ERP Implementation in the Pharmaceutical Industry to assure Regulatory Compliance

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ISPE Event – Sydney Chapter
June 8th, 2006

Key Concerns

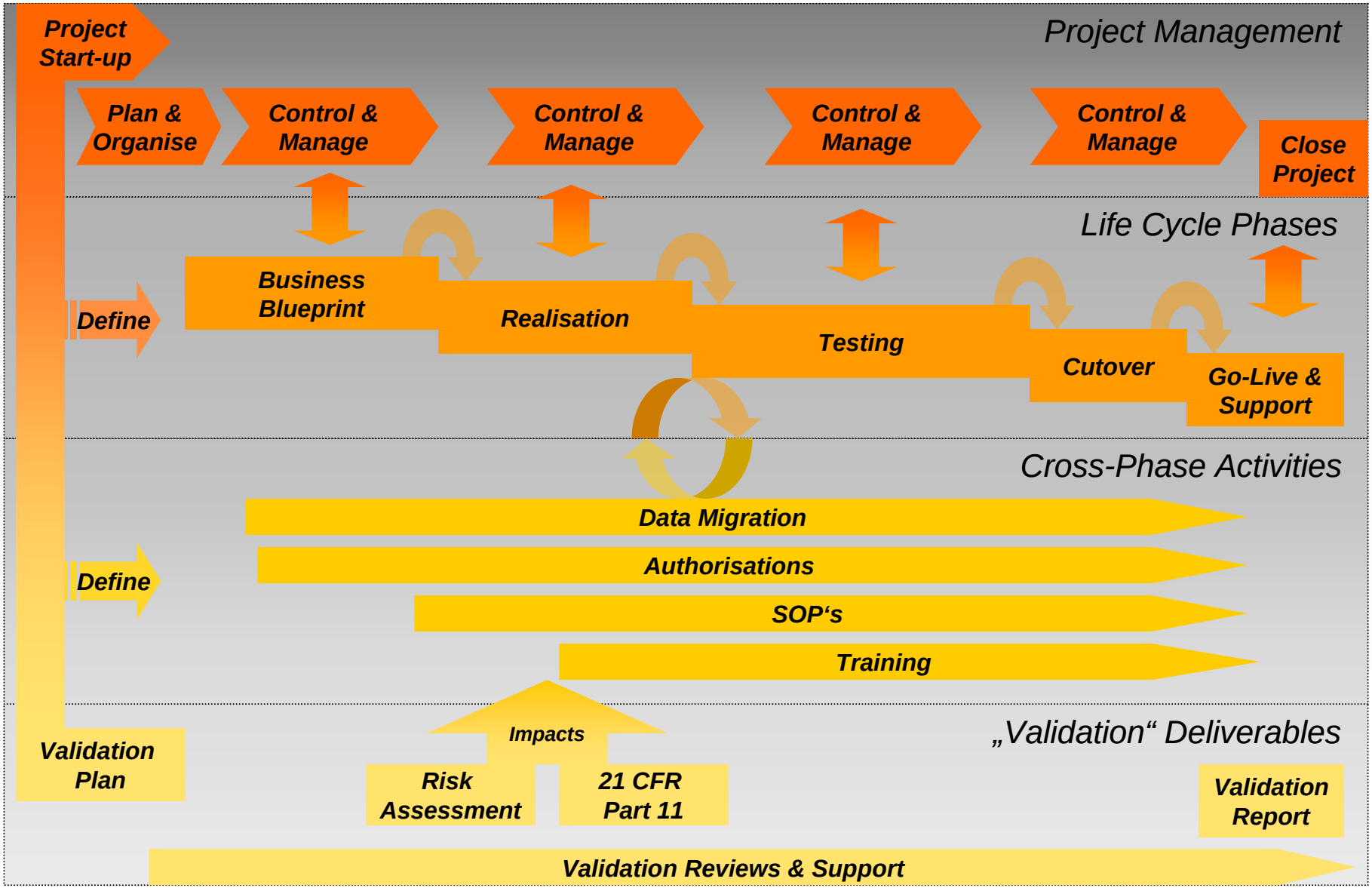
A selection of customers key concerns:

