures in open and closed computer systems
Objective	• Using a computerized system should ensure product quality and patient safety	• Electronic records and signatures should be trustworthy and reliable

*1997 Part 11 issued, 2003 guidance published.

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