URS – User Requirements Specification
FDS – Functional Design Specification

URS and FDS in Project Work

Engineering, Manufacturing, Delivery/Installation, Commissioning, Test Runs/Start-up, Process Optimisation, Production

Basic RA, Detail RA

URS, DQ/FDS, FAT, IQ/SAT, OQ, PQ, PV/CV, Re-Val.

Change Control / Requalification
Specifications

Appropriate Specifications - Key Factors for successful Engineering Projects

• Specifications should provide clear definition, communication and understanding of project scope, objectives and requirements!

• Various specification steps are developed during the lifetime of a project. Details are depending on project type (size, complexity, ...)

• Specification usually undergo various iteration steps

• Names and scope of “specifications” vary within different companies and organisations
**URS and FDS - General Issues**

**Definitions**

**URS = User Requirement Specification**  
**FRS = Functional Requirement Specification**  
Definition of requirements to fulfil the demands of the process (from the Users's point of view)  
Issued by: User

**FDS = Functional Design Specification**  
**FS = Functional Specification**  
Specification in which the demands of the manufacturer are transferred into a technical solution (from the Manufacturer’s point of view)  
Issued by: Manufacturer

**Contract Specification (CS): FDS/FS approved by User + Supplier**

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**User Requirements Specification – a new requirement in EU-GMP Annex 15**

*User requirements specification (URS)*  
3.2 The specification for new facilities, systems or equipment should be defined in a URS and/or a functional specification. The essential elements of quality need to be built in at this stage and any GMP risks mitigated to an acceptable level. The URS should be a point of reference throughout the validation life cycle.

- no further definition in the glossary

In general:
- prepared by the user → Production / QC unit
- less technical than an FDS, technical specification, functional requirements specification
- it is assumed that the URS includes all functional and critical requirements, i.e. includes GMP-requirements
**URS: General considerations**

- URS is defined by the „User“ of the equipment / process (e.g. production engineer, operators, ...)
- Other functions such as (maintenance, validation, QA, safety, product development, ...) shall participate in developing the URS
- URS shall include a general description of the process- / product requirements
- Definition of specific technologies and technical details are included only if important for the production process
- Requirements for the URS shall be result of a Basic Risk Analysis

**URS and FDS - General Issues**

**URS: What needs to be included?**

- Process description, operational restrictions, product quality requirements and general GMP-requirements
- Capacity data (output, consumption figures, etc)
- Range and tolerances of process parameter (temperatures, pressures, flows, etc)
- Material and surface requirements
- Interfaces (Mechanical, Electrical, Signal)
- Controls and automation concept, staffing
- Safety requirements and environmental conditions
- Cleanability, sterilisation requirements (CIP/SIP)
- Documentation, acceptance test criteria, qualification requirements
- Applicable codes, standards and guidelines
- ....
User Requirement Specification – a new requirement!

Start with drafting a URS ... it will be refined later

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Critical = GMP-/CPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Temperature</td>
<td></td>
</tr>
<tr>
<td>2.1 The temperature of the product must be maintained between 30 and 50°C</td>
<td></td>
</tr>
<tr>
<td>2.2 Temperature sensors are required to monitor the temperature</td>
<td></td>
</tr>
<tr>
<td>2.3 Temperature should be recorded</td>
<td></td>
</tr>
<tr>
<td>3. Transfer of product</td>
<td></td>
</tr>
<tr>
<td>3.1 Transfer must be done via pump</td>
<td></td>
</tr>
<tr>
<td>3.2 Transfer of 100 L must be performed within 30 min in order to ensure efficient production</td>
<td></td>
</tr>
</tbody>
</table>

URS is sent to equipment vendors / suppliers / manufacturers

Equipment suppliers “respond” to the URS with their FDA

FDS: General Considerations

- FDS is defined by the manufacturer of the equipment
- more technical details are contained than in the URS
- something you did not want may be included!
- something you really want to have, but you did not think it is existing may be in the FDS
- FDS is based on the specific capabilities of the manufacturer (manufacturing program, know how, etc ...)
- All requirements of the URS need to be covered by the FDS.
- A jointly approved FDS is part of the contract between user and manufacturer (Contract Specification)
How to find out, if the vendor will deliver what you wanted?

Compare URS with FDS

URS

FDS

DQ

Some practical hints for URS / RA and DQ

URS, FDS and Contract Specification are linked with each other (example for standard equipment)

When more than one (potential) supplier is involved: more than 1 DQ may be required
Who is the “User” and who is the “Manufacturer”?

The roles may vary! They depend on the project type!