- *How much time & resources do we need to implement the ERP System?*
- *Partner Selection – how do we find an experienced implementation partner?*
- *Are Standard Methodologies sufficient to support implementations in the Pharmaceutical Industry?*
- *Can our Business Quality System support an ERP Implementation?*
- *Can we validate the ERP system?*
- *How much will validation cost?*
- *Who is doing the validation?*
- *What are the top reasons for project failure / delay?*

Content

- *Methodology Overview*
- *Life Cycle Phases*
- *Data Migration*
- *Validation Deliverables*
- *Questions / Discussion*

Methodology Overview

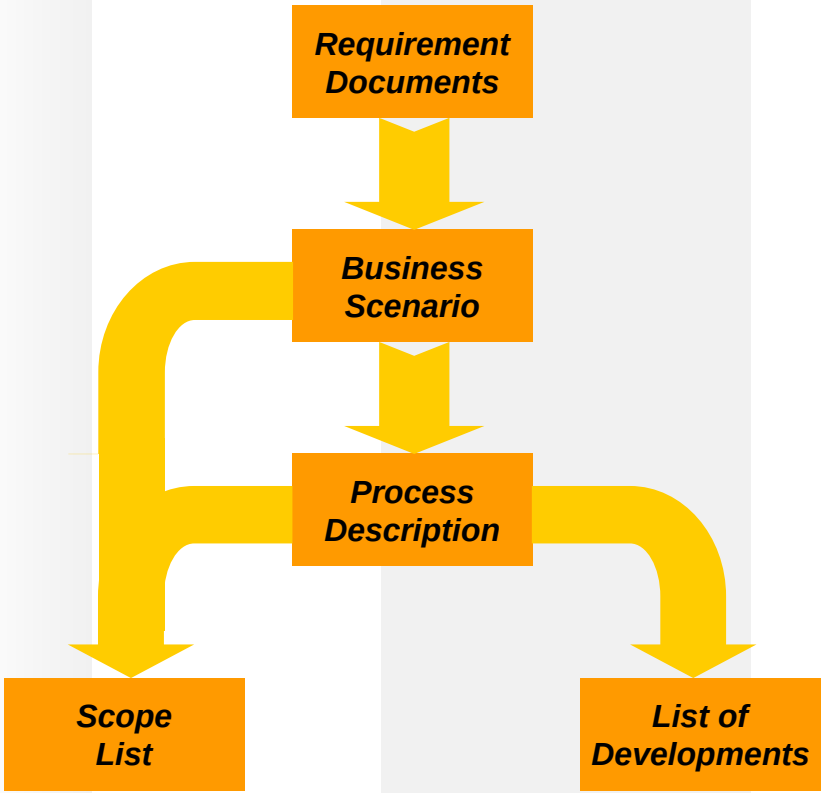


Project Start-up / Validation Plan

Purpose

- *Define the framework for all Project Activities*
- *Describe the Project Methodology in detail and list the Project Deliverables per Phase*
- *Set Completion Criteria for all Life Cycle Phases as well as for Cross-Phase Activities*
- *Define Roles & Responsibilities*
- *Establish Project Management & Project Control Tools*

