

Computer System Validation Overview

Topics

- What is validation and why do we do it?
- What does the validation process look like?
- What do I have to do?
- Helpful references and training info

What is validation?

- Computer systems installed in the corporation are validated to assure that they are of high quality, meet business needs, and are designed, implemented and managed in compliance with appropriate regulatory requirements to perform in a manner consistent with their intended functions.
- The intent of validation is to ensure that regulated systems meet the criteria listed below.
 - Systems are developed according to quality software engineering principles.
 - Systems meet the business needs of their users and
 - Continue to operate correctly and reliably throughout their life cycle.

What is validation?

- Validation is mostly just good software engineering practice in a formal setting
 - Making sure the system is built right
 - Making sure the right system is built
 - Managing change

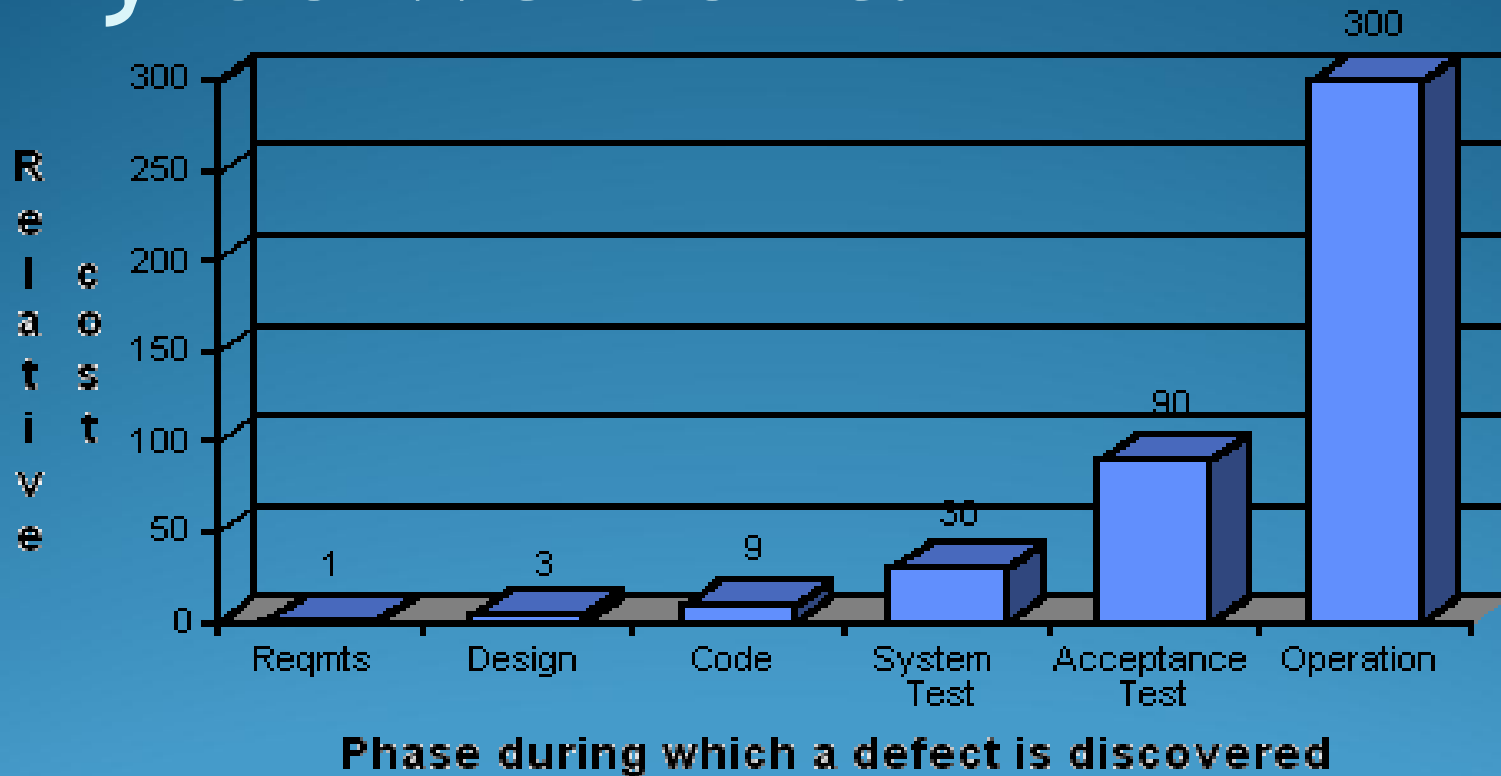
What is validation?

