Overview

- In our business, success is achieved by taking on difficult, sometimes seemingly impossible tasks, and accomplishing them on-time, on-budget, and meeting all functional requirements. To do this requires a plan and the discipline to follow that plan.

- There are numerous approaches to project management, some more effective than others. Most focus on the Engineering & Design side of the project, ignoring, to some degree, the importance of the start up and commissioning aspects.

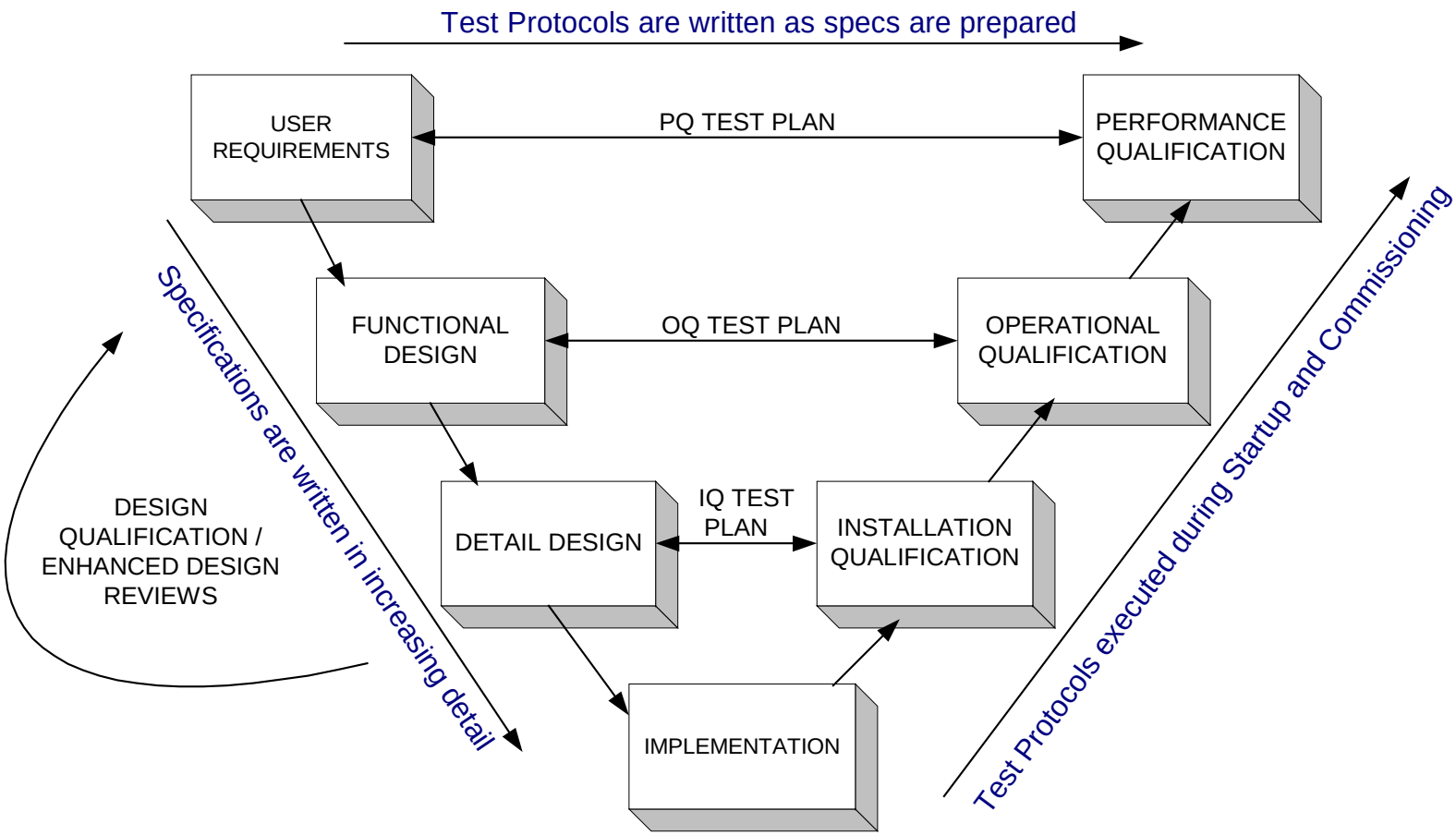
- Process-Logic has standardized their project design, execution, and commissioning services on the use of the Lifecycle Development “V” Model. This presentation provides a brief introduction to the V-model and it’s benefits.