Business Blueprint Overview

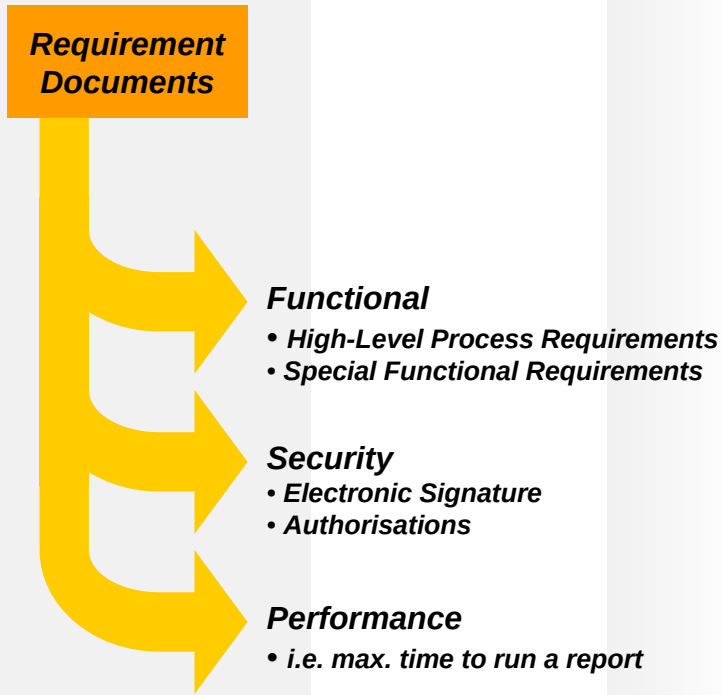


Goal

- *Define the Business Processes to be supported by the ERP System to the level of each individual process step*
- *Create a set of documentation that enables experienced professionals to configure the process within the ERP standard configuration options*
- *Identify all gaps that can not be delivered by the ERP standard configuration options*
- *Enable Project Scope Control*

Business Blueprint - Requirements

- *Where a vendor selection was performed, requirement statements defined by the business should be available in the form of an RFI / RFP*
- *Where no vendor selection was performed, high level requirement statements should be captured by the individual business areas*
- *Identify not only functional, but also security and performance requirements*
- *SWQM prefers individual "Requirement Statement Documents" vs. one "URS Document"*



Business Blueprint – Business Scenarios

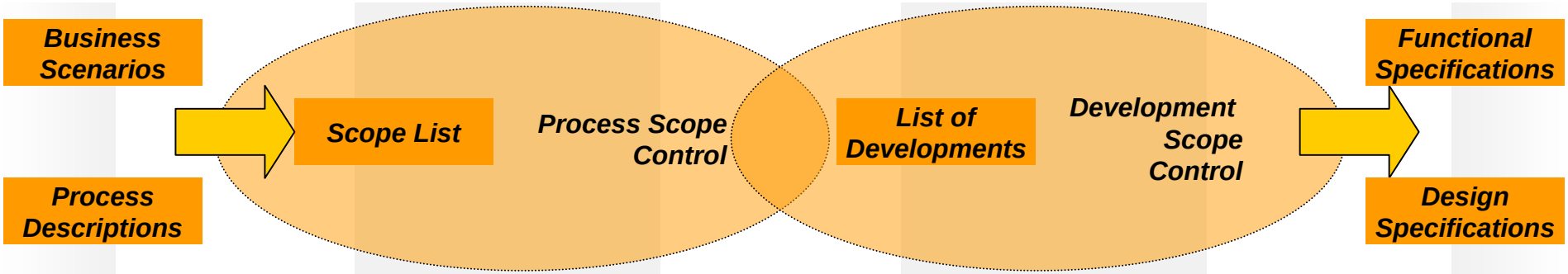
- *High Level Business Process View of main business activities to be supported*
- *Includes:*
  - *Short Description: 3-4 sentence description of Business Scenario*
  - *Trigger: What action is required to kick-off the process?*
  - *Input: Define pre-requisites for process execution*
  - *Execution: Actual process that is executed*
  - *Output: Define results of process execution.*
- *Mapped back to the individual Requirement Statements*

Business Blueprint – Process Descriptions

Step ID (####.Stp)	Process Steps	Description	Trigger	Result	Delivered by	Role
0008.001	New supplier identified	Procurement identify and register new supplier and communicate to QA	Requirement for new supplier	New supplier communicated to QA	SAP Function	Procurement Officer
0008.002	QA determine audit requirements	Initial assessment of supplier relating to current supply status to *company* type of supplier, level GMP criticality, pharmaceutical supplier.	New supplier identified	Initial assessment of supplier completed	SAP Function	Audit Coordinator
0008.003	Send vendor questionnaire	Corporate defined questionnaire sent to supplier.	New supplier identified	Questionnaire completed	Manual	Audit Coordinator

- *Detailed description of Business Process (see example above)*
- *Additionally provide details on:*
  - *Business Process Variations*
  - *Integration Points*
  - *Data Requirements*
  - *Authorisations / Roles*
  - *Developments / Gaps*
- *Process Descriptions must map backwards to Business Scenarios*
- *There is a 1 : n relationship from Business Scenarios to Process Descriptions*

Business Blueprint – Scope Control



Scope List

- Lists all Business Scenarios and the underlying Processes
- Sign off by System Owner & Project Sponsor recommended
- Baselines the Business Process Scope for the project

