Training Course
Computerized System Validation in the Pharmaceutical Industry
Istanbul, 16-17 January 2003

Industry Guidelines for Computerized Systems Validation (GAMP, PDA Technical Reports)

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Agenda

New Trends

GAMP

Categorization

Risk

GAMP SIGs

IT infrastructure

PDA technical reports

2001 / 2002 - Busy Years for Guidances

- PIC/S Draft Guidance - “Good Practices in the GxP Regulated Environment”
- Many FDA Guidances (21 CFR Part 11)
- GAMP 4 and other GAMP Guidances
- GERM documents (21 CFR Part 11)

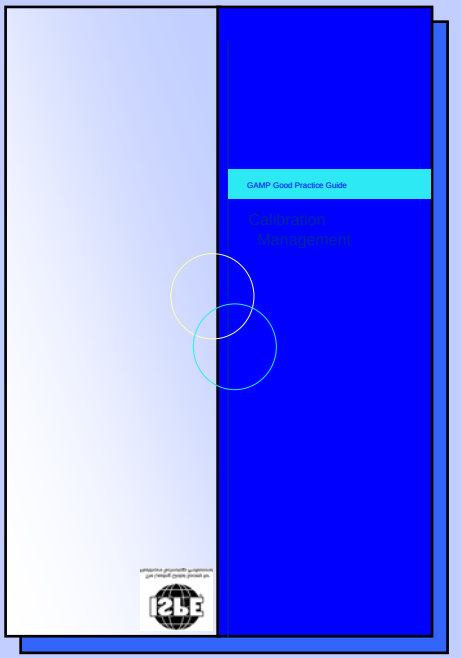
FDA Guidances

- FDA - “General Principles of Software Validation”
- FDA - 21 CFR Part 11 Guidances
  - Glossary
  - Validation
  - Time Stamps
  - Maintenance
  - Copies

Industry Guidance

ISPE Calibration Management

- practical approach to calibration management
- regulatory, quality, safety and environmental issues
- instrument criticality assessment
- instrument lifecycle approach
- examples as appendices



GAMP 4

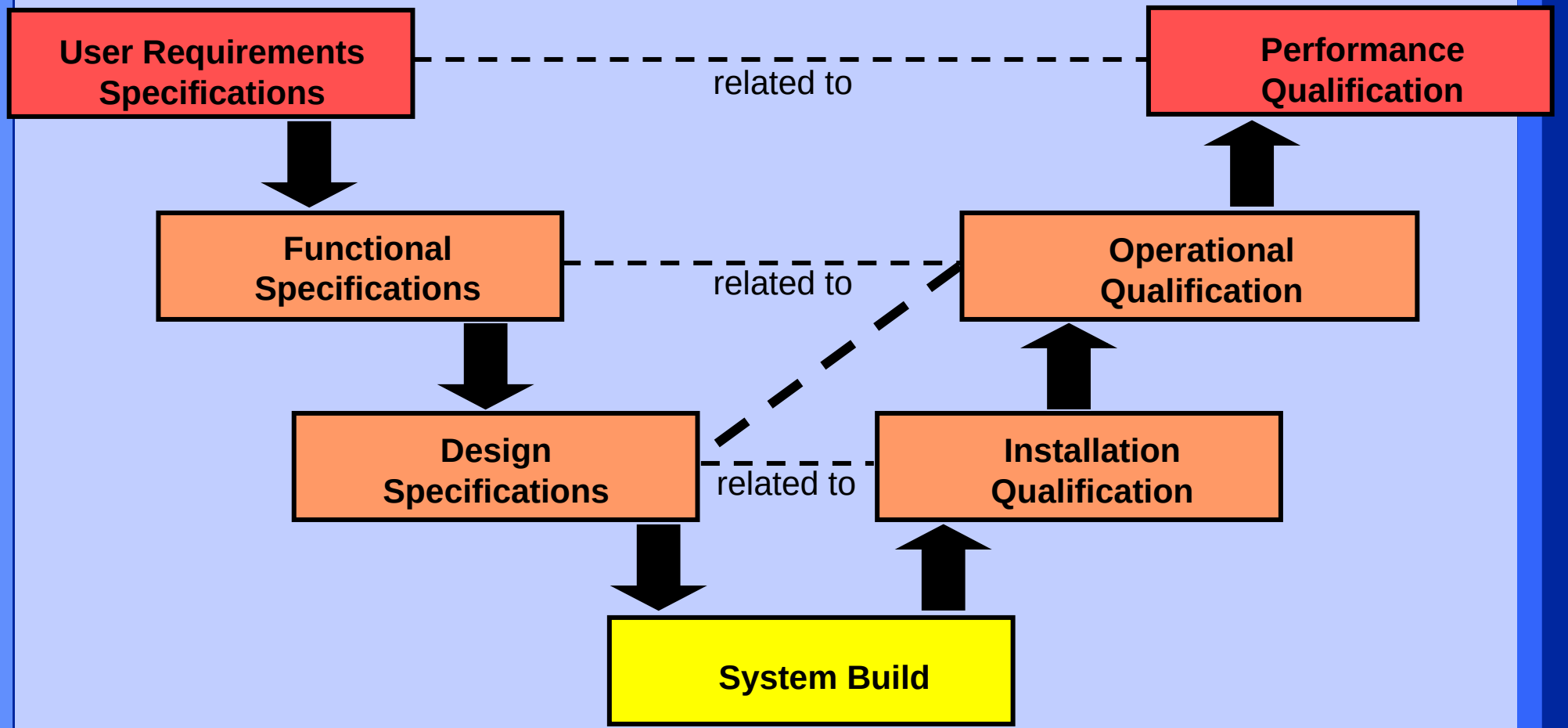
- Strategic Principles
- Structure
- Project Management
- Project Development
- Operational Support
- Good Practice Guidance