- Validation is a formal (i.e., documented) process:
 - plan
 - execute
 - summarize
- Documentation provides evidence of execution & management involvement

Why do we do it?

- Because we have to
 - Regulatory requirements, both US and international
- Because it makes good business sense
 - Quality is built in to the system
 - The system does what it needs to do
 - Less effort needed for system maintenance
 - Reduction in business & regulatory risk
 - Cost savings

Why do we do it?



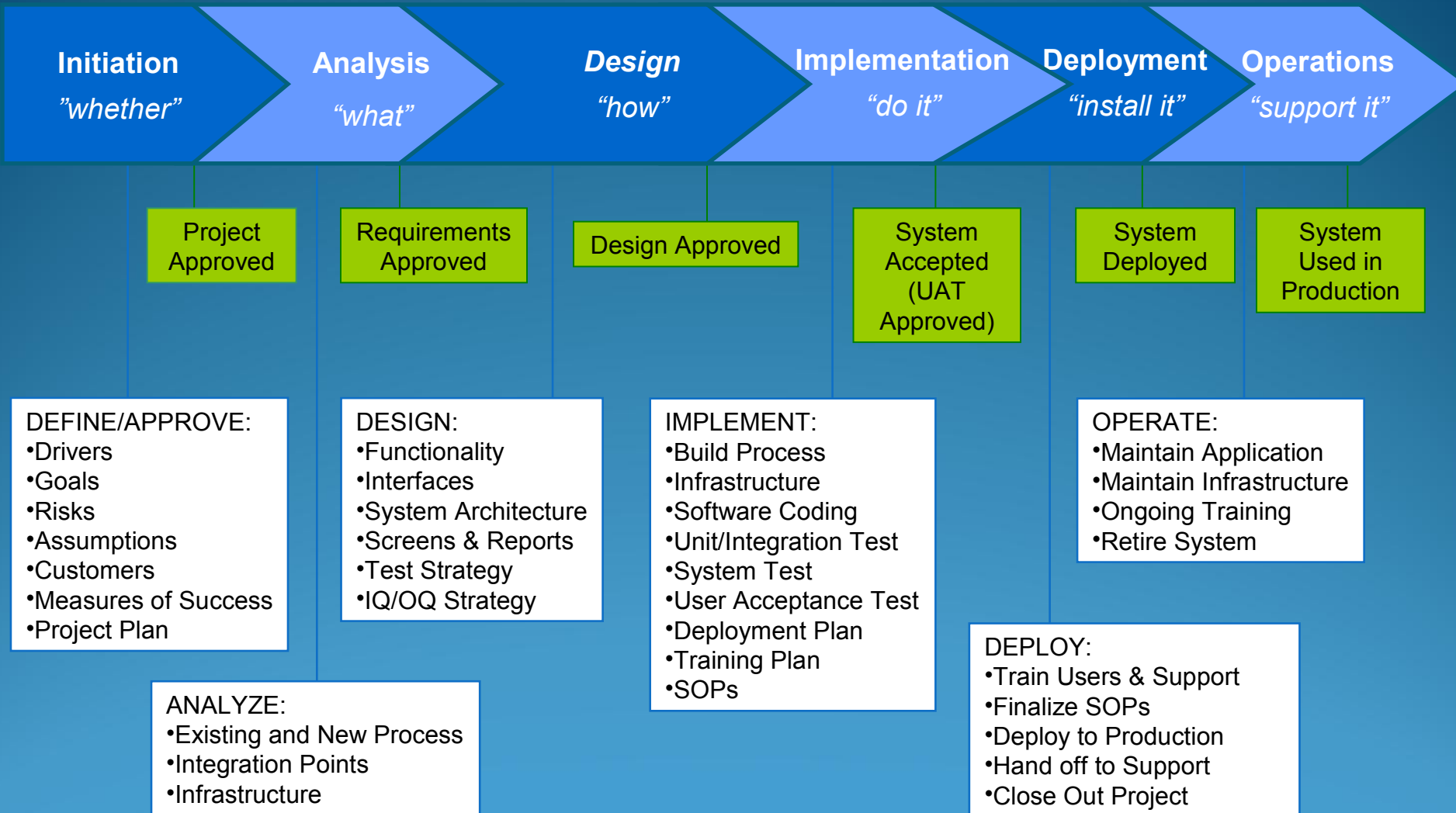
Software Engineering Economics
B.W. Boehm, 1981

