



symposium on
RADIOPHARMACY
DESIGN

Barts Health **NHS**
NHS Trust

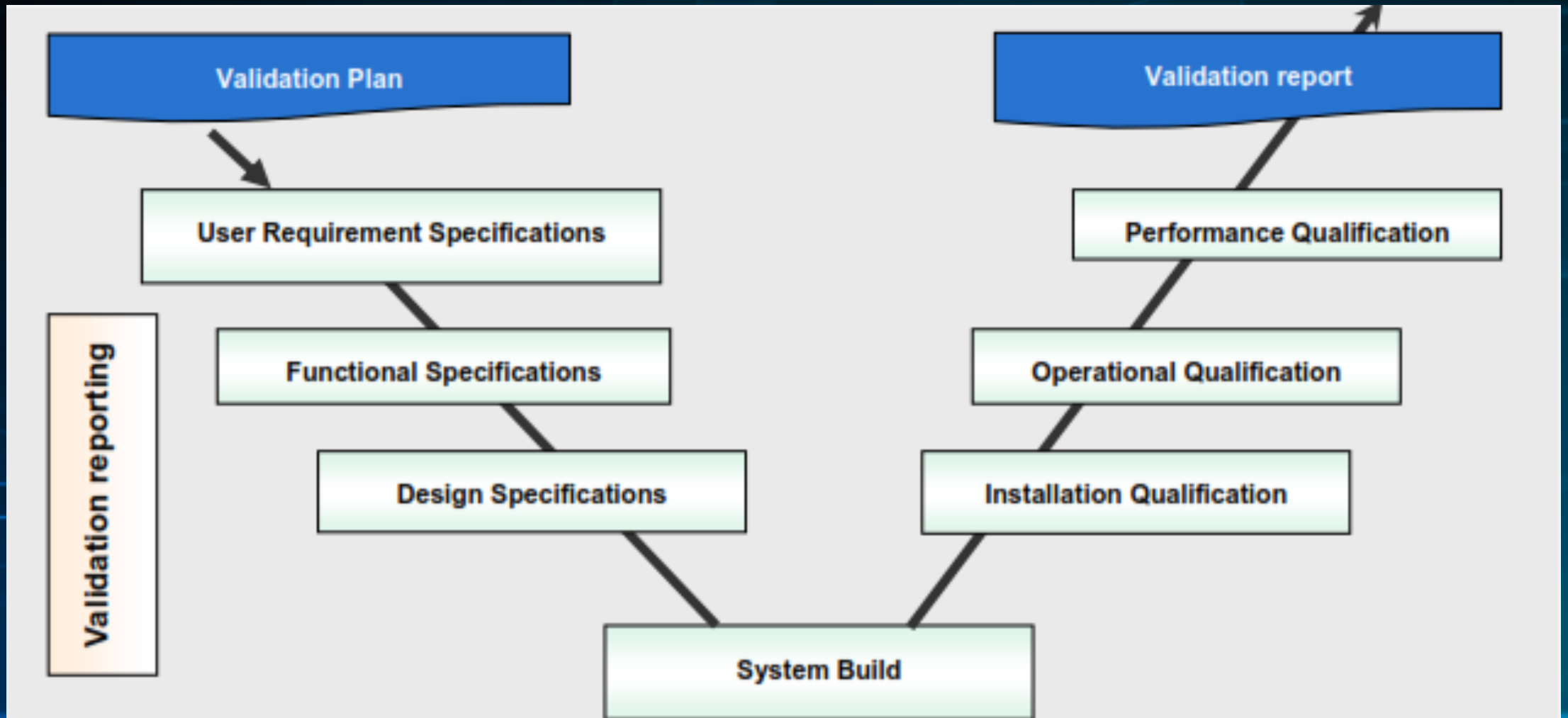
Commissioning

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Background

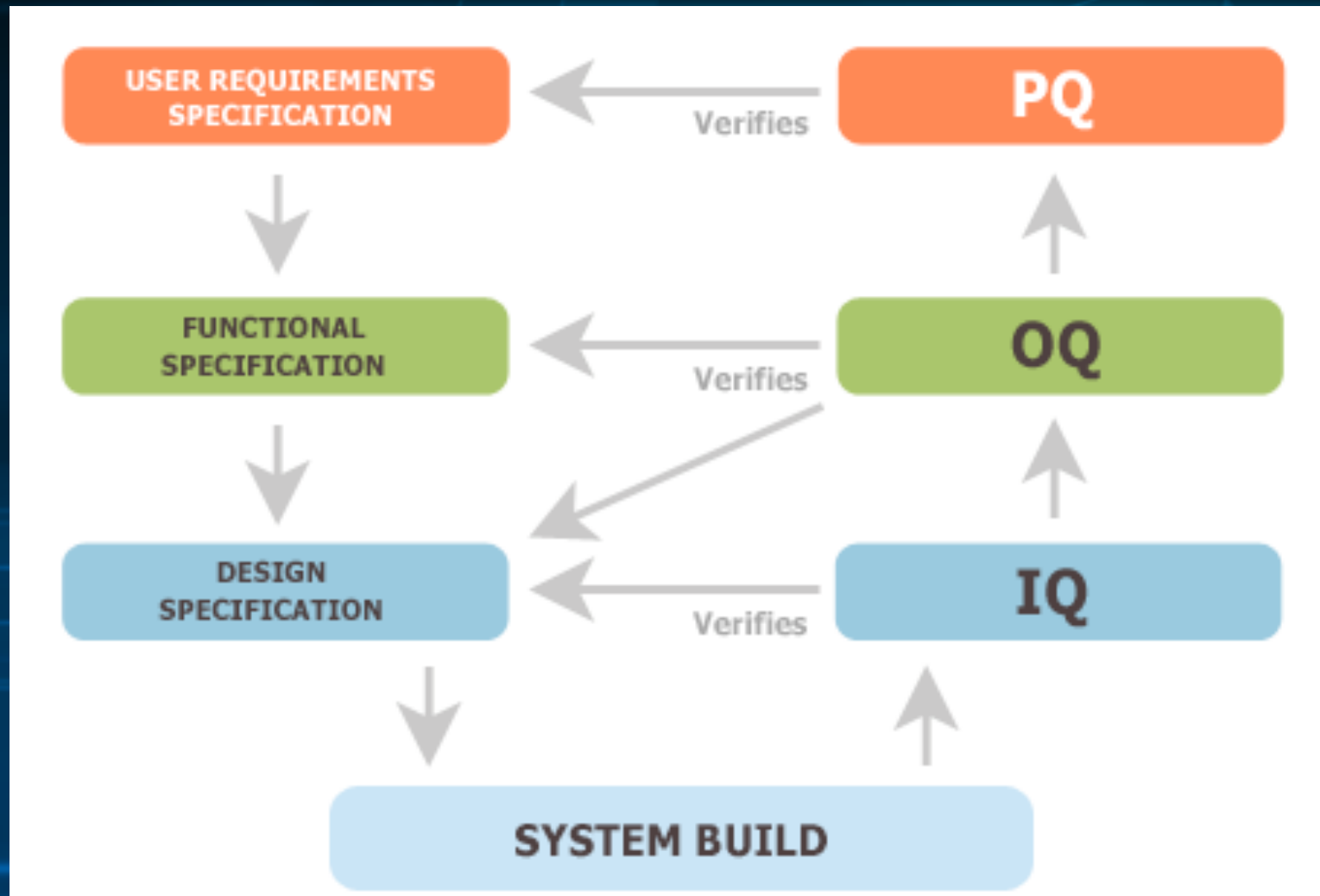
- Pharmacist since 1983
- Managed cGMP facility for Baxter Healthcare
- Member of USP Sterile Compounding Expert Committee responsible for USP Chapter <797> Pharmaceutical Compounding-Sterile Preparations
- I am not a nuclear pharmacist but completed 65 hours of live training at Purdue University-Dr. Kara Duncan Weatherman
- Consultant-involved in designing and auditing sterile compounding operations including nuclear pharmacists, PET-hot cells and Cyclotrons

V Model



From: Deshpande G. [V Model and Validation Process-in the Pharmaceutical Industry-FDA Perspective](#). Dec 30, 2008.

Another view of the V model



Validation, Qualification and Commissioning

- It is important to understand the definitions of
 - Validation
 - Qualification
 - Commissioning
- Understanding this distinction provides insight about how each can effectively work together.

Validation/Qualification vs. Commissioning

According the FDA Validation is:

“Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.”

-Guidelines on General Principles of Process Validation

Validation/Qualification vs. Commissioning

Qualification is a subset of Validation

- It includes IQ/OQ/PQ
- Qualification is the documented verification that all aspects of a facility, utility or equipment that can affect product quality . . .
 - ... adhere to approved specifications (Installation Qualification or IQ)
 - ... operate as intended throughout all anticipated ranges (Operational Qualification or OQ)
 - ... perform as intended meeting predetermined acceptance criteria over time (Performance Qualification or PQ)

Validation/Qualification vs. Commissioning

Commissioning is “a well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the End-User that results in a safe and functional environment that meets established design requirements and stakeholder expectations.”