GAMP 4 Strategic Principles

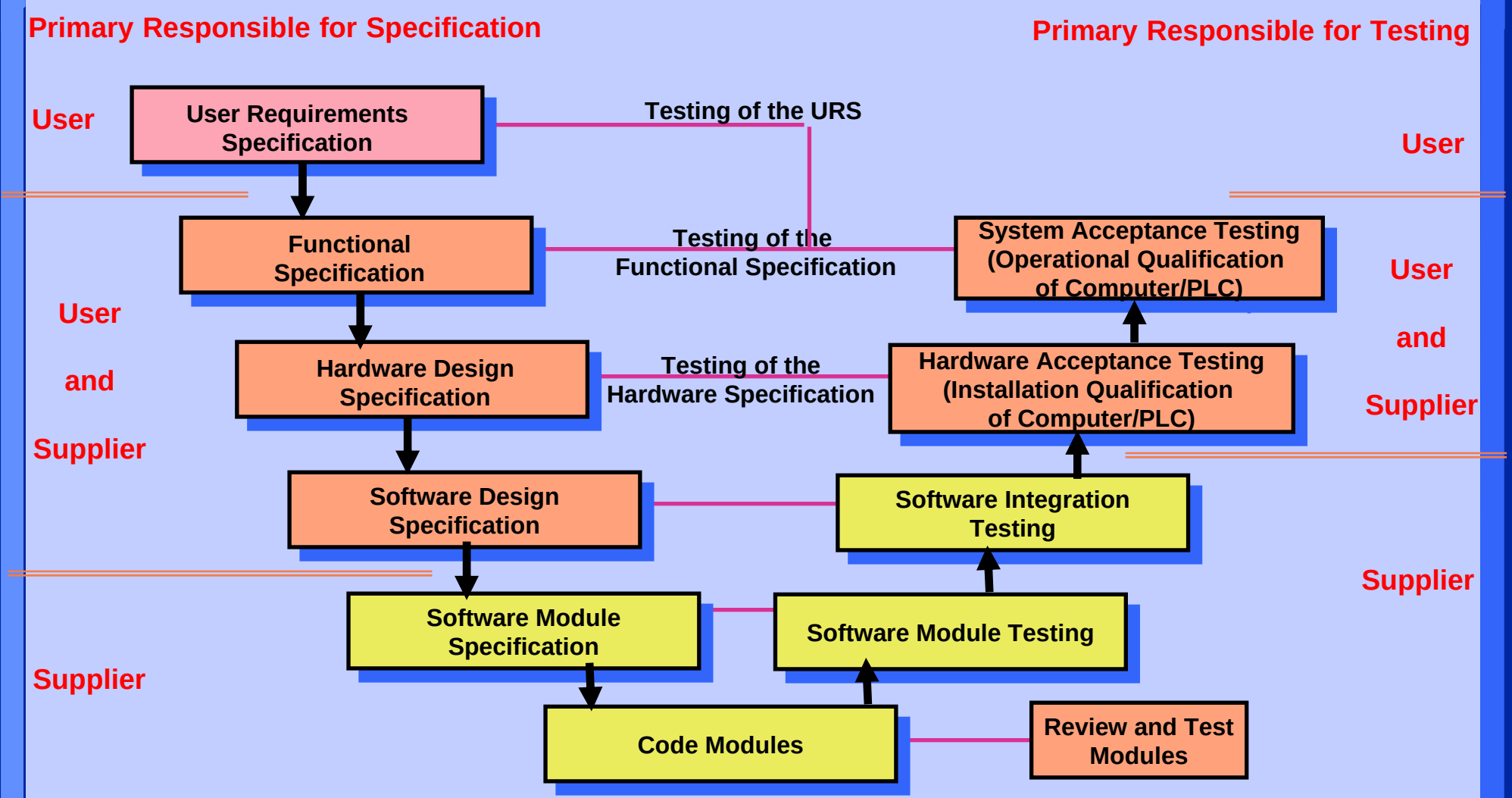
- Scalability of GAMP approach
- Leverage of suppliers expertise
- Guidance on maintaining “validated state”
- Harmonisation of terminology
- Raise awareness internationally
- Collaboration with other industry groups