What does the validation process look like?

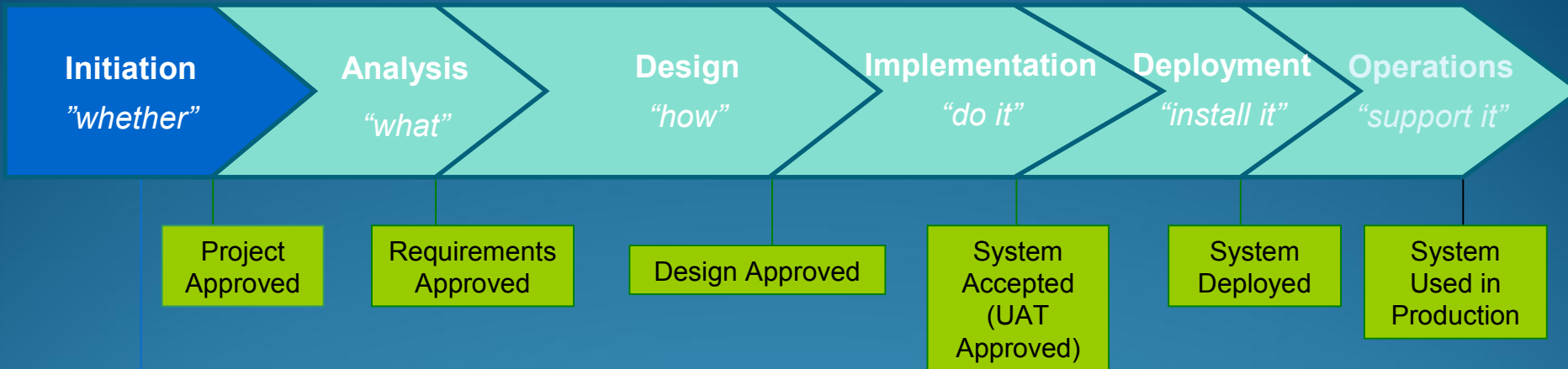
- Life Cycle

An approach to computer system development that begins with identification of the user's requirements, continues through design, coding, integration, testing, qualification, control, and maintenance, and ends only when production use of the system is discontinued.

“Custom” System Life Cycle Model



“Custom” System Life Cycle Model



DEFINE/APPROVE:

- Drivers
- Goals
- Risks
- Assumptions
- Customers
- Measures of Success
- Project Plan/Charter