-International Society for
Pharmaceutical Engineering



Validation/Qualification vs. Commissioning

Commissioning verifies

1. what was specified was installed,
2. that it functions properly,
3. it was successfully turned over to the user and
4. It reasonably ensures Qualification success.

Avoid Qualification becoming a troubleshooting exercise.



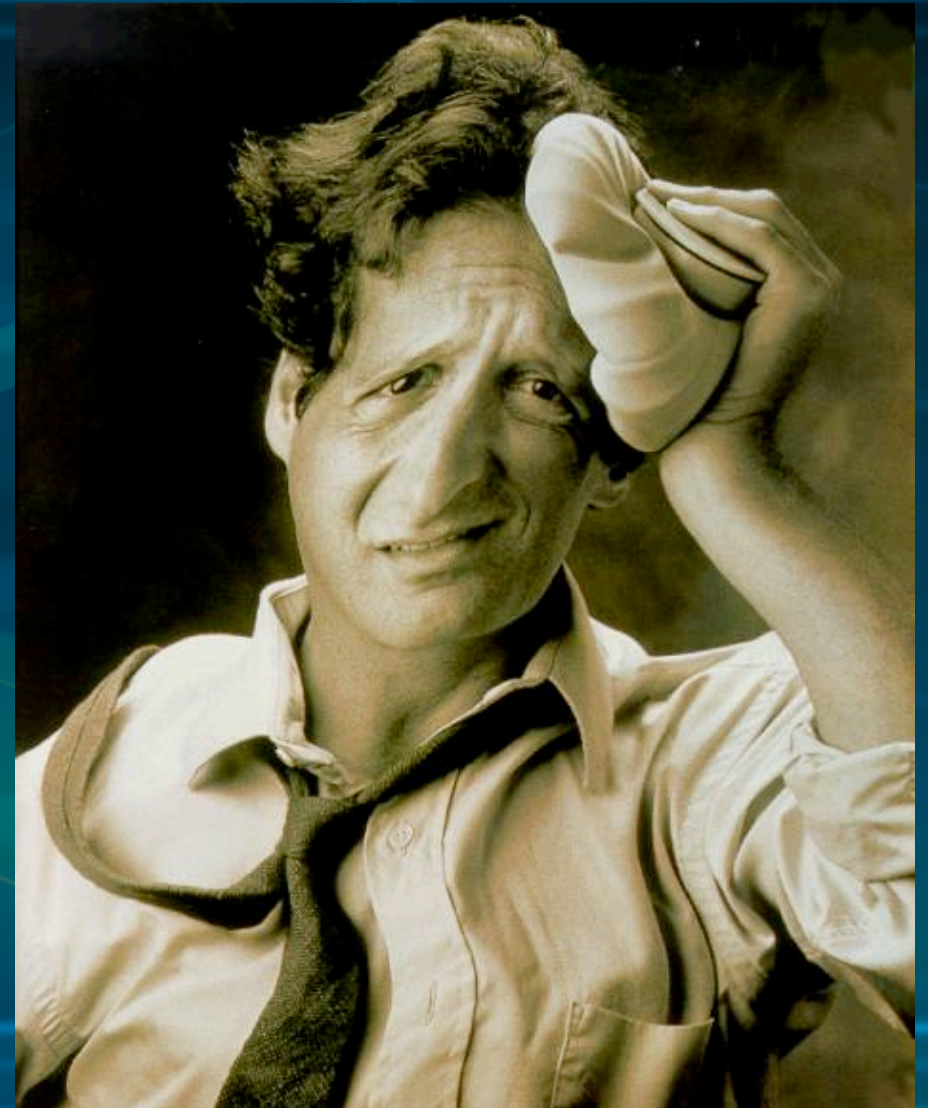
- For cGMP, formal commissioning provides necessary documentation to verify and record commissioning was done and supports Qualification documentation.

Validation/Qualification vs. Commissioning

- The Validation/Qualification definition emphasizes *product*; the Commissioning definition emphasizes *equipment*.
- Validation/Qualification is primarily concerned with verifying aspects that could affect product quality.
- Commissioning is concerned with GEP (Good Engineering Practice) and Qualification success, and is an equipment/system/facility focus.