GAMP 4 Structure

GAMP 4 Lifecycle Continuity



Customer - Supplier Relationship



The GAMP 4 Software Categorization System

Category	Type of Software	Validation Approach
1	Operating Systems	Record version, check applications
2	Firmware	Record configuration, test functions
3	Standard Software Packages	Document requirements, Validate application
4	Configurable Software Packages	Audit supplier, validate application and any bespoke code
5	Bespoke Systems	Audit supplier and validate complete system

What about Tools?

Development tools
Test tools
Monitoring tools

Question: Standard or Customised?

- ➔ Customised tools need validation
- ➔ Change control for upgrades

The GAMP 4 Hardware Categorization System

Category	Type of Software	Validation Approach
1	Standard Hardware Components	IQ, installation and connections
2	Custom-built Hardware	IQ, design specification, acceptance testing

- **Category 1 – standard hardware**
- **Category 2 – customised hardware**

Project Development and Implementation - Risk Considerations 1

- **Risk Assessment much more significant**
  - **each system function evaluated**
    - **for risk (GxP and Business)**
    - **for severity of impact**
    - **for probability of detection before impact**
- **Guidance available (annex to GAMP 4)**

Project Development and Implementation - Risk Considerations 2

Mitigation strategies discussed

- modification of process or design:
  - avoidance,
  - process design,
  - system design,
  - external process
- project strategy:
  - Project structure, auditable ”built-in quality”
- validation strategy: modify test strategy rigour

Benefits of Risk Assessment

- little or no validation for low risks
- more focus on higher risks
- communicating risks
- focussed training
- regulatory confidence

GAMP 4 - Quality Management Procedures

The Management Appendices M 1 to M 10

Revised Quality Management Guidelines

- **Project management and control**
- **Project development**
- **Operational support**

GAMP 4 - Project Management and Control

- Validation Planning
- Quality and Project Planning
- Document Mangement
- Risk Management
- Design Review
  - including Traceability Analysis
- Project Change Control
- Configuration Management
- Validation Reporting

GAMP 4 - Good Practice Definitions (11.1 to 11.3)

Revised good practices

- **Good documentation practice**
- **Good testing practice**
- **Good engineering practice**

GAMP 4 - Operational Support Guidelines

- Backup and Recovery
- Business Continuity Planning
- Operational Change Control
- Performance Monitoring
- Periodic Review
- Record Retention, Archive and Retrieval
- Security
- Service Level Agreements

GAMP Good Practice Guidance (Topics Under Consideration)

- Legacy Systems
- Infrastructure
- Process Systems
- “Skid Mounted” Equipment
- Calibration*
- Electronic Records and Signatures*
- Analytical Laboratory Equipment
- Global IT Systems
- Good Engineering Practice
- Web-based Applications