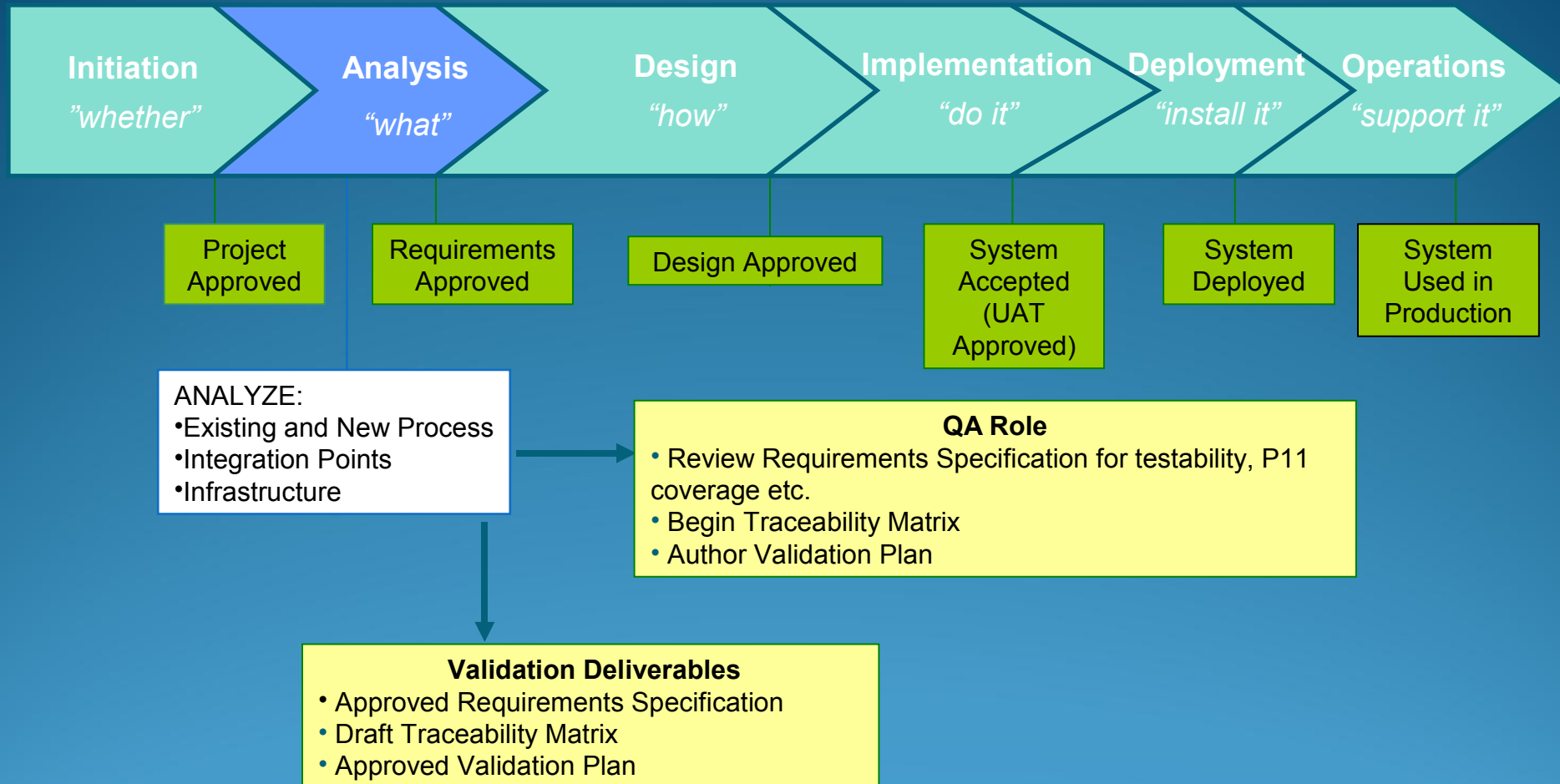
QA Role

- Assign IQA Team Member(s)
- Establish Project Document Management Process
- Begin Project Team CV / Training Records Capture