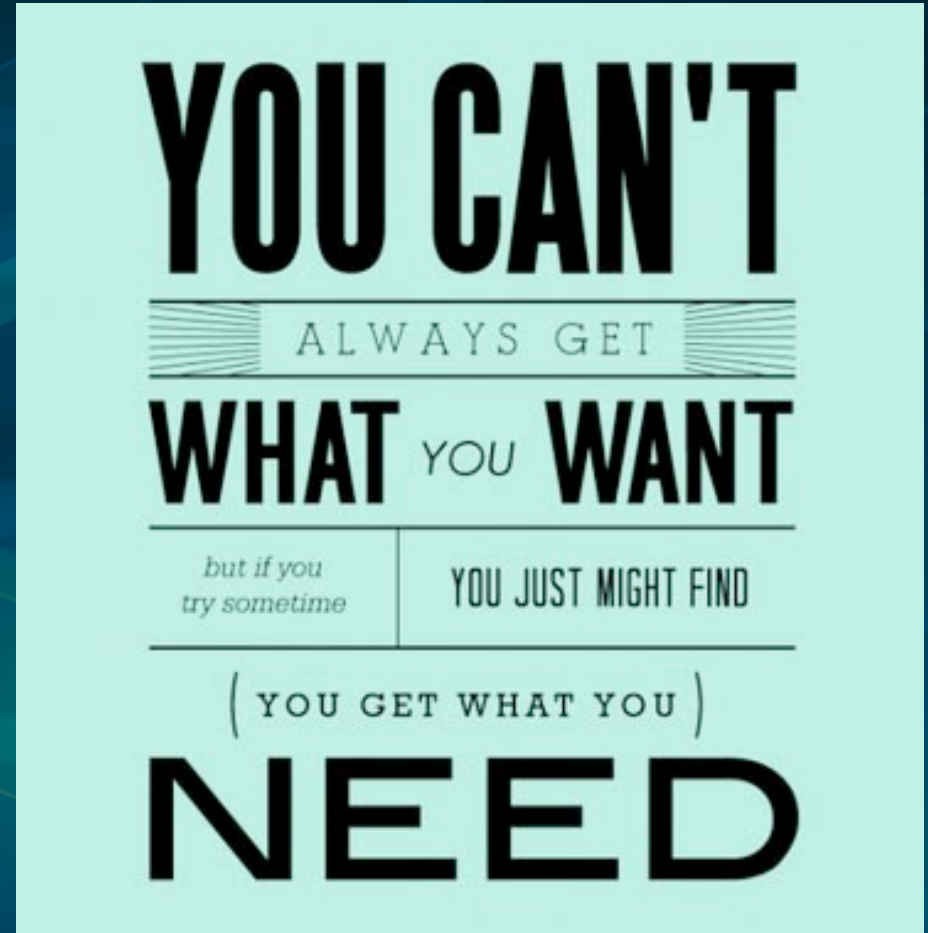
Where to start?

- What is “Commissioning”?
- How does “Commissioning” Work?
- Who provides “Commissioning”?



