# Defining the Needs - The Essential Element of Good Engineering Practice

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**Abstract**

*Proper definition of the needs is the key element in project development. This article will discuss an approach in the context of good engineering practice. Also a parallel is made between project activities and validation.*

## INTRODUCTION

The chemical and petrochemical industry has since long learned that a good definition of requirements is essential for the success of a project, this because of the complexity, high degree of automation and criticality of the processes involved. The definition of requirements has therefore become a key element in the life cycle of a project and is the result of combined efforts between end-users and engineering support groups. The processes in the pharmaceutical industry on the contrary consist generally of an assembly of smaller scale and specific stand-alone equipment, frequently supplied by specialist manufacturers. The specifications for such equipment are frequently defined directly by the end-user or support scientist, often without any need for further engineering. As a result, engineering work in the pharmaceutical industry is usually concentrated on the facilities, environmental, utilities and installation aspects. Furthermore, although the trend is changing, automation is still often being considered as an add-on and compared to instrumentation rather than as an integrated part of the process. Typically this leads to incomplete or conflicting specifications.

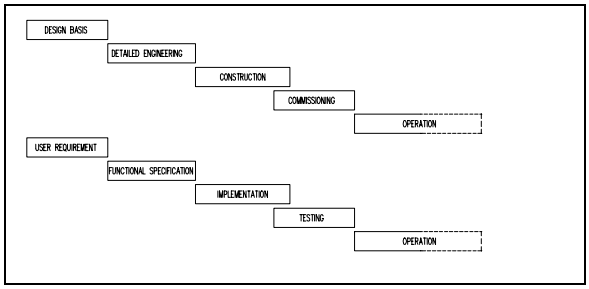
Frequently equipment is purchased, contracts signed, services rendered or complete installations built while the basic requirements have not well been defined. These situations lead to unnecessary disputes, rework, cost and schedule overruns and frustration with all parties involved. Some examples where things may go wrong are:-

- Technical specifications without user requirements;
- Specifications written by users but without technical requirement;
- Specifications without performance or validation requirements;
- Specifications for equipment in an automated environment without defining the overall system integration.

## GOOD ENGINEERING PRACTICE

Good engineering practice means the application of common sense, professional knowledge and a structured approach to any project, large or small in a consistent way. Several companies have established standard procedures or check-lists to ensure that the technical aspects of a project are properly addressed. These address the engineering methodologies and basic definitions rather than the technical details which are covered by engineering standards.

A project usually is preceded by a feasibility or scoping study during which an evaluation is made from an economic point of view. It is normally carried out as part of marketing evaluations and investment plans. The project itself is carried out in major phases as shown in Figure 1. The equivalence with a computer related system is also shown.
During the Definition phase the scope of the project is defined within the economical and performance or capacity limits set forward by the Feasibility.




The Definition will work out the basic needs,

confirm the economics and define the design criteria to satisfy these needs. The result of this phase is summarized in a Design Basis or User Requirement Specification. The final budget is usually confirmed at this stage. It may be considered as the most important phase given it forms the basis and reference for all further work.

Projects for the pharmaceutical industry are subject to validation. Today we are being overwhelmed with guidelines, requirements and speculations on what is needed. When considering the actual needs, it is seen that these are perfectly in line with good engineering practice by which a proper development or life cycle is followed. In applying good engineering practice, the requirements are properly defined, all engineering documents are prepared and the installations are professionally installed, tested and commissioned. Wheeler[1] has already recognized commissioning as a vital part to validation. There is indeed a parallel between the formal validation stages and a project following good engineering practice. The final review of the design can be considered as Design Qualification (DQ), the Factory Acceptance Tests (FAT) as Equipment Qualification, the On-Site Acceptance Testing (OSAT) as Installation Qualification (IQ) and commissioning as Operational Qualification (OQ). Given all documentation required for validation is generated during the project development, the validation can be regarded as a part of the engineering efforts in a project. The validation efforts are thus not duplicated and considerable cost savings can be made.

## DEFINING THE NEEDS

Now that more complex equipment is being used and integrated processes and facilities are involved, a complete and unambiguous definition of requirements is needed to form the basis for all further ongoing work. It has to describe the needs of the end-user in the context of the development, implementation and ongoing operation.

Before the period when companies scaled down their staff, project development work was mainly handled within the organization itself, whereas today all work not directly related to the core activity of the business is being contracted outside. Therefore, the definition of requirements could earlier be limited to the technical specification of the equipment because its use or application was well understood by the internal staff. However, now that the project development work is delegated to external organizations or contractors, the definition of requirements must not anymore be limited to mere technical specifications but must contain all information allowing the developer or supplier to fully understand the intent of the needs in the context of the development, implementation and operation. This becomes especially important when dealing with computer integrated process equipment or automated manufacturing systems.

In Information Technology circles, the User Requirement Specification (URS) is used to define the needs. GAMP[2] defines the URS as "*A description of what the equipment or system is supposed to do, and as such is normally written by the pharmaceutical manufacturer. This links to Performance Qualification which tests these User Requirements"*. It says further, "*It defines the functions to be carried out, the data on which the system will operate, and the operating environment. The URS defines also any non functional requirements, constraints such as time and costs, and what deliverables are to be supplied. The emphasis should be on the required functions and not the method of implementing those functions."* In other words, the requirement specification defines what the user wants the system or equipment to do, not how it works.