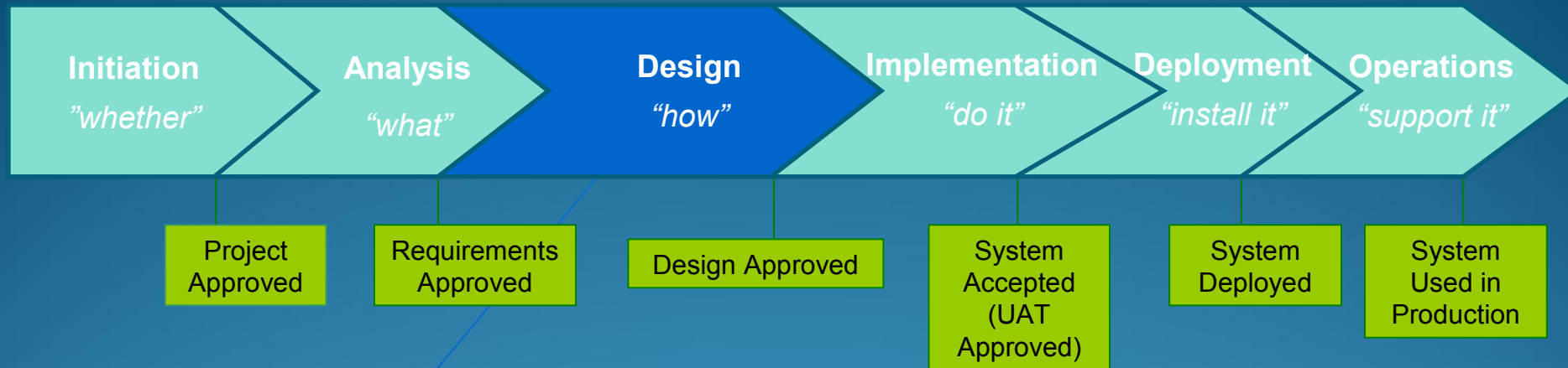
Validation Deliverables

- Approved Project Plan/Charter

“Custom” System Life Cycle Model



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DESIGN:

- Functionality
- Interfaces
- System Architecture
- Screens & Reports
- Test Strategy
- IQ/OQ Strategy