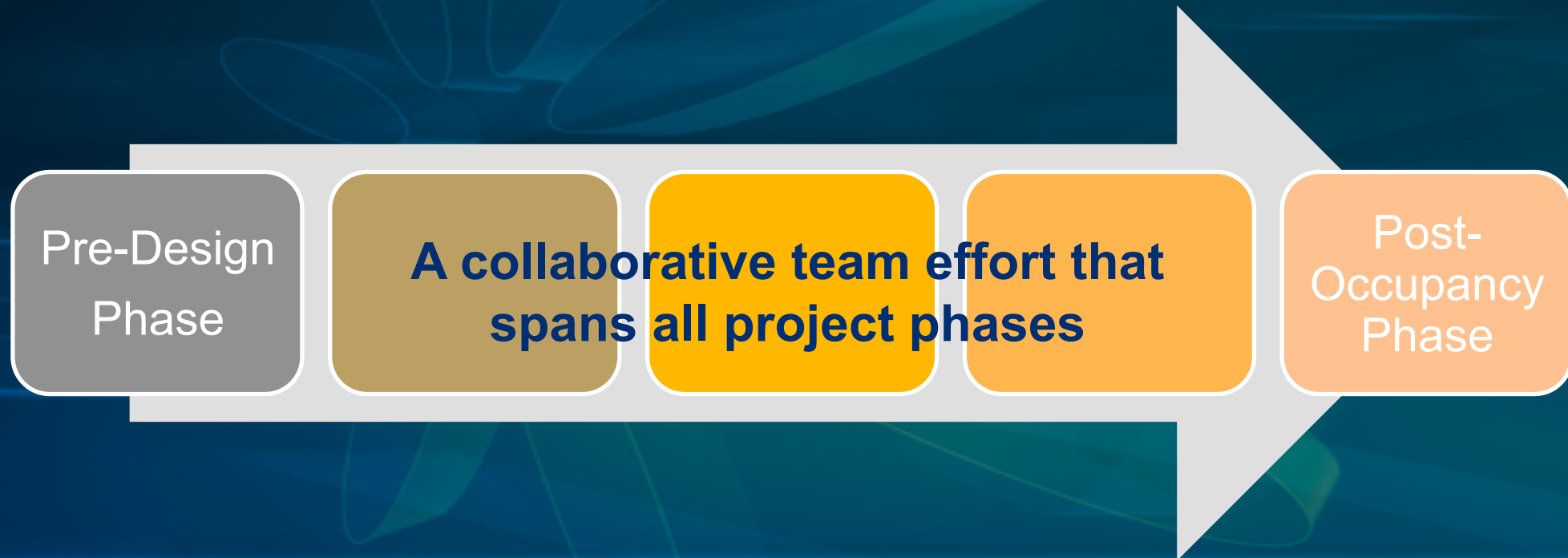
Commissioning (Cx)

- A quality-focused process for enhancing the delivery of a project focusing upon verifying and documenting that the facility (and all of its systems and assemblies) are planned, designed, installed, tested, operated, and maintained to meet the User's Requirements Specifications.



Commissioning (Cx)

- A systematic process that enhances quality control and adds value through optimized building performance.