What is the Lifecycle Development Model ?

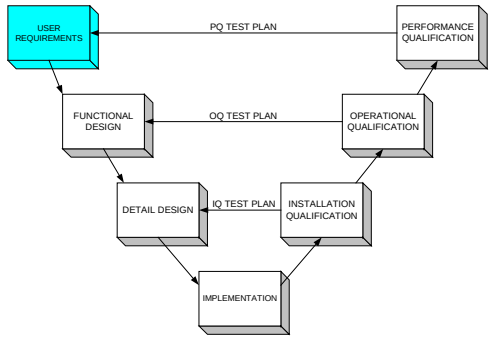
- The Lifecycle Development “V” Model or “V-model” for short, is a framework or structure for undertaking the design, execution, and commissioning of a design project.
- It was first promoted by the International Society of Pharmaceutical Engineers (ISPE) back in 1994 in the first edition of their Good Automated Manufacturing Practices guideline, (gAMP).
- It is called the V-model because of it’s characteristic “V” shape. The left-hand edge of the V is where the project is defined and specified in greater and greater detail. The bottom point of the V is the execution step of the project. The right-hand edge of the V is where the commissioning and qualification testing of the installed system is performed.
- The V-model provides a logical sequence that helps to organize the complex activities of defining a project scope, executing it, and qualifying it.
- The V-model creates a solid basis for testing the functionality of the system against the original design specs and proving that it does what it is supposed to do.

This makes it IDEAL for creating validated systems.

The Lifecycle Development Model



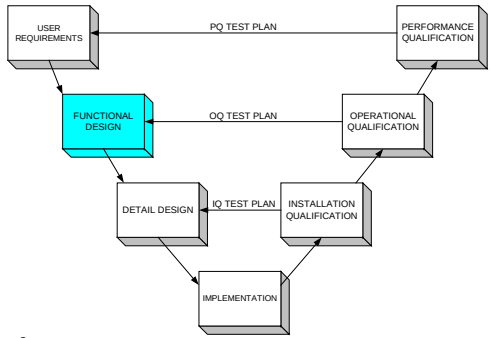
User Requirements Specification (URS / FRS)



- Meant to be a very high level view of the overall project drivers, in terms of the over-arching project objectives and the underlying business case.
- Should be phrased in strategic business terms.
- Should talk about total installed cost targets, resultant net capacity, it should discuss unit costs, cycle time, locations, raw materials, labor content.
- Should address all the critical issues that will ultimately influence whether or not the project is deemed a success or not.
- Functional Requirements Spec is a subsection of the URS is reserved for the required functionality of the system.
- The FRS is also written from a very high level perspective, dealing more with overall capabilities rather than getting into specifics of how the system is to be operated.
- The URS/FRS should not contain specific design stipulations unless the client has already invested time money and/or resources toward achieving a very specific objective.

Process Logic

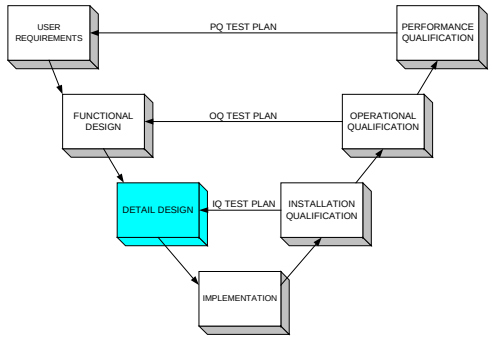
Functional Design Specification (FDS)



- Prepared by a Vendor or Supplier in response to the URS.
- Should address all the elements of the URS, providing sufficient detail to indicate how vendor is planning on meeting all the user requirements.
- There are two flavors of FDS documents: One in which the project is being bid out competitively, and the other where the work has already been awarded or is being sole-sourced.
- The FDS provides a deeper layer of detail, so, in the first case, the FDS provides the client with the basis for comparing and evaluating the technical merit and cost parameters of the proposed solution.
- In the second case, the FDS is intended to begin engaging the client in design details and decisions that will influence the final product.
- All major functionality aspects should be documented and agreed upon at the completion of the FDS.
- The completed, approved FDS will form the basis for design change control management. As functions and features are added or subtracted from the design scope, the URS / FRS and the FDS should be updated and re-issued to all involved members of the project team for impact analysis and possible re-costing of the job.