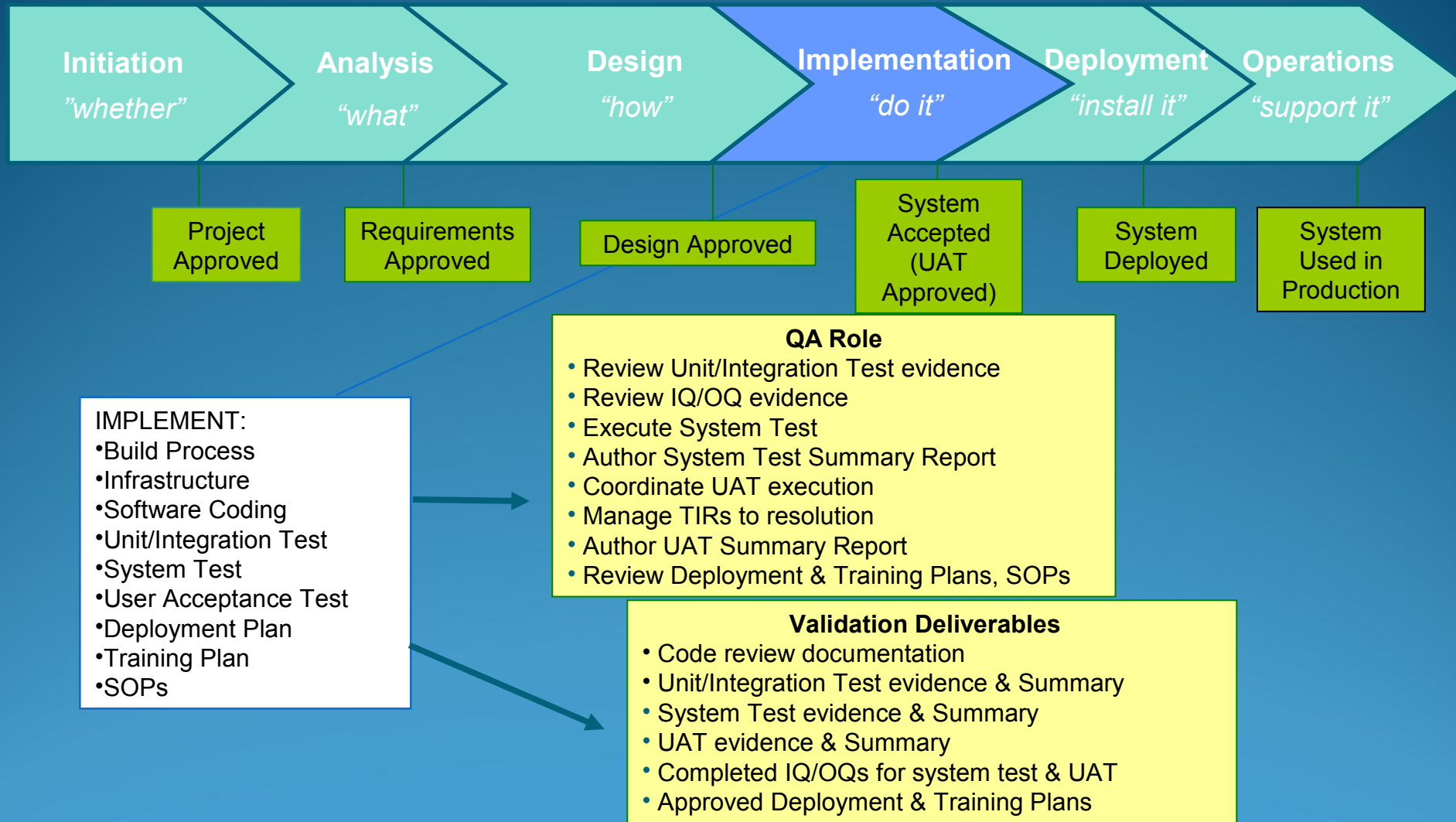
QA Role

- Author Test Plans
- Author Test Scripts/checklists (w/developers & business)
- Update Trace Matrix for System Test & UAT
- Write IQ/OQ Plan