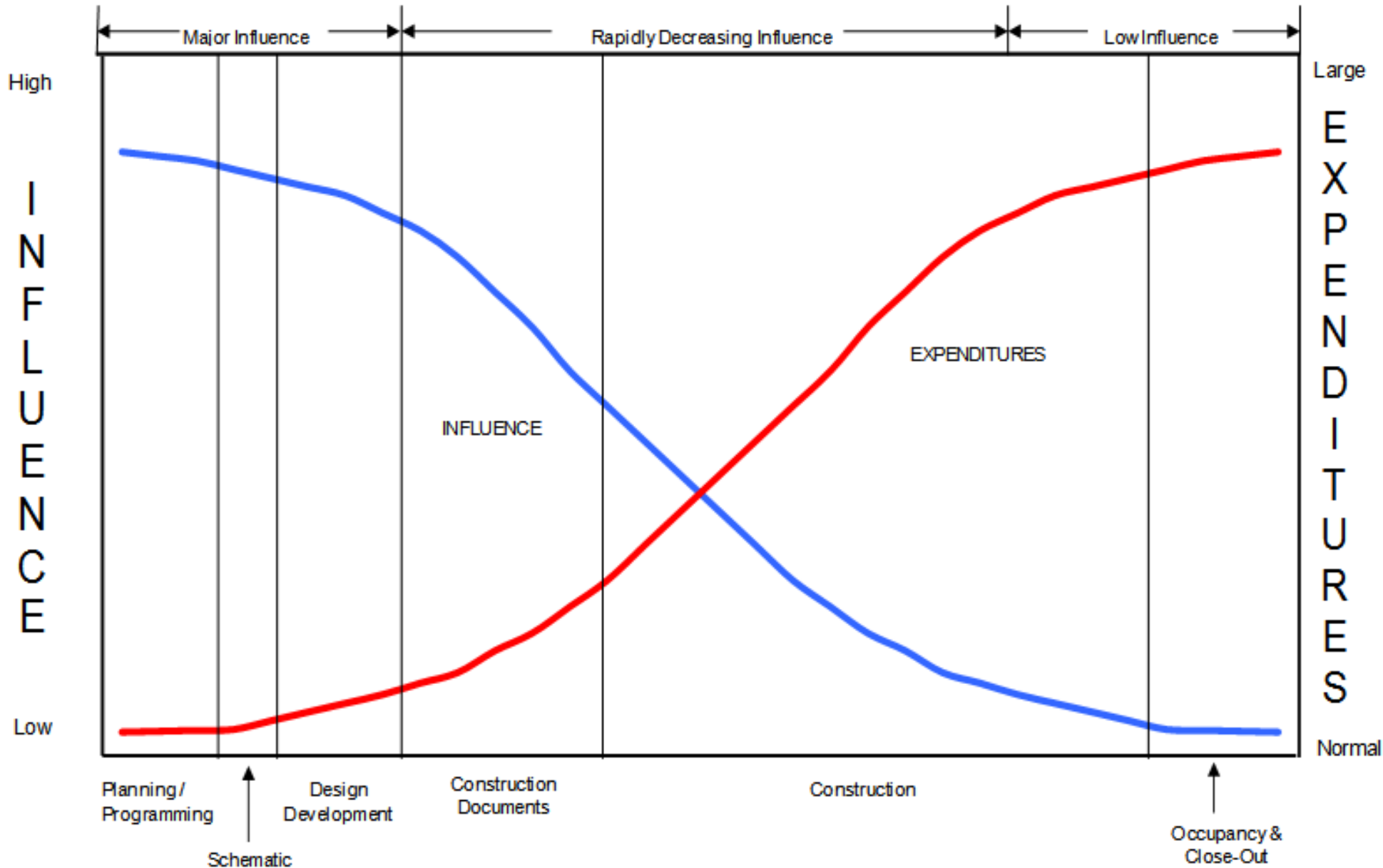


Commissioning Process

- The Commissioning (Cx) process involves steps that are integrated into EVERY phase of the project:
- Commissioning is NOT just testing at the end!
- Provides an independent assurance that URS are met
- Quality must be ***built into*** a process and not inspected into through testing