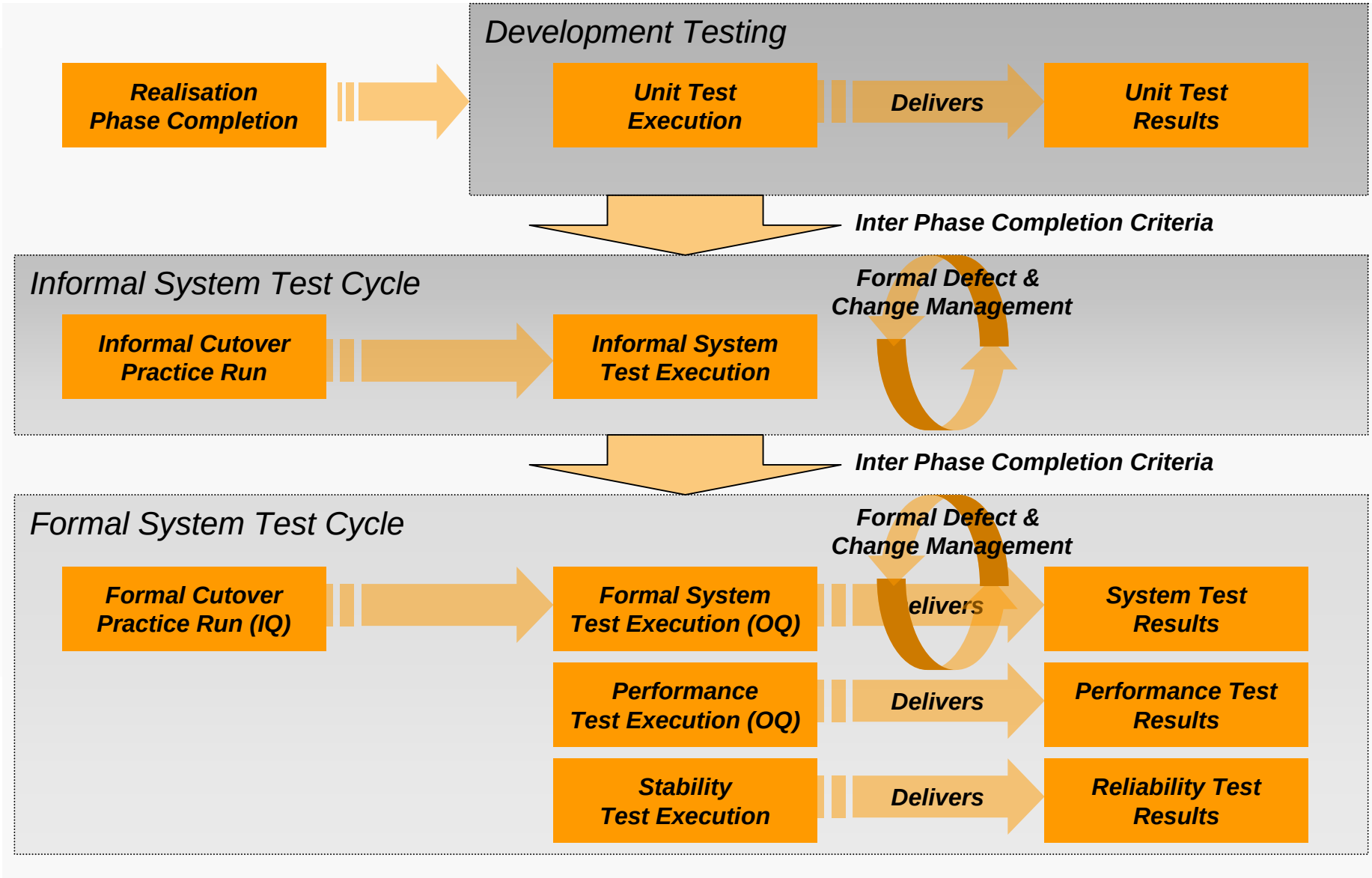
List of Developments

- Lists all Developments (resulting from gaps) that have been identified in the Process Documents
- Sign off by System Owner & Project Sponsor recommended
- Defines the Development Scope
- Identifies Functional & Design Specifications