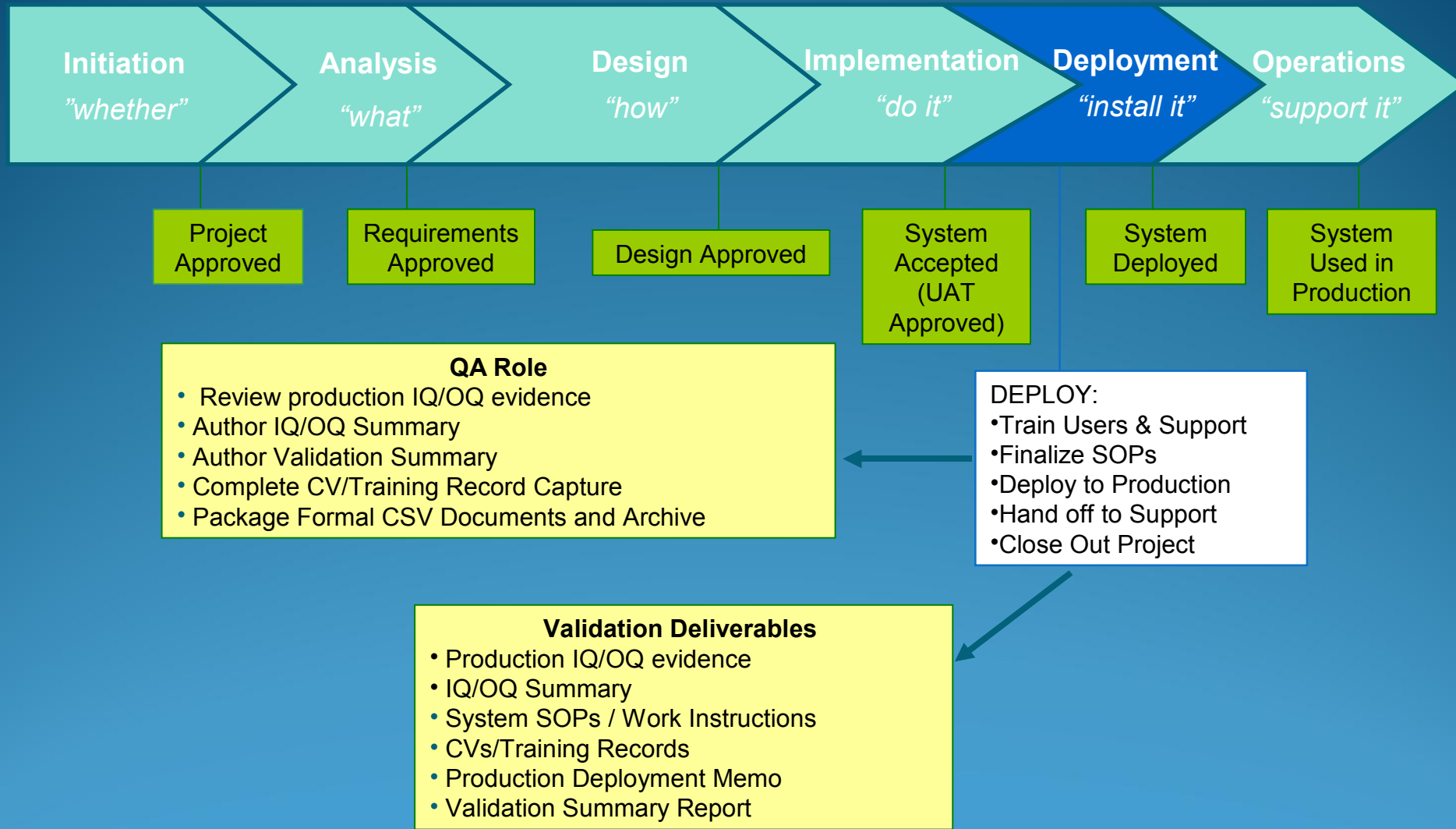
Validation Deliverables

- Approved Design
- Design review documentation
- Approved Test Plans
- Finalized Test Scripts/Checklists
- Trace Matrix
- Approved IQ/OQ Plan