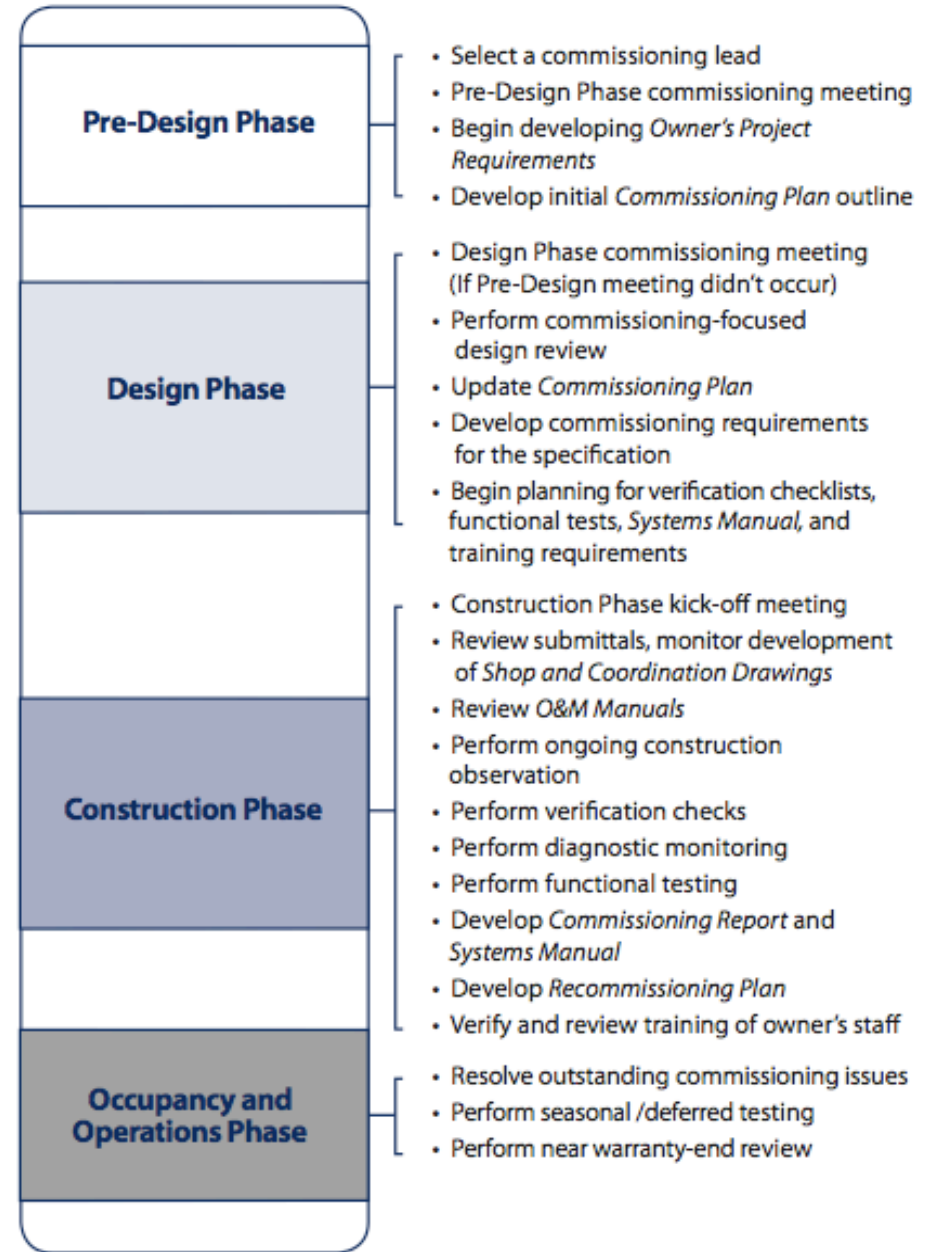
INFLUENCE VS. EXPENDITURES



The ability to control cost on a project diminishes as the project moves from design through construction. Changes should be made as early as possible during the process. Changes made during the design phase are easier to implement than during the construction phase. This concept is summarized by these curves.

Commissioning Process Overview

Commissioning Process Overview



Source: Haasl, T., and K. Heinemeier. 2006. "California Commissioning Guide: New Buildings" and "California Commissioning Guide: Existing Buildings". California Commissioning Collaborative.

Commissioning Authority (CxA)

- A person (or firm) responsible for executing commissioning services
 - Leads the Commissioning effort
 - Extension of owner resources
 - Verifying achievement of the Users Requirement Specifications is primary role
- Potential Providers
 - Independent third-party
 - A/E firm
 - General contractor
 - Key sub-contractor
 - Owner's in-house personnel



Commissioning Team

- A body of subject matter experts who, through coordinated actions, are responsible for carrying out the Commissioning Process.
- Typical members
 - Owner
 - CxA-Commissioning Authority
 - Design Team
 - General Contractor
 - Key Sub-Contractors
 - Specialty Consultants



User Requirements Specifications (URS)

- Design Intent Document
 - Document written by Owner and Cx Authority
 - Details Owner's expectations and goals for how the building will operate
 - Basis of Commissioning effort
 - Living document!
- Typically includes:
 - Project goals
 - Performance criteria
 - Equipment and system preferences
 - Cost considerations
 - Benchmarks
 - Measures for success
 - Basis of Commissioning effort
 - Living document!

Functional Design Specifications

- Produced by the design team
- Design team response to the URS
- Documents concepts, calculations, and equipment selection
- Technical document-plans, drawings, schematics



Commissioning Plan

- Prepared by CxA
- Detailed planning document
- Organization of the Cx Team
- Assigns member responsibilities
- Schedule of Cx events
- Allocation of Cx resources
- Defines Cx documentation
- Living document!



Commissioning Specifications

- Design team responsibility
- Developed in collaboration with CxA
- Reviewed and approved by CxA
- Part of the contract documents
- Defines the Cx Team responsibilities
- Defines Cx support activities



Clearly define owner training requirements!

Establish Cx Scope

- Systems to be Commissioned
 - Building Envelope
 - Primary Engineering Controls
 - HVAC and Controls
 - Lighting Systems
 - Electrical Systems
 - Life Safety
 - Security
 - Domestic Water Heating
 - Other Plumbing Systems
 - Other Specialty Systems



Commissioning Issues Log

- Date Discovered
- Issue
- Plan of Action
- Responsible Party
- Date Resolved
- Not a punch list!
- Change control will be critical to manage!



Pre-Functional Checklists

- Specific to each piece of equipment
- Do we have all the right components?
- Is it installed correctly?
- Is it ready for functional performance testing?