<table>
<thead>
<tr>
<th>User</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production</td>
<td>Component Manufacturer</td>
</tr>
<tr>
<td>Engineering Department</td>
<td></td>
</tr>
<tr>
<td>Engineering Company</td>
<td></td>
</tr>
<tr>
<td>System Integrator</td>
<td></td>
</tr>
<tr>
<td>System Manufacturer</td>
<td></td>
</tr>
</tbody>
</table>

URS and FDS are integral part of the purchasing process

1. User staff defines in URS the general requirements. The URS is based on a general design philosophy which should be looked at in a basic risk analysis
2. User sends URS as part of inquiry documentation to several qualified vendors
3. Manufacturer compare URS with their capabilities and suggest technical solution / FDS in a proposal
4. User and selected manufacturers compare demands and proposed solution. Re-check against URS and DQ requirements
5. User agrees with a chosen manufacturer upon a technical solution that suits the demands of his process (FDS/CS)
From Process Idea to Final Design Specification:

<table>
<thead>
<tr>
<th>Status</th>
<th>Issued by (e.g.)</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process-Idea</td>
<td>R + D</td>
<td>Basic Requirem.</td>
</tr>
<tr>
<td>General Requirements</td>
<td>Production (User)</td>
<td>URS</td>
</tr>
<tr>
<td>Extended Requirements</td>
<td>Technical Dep. / Engineering</td>
<td>FRS</td>
</tr>
<tr>
<td>Technical Solution</td>
<td>Manufacturer</td>
<td>FDS I</td>
</tr>
<tr>
<td>Agreed Technical Solution</td>
<td>User/Techn. / Manufacturer</td>
<td>CS</td>
</tr>
<tr>
<td>Final Design Specification</td>
<td>User/Techn. / Manufacturer</td>
<td>FDS II *)</td>
</tr>
</tbody>
</table>

*) in case of development projects

Special situation in development projects

- Final technical solution is not available at the time when user gives an order to the manufacturer
- Approved FDS that exists as preliminary version is going to be detailed during the project execution phase
- Users and manufacturers technical/validation staff jointly supervise the development process (change control, repeat DQ when necessary)
- The development during execution of the project is checked in design reviews. Reviews have the character of milestones (e.g. PID Review, Layout Review, etc ...)
- The final and approved FDS is issued when the design phase is completed
Common problems in URS and FDS

1. URS does not include all relevant information to fulfil product, process and GMP requirements

2. Specified parameters and features in the URS are not clear and are likely to be misunderstood

3. The FDS does not meet the requirements of the URS

   • Consequences
   • Manufacturer supplies a technical solution that does not comply with the intended purpose meant by the User
   • Equipment does not fit requirements and does not work at all
   • Equipment works, but contains risk for product, process, safety
   • High costs for changes at a late state occur
Common problems in URS and FDS

4. The requirements in the URS are higher than necessary, demands are not realistic or more details are specified than necessary

Consequences
• The Manufacturer has limited freedom for choosing proper solution
• Difficulties to find Manufacturers for the equipment
• Prices for the equipment are unnecessarily high
• The technical solutions might be complicated and may contain unnecessary potential risks of failure

Common problems in URS and FDS

5. URS and FDS do not consider the requirements for later testing such as FAT, SAT, IQ, OQ, PQ

Consequences
• Tests can not be performed - fulfilment of acceptance criteria can not be verified
• No documented proof of the quality is available
• No GMP compliance of the equipment
• Unexpected additional costs and time delay
Common problems in URS and FDS

Mistakes in URS and FDS can be avoided by:

- Execute Risk Analysis before finalizing the URS to identify and fix all relevant issues
- Evaluate the impact on other systems in the project (definition of interfaces/battery limits)
- Cross check of URS against FDS in Design Qualification
- Have Change Control implemented in the project work
- Open communication between Manufacturer and User with frequent review of the design to avoid misunderstandings
- Careful review of URS and FDS before approval by all involved experts

URS/FDS – Practice - simulation
Common problems in URS and FDS

what the sales man sold  what was assumed to be required  what has been designed

how it was installed  how it was put in operation  and what the customer wanted!!!

Summary

Equipment that is reliable and suiting the demands of production process and final product is:

- a result of carefully specified requirements in URS and FDS that consider the principles of GMP
- based on a common understanding of demands and capabilities on both sides (User and Manufacturer)
- designed to be able to pass the required tests during manufacturing, acceptance testing and qualification phases

URS + FDS = Basis for safe products and reliable processes!
An important thing to keep in mind:

It is a GMP requirement that manufacturer’s control the critical aspects of their particular operations through qualification and validation over the life cycle of the product and process.

Critical Aspects = relevant Aspects:
• CQAs = Critical Quality Attributes
• CPPs = Critical Process Parameters

When you identified as aspect as relevant, keep it in your documents from the beginning on – don’t lose it!

„Der rote Faden“ (the red thread) – the central themes – permanent and traceable throughout the life-cycle

Group work – Team Work Task

Prepare a URS for a backpack, in which you want to carry your computer

• describe the requirements precisely
• use one line per requirement

some words that may help:
• compartment
• velcro
• shoulder strap
• padding
• lining
• zipper
• dimension
• weight
• color
• top grab handle
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