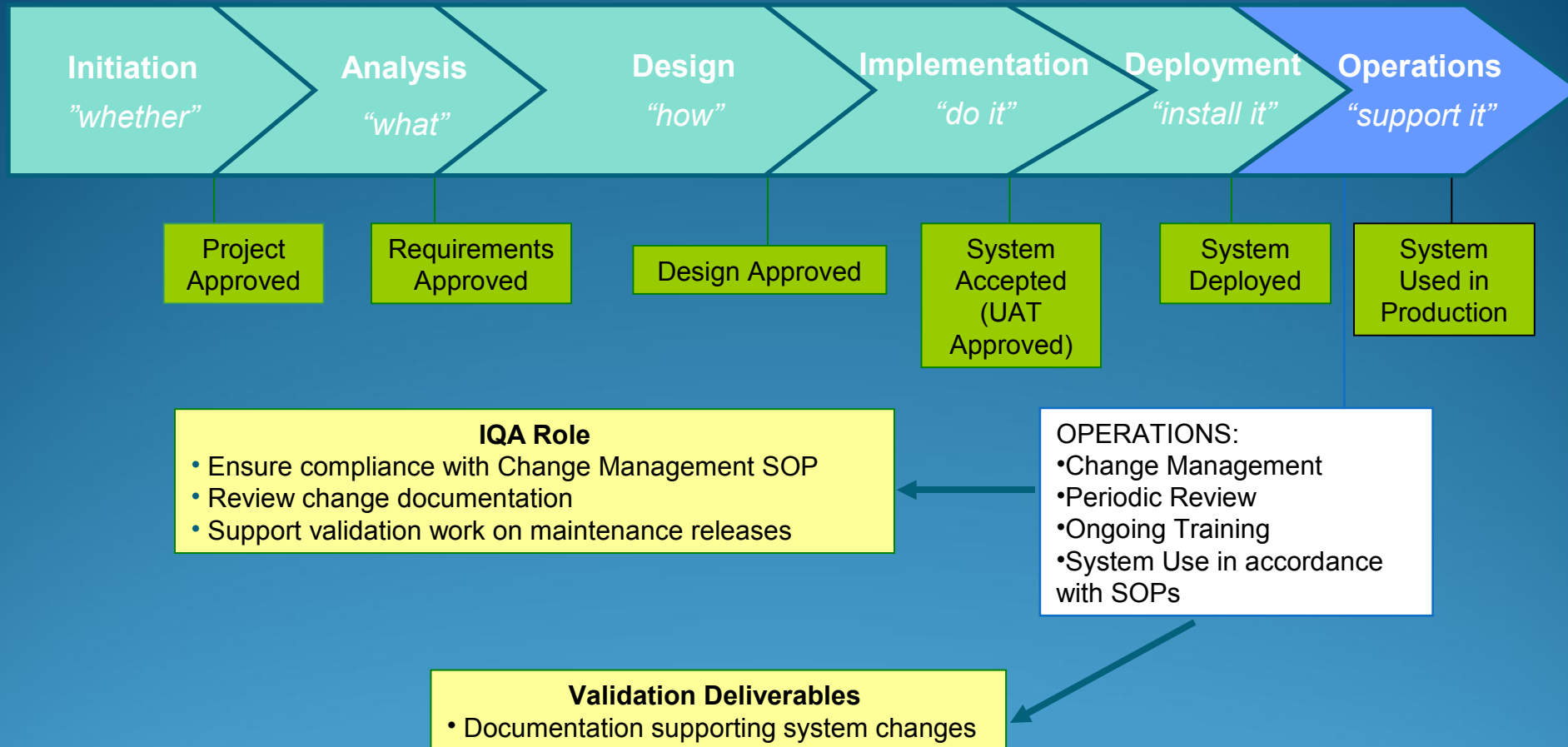
“Custom” System Life Cycle Model



“Custom” System Life Cycle Model



“Custom” System Life Cycle Model



Roles & Responsibilities

- System Owner/Business Management
 - Overall responsibility for system validation
 - Review and approval of key deliverables
 - Provide business resources to the project
 - Deployment approval
 - Support ongoing use of the system in a compliant manner

Roles & Responsibilities

- Development Team
 - Project management (shared with business)
 - Hardware and software implementation
 - Testing
 - Installation/Operational Qualification
 - Technical documentation
 - Deployment
 - Support Model

Roles & Responsibilities

- Business Team
 - Project management (shared with Informatics)
 - Requirements Definition
 - User Acceptance Testing
 - Standard Operating Procedures for system use and administration
 - Training (often shared with Informatics)

Roles & Responsibilities

- Quality Assurance
 - Validation approach/oversight
 - Vendor audits (as needed)
 - Validation documentation
 - System testing (sometimes shared with Development Team)
 - UAT coordination (shared with Business Team)
 - Organization and archiving of validation package
 - Ensure compliance with Corporate validation policy and SOPs

Roles & Responsibilities

- Regulatory Compliance
 - Advise on regulations
 - May review and approve key deliverables
 - Perform systems and documentation audits

Summary

- Validation makes good business sense (and it's a regulatory requirement)
- Validation looks a lot like good software development practices
- Keeping a system validated requires activity over the life of the system
- A successful validation project requires involvement from the business, Informatics and Regulatory Compliance.

References & Resources

- ISPE's GAMP4 Guide for Validation of Automated Systems (start/specialized applications)
- FDA Web Site
 - 21 CFR Part 11; Electronic Records & Signatures
 - Guidance for General Principles of Software Validation (CDRH)
 - Guidance for Computerized Systems used in Clinical Trials