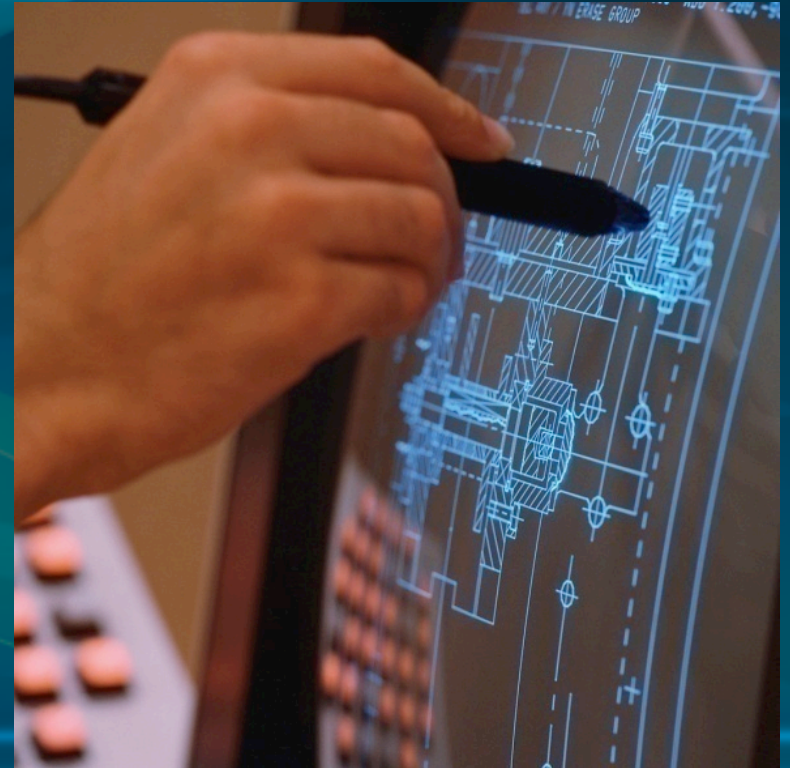
Functional Performance Testing

- Specific to each system
- Evaluates system integration
- Is it working properly under normal and design conditions?
- Is it working properly under emergency conditions?
- Is it working efficiently?
- Seasonal testing



Operator Training

- New equipment/new processes/procedures
- Involvement throughout construction process
- Pre-Test
- Classroom Training
- “Hands-On” Training
- Post-Test



Commissioning Report

- User Requirement Specification
- Functional Design Specification
- Cx Plan
- Pre-Functional Inspections
- Installer Test Results
- Functional Performance Test Results
- Operator Training Test Results
- Open Issues

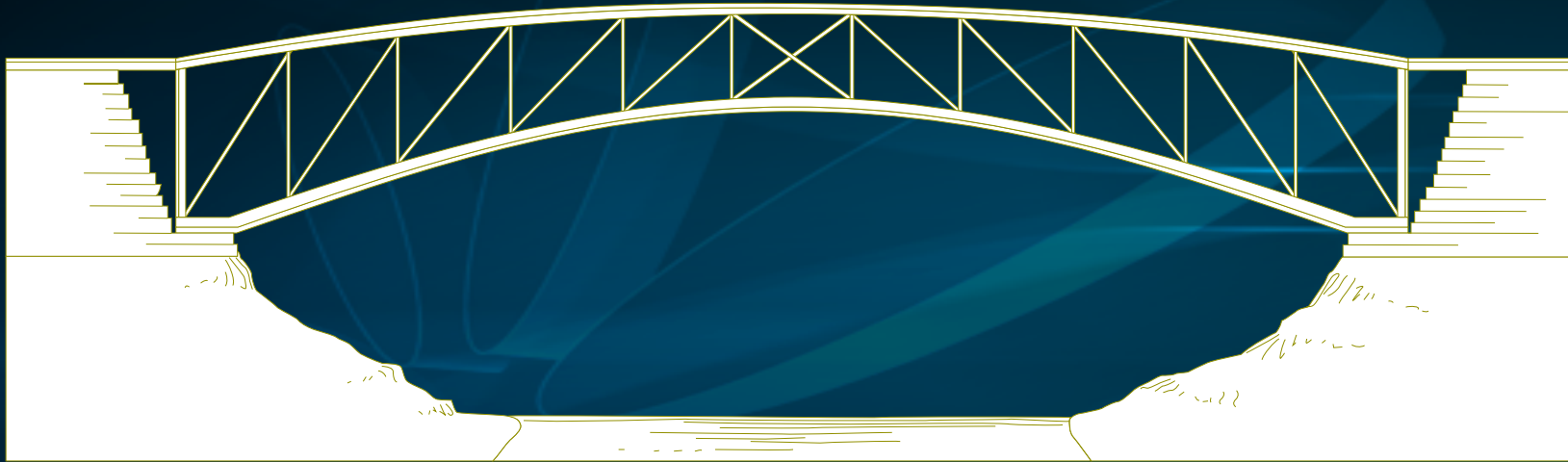


Remember the Patient

- Even though you may not see the patient, always remember that real people, the patients, receive radionuclides made at your pharmacy.
- Patients who receive CSPs are mothers and fathers, brothers and sisters. They are loved ones who need to receive our best efforts.



Thank you



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