*** Published**

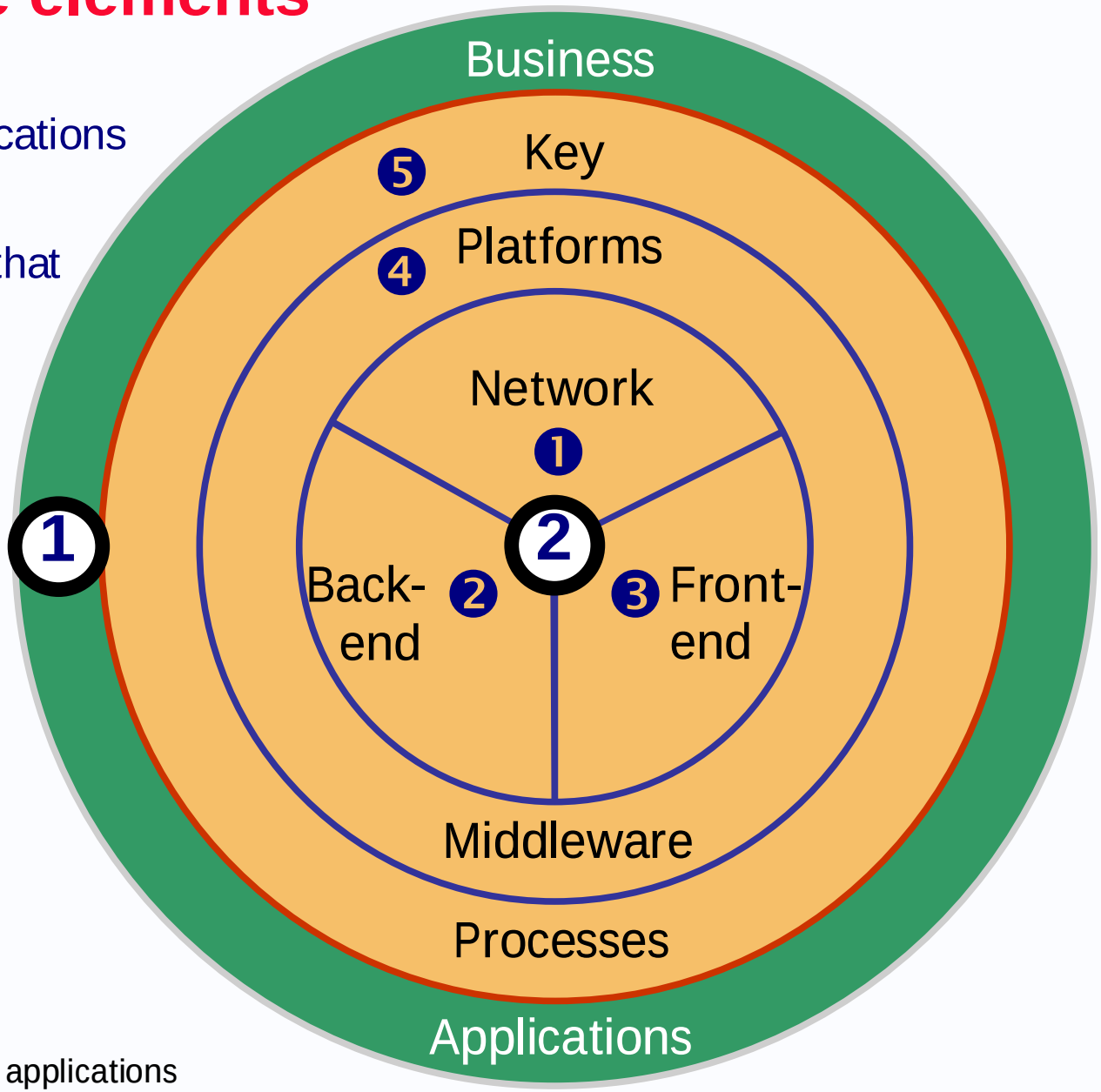
IT Infrastructure - Important Aspects

- design specification
- layout and hierarchical drawings
- installation records
- change control