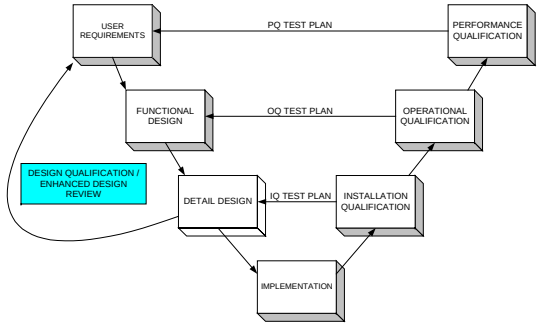
Process Logic

Detailed Design Specification (DDS)



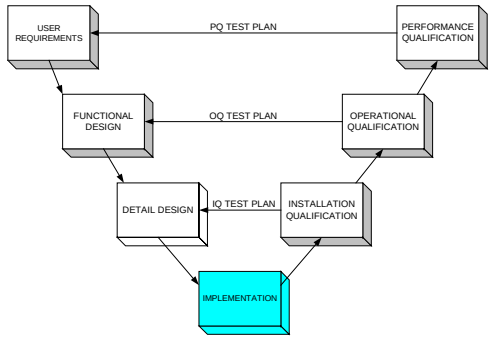
- Detailed Design Specs encompass all design documents produced by the Vendor or Supplier of services.
- DDS may be a single document or it may be the entire body of detailed design deliverables that are generated during the course of the design phase.
- At the time when the Detailed Design Specs are being prepared, the scope of work should be very clear and the detailed design is generated to fulfill and implement the features that were described in the Functional Design Spec.

Design Qualification (DQ)



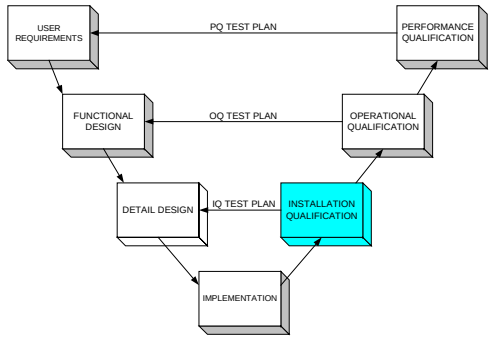
- The purpose of Design Qualification is to keep track of any changes that have occurred in the Design Specifications throughout the period of time that active design work has been going on.
- Specific items added to or deleted from the scope of the project must be picked up and carried backward through the appropriate design specs and requirements documents, as well as the appropriate qualification protocols.
- A traceablity matrix is used for keeping track of all the design elements. It is appropriate to have at least one or more enhanced design reviews in which the traceability matrix is reviewed, along with drawings and/or other design documents, so that all involved parties are fully apprised of the status of the design.
- Other issues that should be addressed during the Enhanced Design Reviews include Constructability issues, Process Safety Management issues (PHA, HAZOP, FMEA, etc), Construction Safety Issues, Construction Coordination, Shutdown Management, and Commissioning Planning and Execution Strategy.

Implementation Phase



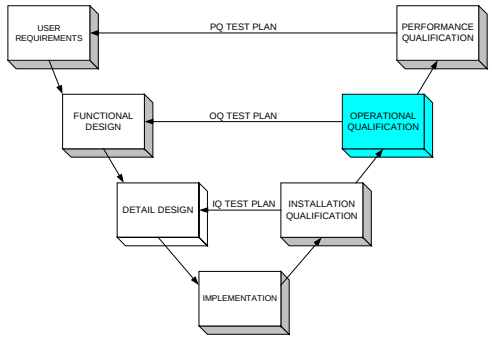
- This is the phase of the project during which the actual physical work is performed.
- Construction of the equipment occurs during this phase, as does the programming of the software.
- Note that the Implementation Phase is the “turning point” of the V-model. At this point, all the tasks turn from specification of what is supposed to happen to verification of what actually happens.
- Very critical that any RFI and As-built information is recorded and worked back into the detailed design documents!