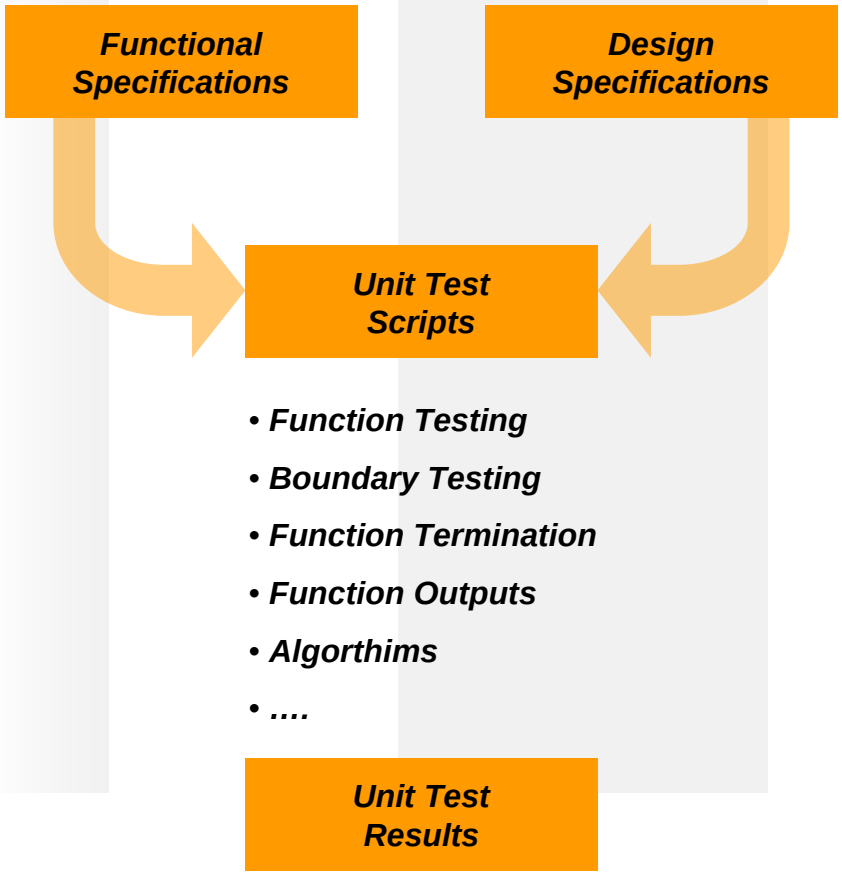
Realisation Phase

- *Developments*
  - *Develop Functional Specification that describe the solution for the identified functional gap in business language. Should be in sufficient detail to prepare software design based on it.*
  - *Developers to prepare Software Design Specifications based on Functional Specification.*
  - *Ensure Development Standards are available covering all development types.*
  - *Include backwards traceability to Process Descriptions in all Realisation Documents.*
- *Configuration*
  - *If possible, use ERP database to capture configuration settings and configuration change history.*

Test Cycle Overview



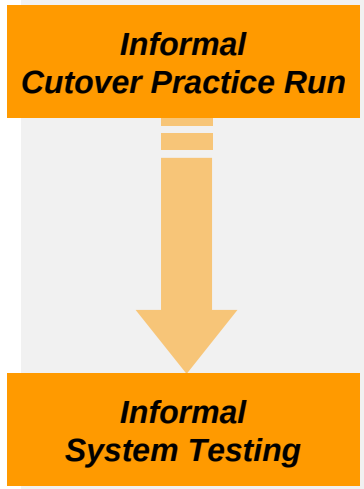
Test Phase – Development Testing



- *Develop at least one Unit Test Script per Design Specification*
- *Test Requirements must be traceable back to the Specification*
- *Unit Testing should be performed in a qualified environment (Q)*
- *Execution by peer developer*
- *Unit Testing must be completed for all developments prior to System Testing*
- *Source Code Reviews might be a part of Development Testing if required*