Once a requirement specification has been issued, it will be worked out by the supplier, developer or contractor as part of the project cycle and "translated" into a functional specification. This will contain all technical and functional details allowing the detailed design of the system or equipment. Both the requirement and functional specifications are complementary and will be used to verify mutual understanding of the needs between all parties involved. Often, technical or functional alternatives are proposed during the development of the functional specification as a result better understanding. In such cases the requirement specification must be revised through an eventual scope change to ensure the project objectives and to keep consistency between both specifications.

## THE REQUIREMENT SPECIFICATION

The requirement specification must not describe the technical details of a particular equipment or system. It must define the needs in terms of criteria rather than in specific technicalities. Often

specifications are repeats of a vendor catalogue or specification sheet. In such case there is insufficient freedom for the supplier or developer to provide his best solution. Unless a specific piece of equipment is required, such approach is discouraged. A better way is to describe clearly the basic requirements in terms of needs and functionality in addition to the technical design criteria relevant to construction, installation, testing and validation. It is also important to link contractual and commercial terms to the specifications such that a single reference document can be used.

Requirement specifications related to devices, equipment or systems in an automated environment must also contain the description of their place and use within this environment. Given automation is an all encompassing function, it cannot be considered as an independent entity. It is therefore necessary that such specifications or user requirements be handled from an engineering point of view.

In a requirement specification, the auxiliary verbs *shall*, *should*, *may* and *will* are to be used as follows:-

- *Shall* is used to express a binding requirement
- *Should* and *may* are used only to express non-mandatory provisions
- *Will* is used only to express a declaration of intend

Generalized expressions such as "sufficient", "reasonable" must be avoided. Specific and well defined metrics must be used to define performance related requirements. These metrics can then later be used as the basis for performance testing.

It is recommended that the requirement specification is formatted in numbered paragraphs, each written as a requirement statement addressing a specific issue. This will allow the supplier or developer better to refer to the needs when responding to the specification. It is furthermore recommended to identify each paragraph for being Critical, Essential or Non-Essential.

Typically the following sections should be included:-

**Scope** - This section will describe the intend of the requirement, identify the different parties involved and set the context for the needs. Specific points that are excluded from the needs will be identified in this section also.

**Process and Facilities Description** - This section will describe the process and facilities from a process standpoint. It is a good habit to include at this point the history or background of the project and a discussion on alternate solutions that have been considered.

**Operational Requirements** - This section will describe the functional requirements from an operational point of view. This includes how the system or equipment will be used, the organization in which the operations take place and the various support aspects that are required. It will include the requirements for operator interfaces and workstations including their layout and location within the facility. This section will also define the integrating needs with external equipment in terms of functionality and eventual integration with other computing systems.

**Data Requirements** - This section is specifically needed for computer related systems. It describes the type, volume, format and use of the data relevant to the system or equipment.

**System Requirements** - This section describes the technical requirements for the system or equipment. This would be the design criteria rather than a summary of technical specifications. For computer related systems, it would describe here the requirements for hardware and software. Unless specific needs are required, there should be sufficient freedom to allow alternatives to be proposed. Specific attention must be paid to security, safety and overall integrity. This would include the issues on reliability and fault tolerance. This section addresses also the documentation and documentation language, training and support issues.

**Installation Requirements** - This section defines the requirements for installation, packaging, maintainability and all other aspects dealing with the installation. Emphasis must be made area classification, compliance with local rules and regulations and to specific industry requirements such as GMP.

**Implementation Phasing** - For projects that will be implemented in different phases, this section will contain the details of the phasing in terms of organization and timing. If contractual terms are considered, the relevant milestones will be identified and clearly specified here.

**Life Cycle and Validation** - This section will address the issues on the development life cycle and validation for the systems or equipment. Although these issues may be commonly known, it is important to formally repeat them here to ensure a full understanding of the needs. The outline of the Validation Master Plan will also be included in this section.

**Glossary** - This section has to contain all abbreviations, acronyms and technical terms used in the requirement specification.

## CONCLUSIONS

It has been shown that proper definition of the needs is essential for the success on any project and is part of good engineering practice. The definition must contain all elements allowing further engineering and project development to succeed including the background information of the project, operating principles, alternate solution evaluation, technical design and equipment selection criteria and testing and validation requirements. The overall responsibility for the definition of basic needs lies with the end-user, but preparation, release and follow-up is to be considered as part of the engineering work.

[1] *Wesley P. Wheeler, Commissioning: A Vital Precursor to Validation, Pharmaceutical Engineering, Volume 14, Number 4, July/August 1994, pp 48-56.*

[2] *GAMP, Good Automated Manufacturing Practice, Supplier Guide for Validation of Automated Systems in the Pharmaceutical Industry, UK Pharmaceutical Industry Computer Systems Validation Forum, Second Draft, January 1995.*

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