The IT Infrastructure elements

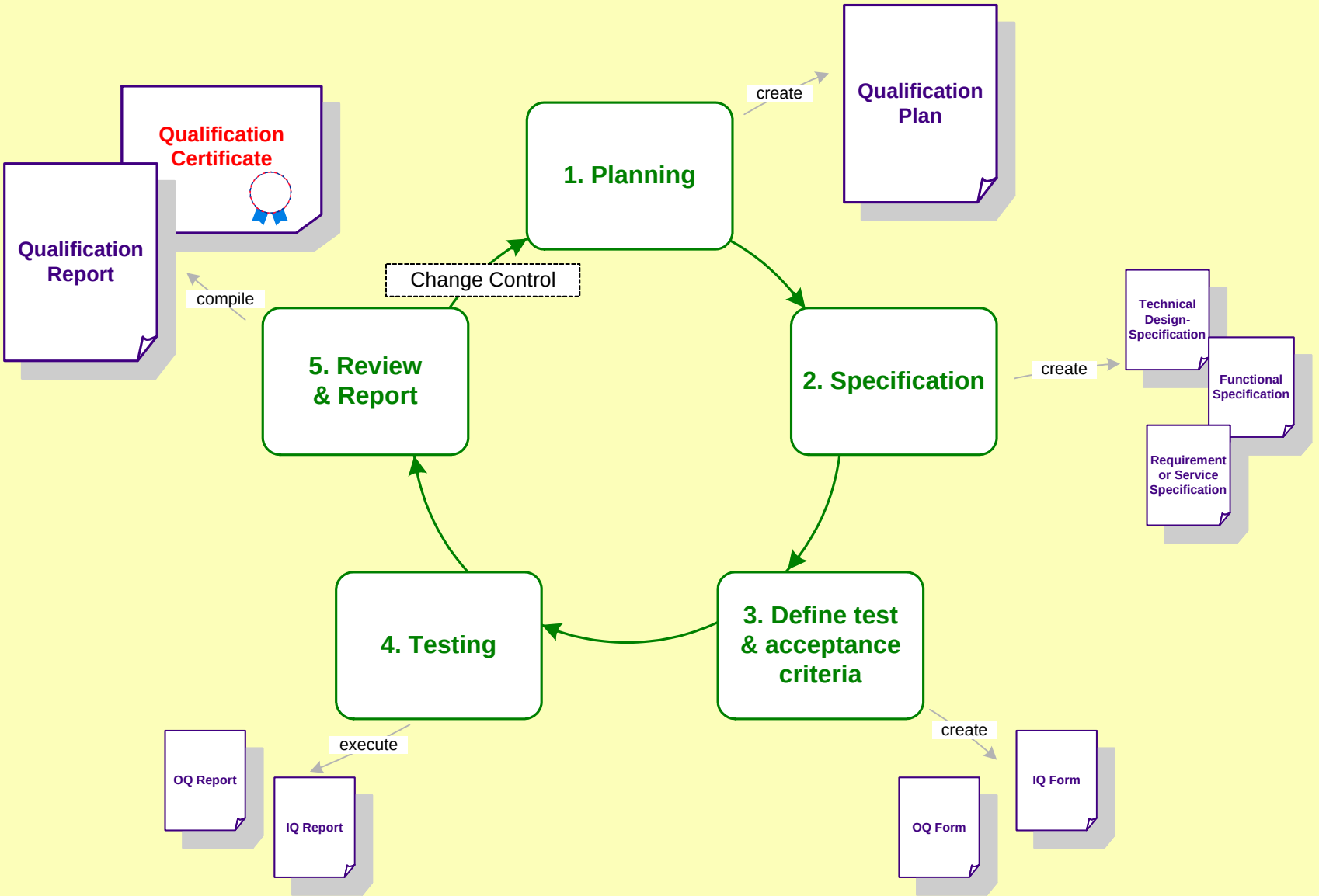
1. GxP-relevant business applications dealing with GxP-data
2. GxP-relevant infrastructure that delivers a qualified platform

1. Network (WAN/LAN)
2. Back-end (servers)
3. Front-end (desktops)
4. Platforms and middleware*
5. Key processes



* also called enablers, core or base applications

IT Infrastructure - the Qualification Lifecycle



The APV interpretation of Annex 11 EU Guide to GMP

- Published already in 1994
- Regulators contributed to interpretation
- Good document, easy to read
- Contains many useful information
- English translation in GAMP 4

- Recommended reading for CSV beginners

APV: Arbeitsgemeinschaft Pharmazeutische Verfahrenstechnik

PDA Technical Report No. 18
Validation of Computer Related Systems

- Published in 1994
- Consultants contributed to guidance
- Contains advanced, but useful information
- Recommended reading for CSV beginners
- Can be ordered via PDA

PDA: Parenteral Drug Association

PDA Technical Report No. 31

Validation and Qualification of Laboratory Data Acquisition Systems (LDAS)

- **Published in 1999**
- **Contains advanced information for LDAS system owners**
- **Recommended reading for LDAS experts**
- **Can be ordered via PDA**

PDA: Parenteral Drug Association

PDA Technical Report No. 32

Auditing of Suppliers providing computer products for regulated pharmaceutical operations

- **Published in 1999**
- **Contains advanced information for auditors of computerized system suppliers**
- **Recommended reading for Auditors**
- **Can be ordered via PDA**

PDA: Parenteral Drug Association