Test Phase – Informal Test Cycle

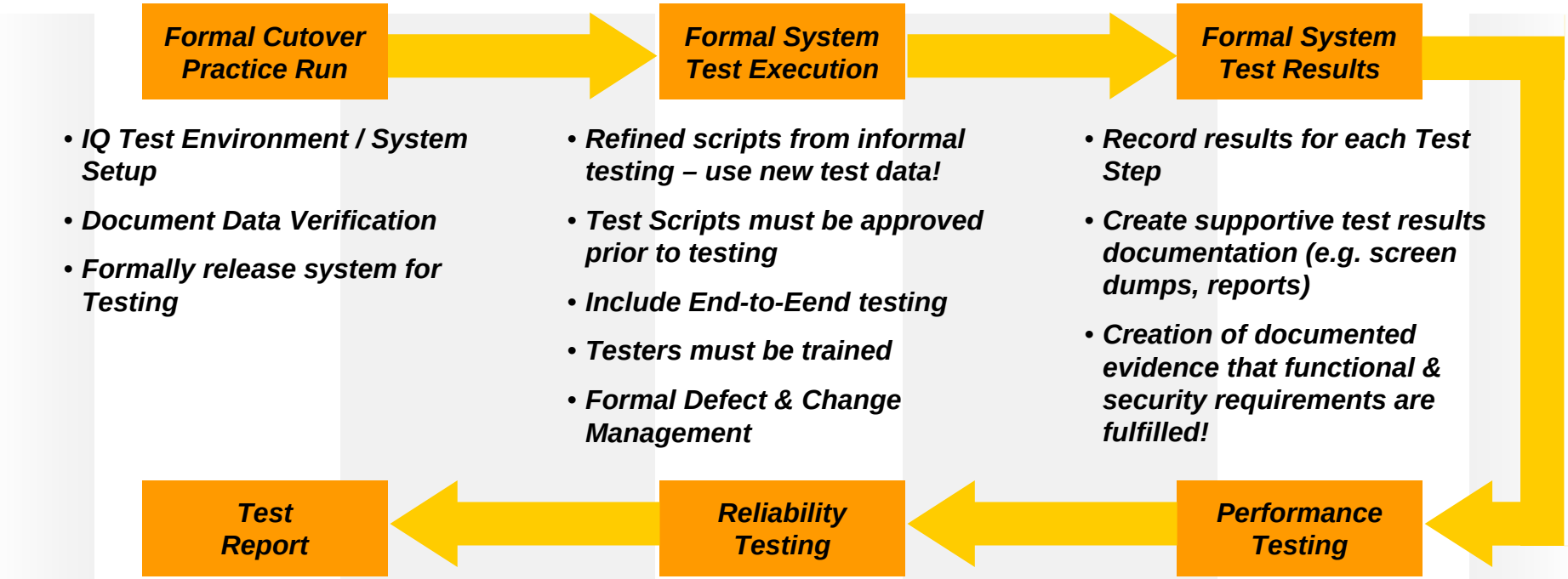
- *Develop System Test Scripts based on Process Descriptions (Test Steps mapped to Process Steps)*
- *Test Scripts prepared by Key Users*
- *Breadth & depth of test determined by Risk Assessment*
- *Test environment prepared during Cutover Practice Run*
- *No formal Test Results Documentation needed*
- *Formal Defect & Change Management*



- ***System setup***
- ***Data imports***
- ***Security setup***
- ***…***

- ***Refine Test Scripts***
- ***Verify Test Coverage***
- ***Assess Data Quality***
- ***Verify Security Setup***

Test Phase – Formal Test Cycle



- *IQ Test Environment / System Setup*
- *Document Data Verification*
- *Formally release system for Testing*

- *Refined scripts from informal testing – use new test data!*
- *Test Scripts must be approved prior to testing*
- *Include End-to-Eend testing*
- *Testers must be trained*
- *Formal Defect & Change Management*

- *Record results for each Test Step*
- *Create supportive test results documentation (e.g. screen dumps, reports)*
- *Creation of documented evidence that functional & security requirements are fulfilled!*

- *Prepare Performance Test Scripts based on Requirement Documents*
- *Simulate „Production like load“ for test purposes*
- *Create documented evidence that performance requirements are fulfilled!*

- *Re-execute most critical System Test scripts to ensure no corruption through defect fixes in earlier test cycles*
- *Update test data used for Formal System Test*
- *Final verification of critical system functionality*