Installation Qualification (IQ)



- This is the first of the qualification protocols that is executed during the start-up and commissioning phase of a project.
- The IQ ascertains and documents that the equipment that was ultimately installed is truly what was described by the design documents.
- It is often described as a “hands in the pocket” activity, in that no equipment is actually operated during IQ.
- Part numbers are verified off the original design drawings, parts lists, bills of materials, and the like.
- P&ID’s are walked down in the field insuring that all piping runs match up with what is shown on the drawings.
- Note that the IQ protocol is directly across from the Detailed Design Spec, with an arrow between the two. This is meant to imply that the IQ Protocol is written directly from the Detailed Design Spec.
- Every element of the Detailed Design Spec should be listed and checked by the IQ.

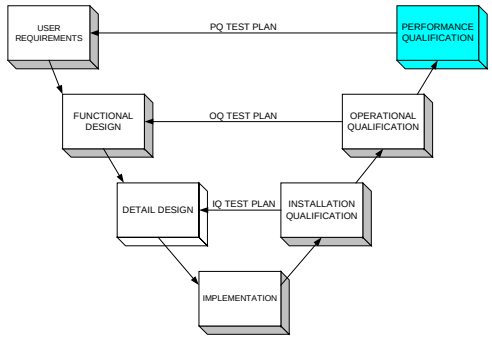
Operation Qualification (OQ)



- The OQ is the second qualification protocol that is executed in the start-up and commissioning phase of a project.
- During OQ, the equipment is operated to demonstrate that the performance parameters of the various pieces of equipment conform to the design parameters that were originally specified.
- Things like temperature, flow, and pressure ranges are checked and verified.
- Accuracy and precision of these parameters and conformance to requirements are verified and documented. This can involve water batches, pilot runs, and not-for-production runs.
- Note that the OQ protocol is directly across from the Functional Design Spec, with an arrow between the two. This is meant to imply that the OQ Protocol is written directly from the Functional Design Spec. Every element of the Functional Design Spec should be listed and checked by the OQ.

Process Logic

Performance Qualification (PQ)



- The PQ is where the final functionality of the equipment is truly verified, in that product is actually made under production conditions, and the quality of the product is compared to the product specs.

- Generally, three consecutive batches are made as part of a Qualification run. All three batches must be within product specs in order for the Qualification to pass.

- Note that the PQ protocol is directly across from the User Requirements Doc, with an arrow between the two. This is meant to imply that the PQ Protocol is written directly from the User Requirements Doc. Every element of the User Requirements Doc should be listed and checked by the PQ.

What's it good for ?

- The original mission of the V-model was to impart a high degree of quality assurance in the development efforts for the design of automated systems and the creation of the associated software programming.
- In the pharmaceutical industry, much of the automation and programming work was, and continues to be contracted out. ISPE saw a need to provide some degree of standardization in the approach to contracting.
- The primary goal of the guideline was to establish the roles and responsibilities of the involved parties, and to create strong links between the project specifications and the acceptance testing done at the end of the project.
- The basic elements and techniques of the V-model apply to virtually all engineering projects, not just automation and software!

How do I use it ?

- The V model is a process or a path to follow.
- Following the path means making sure that all the required specifications are created in the right time frame, in the right sequence, and approved by the right parties.
- Following the path means that good design qualification practices are followed during the detailed design phase.
- Following the path means making sure that all the commissioning and qualification protocols are prepared in concert with the design specs and executed in the right order.
- Following the path means that all deviations and discrepancies that are noted during commissioning phase are recorded, investigated and closed out.

What are the Benefits?

- The V model creates a tight linkage between the design specifications and the subsequent test protocols and methods used during start up.
- Using the v-model virtually assures that the project, as installed, will fulfill the objectives that were intended for it.
- By using the v-model, the project design is documented thoroughly and fully capable of being validated.
- Lastly, the V model provides an excellent basis for design control and tracking design changes through the proceeding of the project.

What are the Detriments?

- Using the V model involves the creation and updating of a lot of documentation. This may seem cumbersome to those who like to “wing it” when it comes to rigorous discipline.

Who uses it ?

- Bulk Pharmaceutical and API Manufacturers,
- Final Dosage Form Pharmaceutical manufacturers,
- Medical Device Manufacturers,
- Bio-Technology Companies,
- Cosmetics Manufacturers,
- Food and Beverage Manufacturers

Any company that is regulated by FDA cGMPs will strive to use it!

Where can I get more information ?

- The ISPE Good Automated Manufacturing Practices guideline is now in it's 4th edition, (gAMP4). It is can be purchased online at www.ispe.org.