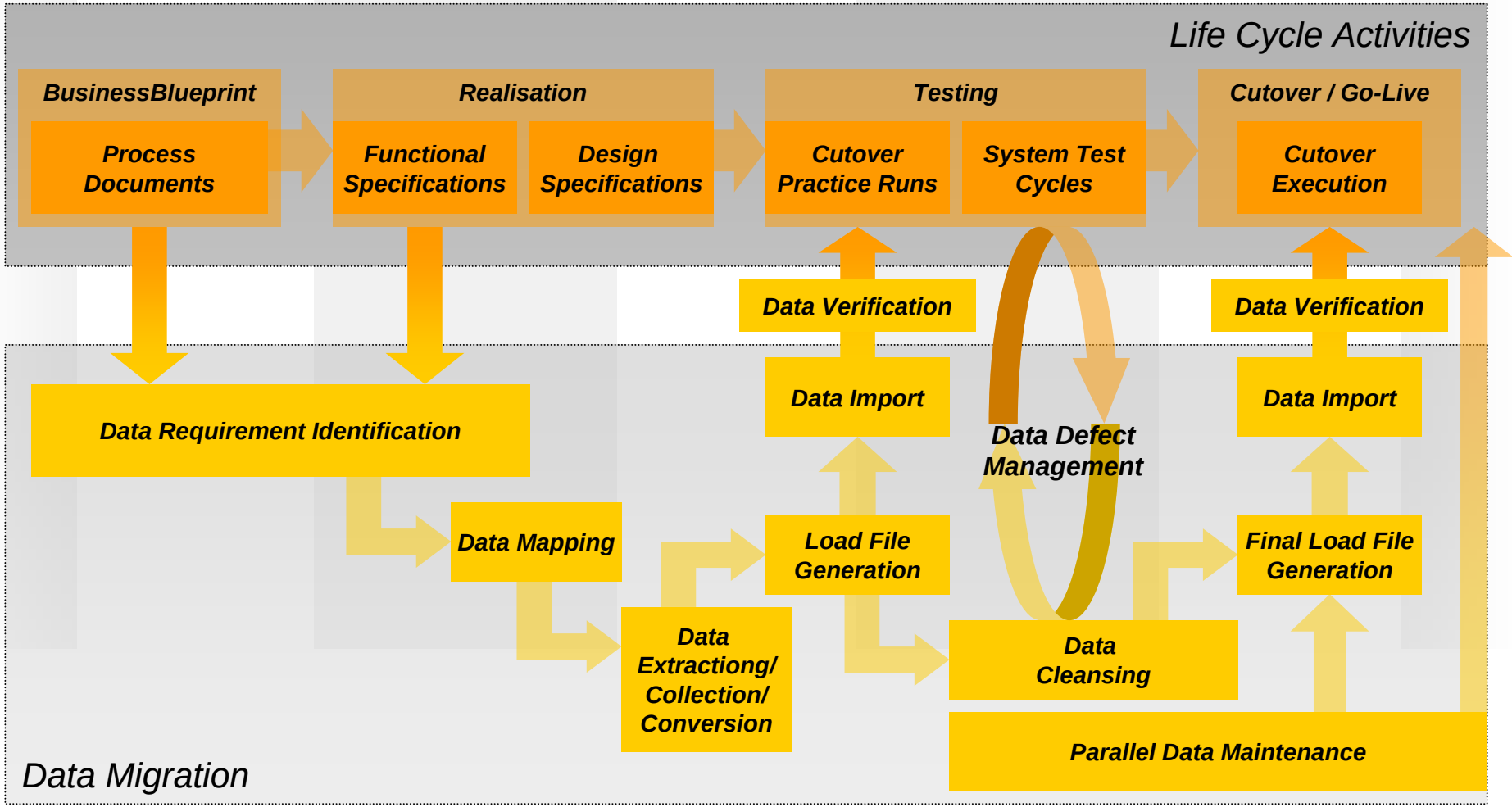
- *Summarize and assess test results from all test cycles*
- *Sign off by System Owner to indicate functional System Acceptance*

Cross Phase: Data-Migration

Phase Activities include:

- *Data Requirement Identification*
- *Data Mapping – legacy data source to new system*
- *Data Extraction (if legacy system) / Collection (if not available)*
- *Data Conversion – converting data into correct format*
- *Data Cleansing – clean legacy and collected data*
- *Load File Creation – create data upload file*
- *Data Verification – create documented evidence that data is correct*
- *Import Data – either by program (upload) or manual*
- *Parallel Data Maintenance – keep consistent with your production data*
- *Setup Data Organisation – how to manage data after Go-Live*

Cross Phase: Data Migration – Life Cycle Map



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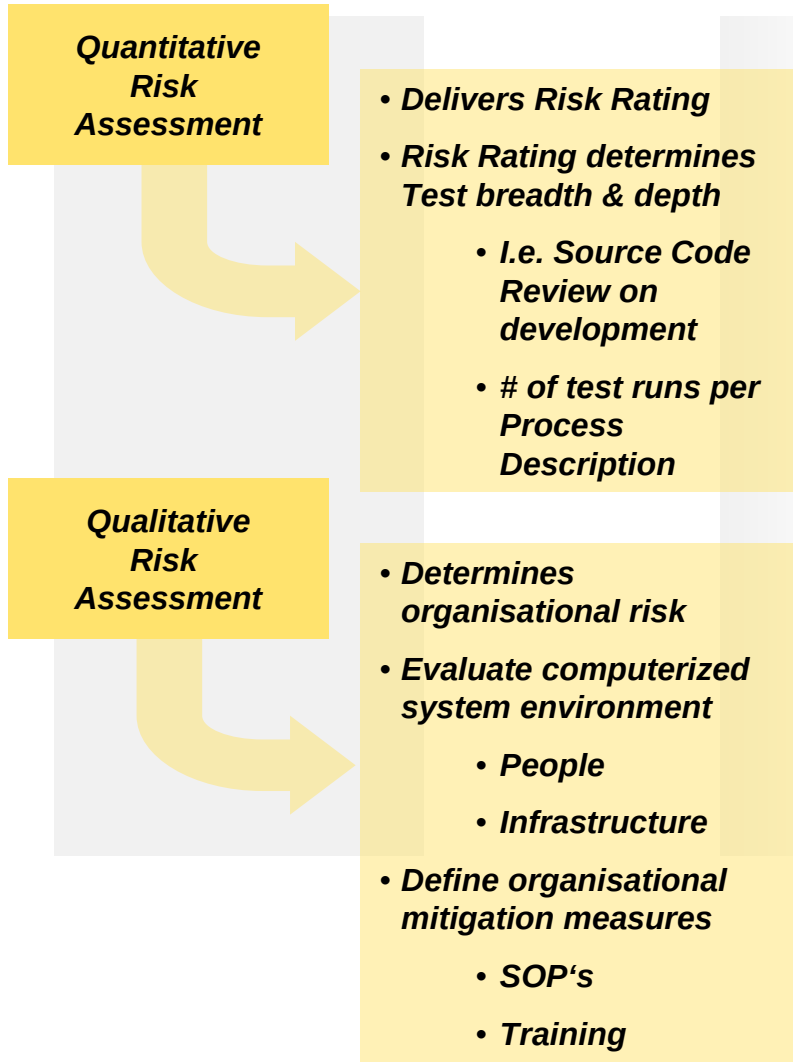
Validation Deliverables: Risk Assessment

- *Assessment performed on Process Description / Functional Specification Level*
- *Pharmaceutical, functional and general business risk associated with the process / function should be assessed*
- *Gather subject matter experts (business / system / quality) to perform assessment*
- *Requires an experienced facilitator*



Validation Deliverables: Electronic Records & Signature Assessment

- *Electronic Records*
  - *Evaluate audit trail functionality of your ERP System early*
  - *Determine GxP impact of records on a business and on database level*
  - *Assess state of compliance of the identified records*
  - *Define organisational and system measures to achieve compliance*

- *Electronic Signatures*
  - *Determine Electronic Signature Requirements already in Business Blueprint*
  - *Build Electronic Signature Design Specification in accordance with legal requirements*
  - *Prevent retrospective assessment of your design – might have a big impact on time & budget*

Validation Deliverables: Validation Report

- *Reporting against all activities defined in the Validation Plan*
- *Reference all documented evidence that was created during the project*
- *Elaborate on all deviations from the pre-defined methodology that occurred during the project*
- *Include references to internal quality standards that have been fulfilled (if available)*
- *State that the system is validated and that measures are in place to keep that status!*
- *Sign-off by System Owner*

Questions?

Contact Details

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