Serialization projects in the pharmaceutical industry are complex and labor-intensive undertakings. Interdisciplinary project teams compile company specific URS.

What makes a good user requirement specification (URS)

The user requirement specification is the essential starting point for every serialization project. The requirements must be described clearly, unambiguously and comprehensively. Stefan Öing, head of track & trace software at Atlantic Zeiser, has produced some useful tips for users.

Serialization projects in the pharmaceutical industry are complex and labor-intensive undertakings. With the benefit of hindsight, projects could be implemented much more quickly and efficiently in many cases if the specific requirements were precisely defined in advance. The URS plays a critical and imperative role throughout the entire implementation process.

A number of different divisions should be involved in drawing up the URS. These are at least the following:

- Packaging division (production), mainly for Level 1 and Level 2 solutions
- IT division, mainly for Level 3 and Level 4 solutions
- Logistics division, mostly for Level 4 solutions
- Qualification and validation division / quality assurance
- Procurement / purchasing division

The URS is also to be signed by management, which may wish strategic considerations to be taken into account that will require subsequent review by all involved experts.

Before an URS is adopted, different subsidiary specifications are often written and circulated that serve as the basis for the URS and need to be gradually amalgamated:

- URS for initial pilot projects (usually Level 1 and Level 2)
- URS for packaging division (usually Level 1 and Level 2, up to Level 3)
- URS for serialization management in software / IT division (usually Level 3 and Level 4)
- URS for handling serialization throughout the supply chain (usually Level 4). This aspect must be dealt with by the logistics department and frequently poses different IT requirements to those for internal processes.

In every case the URS must summarize all the requirements that are mandatory for the complete serialization system and will be explicitly tested by the customer.

Once a supplier has been selected, it is advantageous for both sides to reflect the URS in the "design qualification" (DQ) documents entitled "requirements specification" (RS) and "functional specification" (FS). These documents should be written by the system supplier and undergo acceptance in consultation with the customer prior to the implementation and deployment phases of the project. The URS is the

starting point for RS and FS, but ultimately RS and FS will become the binding documents for the project. By adopting this procedure, potential inconsistencies in the URS can be clarified in a precise description of the delivery scope before project implementation. The design specification (DS) of the product that is to be delivered forms the basis of both the RS and the FS.

How is an URS structured in practice? The following example focuses on software aspects, which are not only the main drivers of serialization projects, but also shape the processes and workflows that have to be accommodated by the hardware. The principal chapters of an URS are typically the following:

1. General requirements
   a. Adaptations and extensions
   b. Release and life-cycle management
   c. HMI/GUI and interfaces in general
   d. Conformity to several standards, e.g. EG-GMP, 21CFR Part 11
   e. Automatic plausibility checks
   f. Communication interfaces to neighboring software levels
   g. IT environment, etc.
2. Documentation
   a. User manual
   b. Service manual / IT manual
   c. Administration manual
   d. Training documentation
   e. Full set of CSV documentation, etc.
3. User management (with subitems)
4. Flexible production and alarm reports (with subitems)
5. Audit module / audit trails (with subitems)
6. Product, workflow and recipe management (with subitems)
7. System operating modes
   a. Production mode
   b. Query mode, etc.
8. Error handling (with subitems)

From a different perspective, the URS must define the required system properties clearly. Each requirement should be checked against the following criteria:

1. Verifiable
2. Clear and concise
3. Complete
4. Consistent
5. Traceable
6. Viable
7. Necessary
8. No precise, technical implementation details

Note that requirements may not initially be fully defined, but will be developed during subsequent phases of the project. The initial URS should recognize this and be updated as information becomes available. The URS should not contain implementation details at this stage.

Furthermore, the individual requirements described in the URS should be prioritized, with the strongest emphasis being placed on the mandatory requirements. A simple classification structure is as follows:

- Mandatory (high)
- Beneficial (medium)
- Nice to have (low)

None of these characteristics and examples focuses on the bits and bytes of technology for the software solution. This is a requirement specification for computerized support of the user's work process, not a technical specification for the computer technology itself. Formulation of the URS should be driven by the users, rather than by IT experts. Only experienced users involved in the work process know how the process really operates and what is actually done with the data.

A good URS must enable users subsequently to test whether the delivered system matches their needs, as described. If the requester is unable to devise a work-based test for what is wanted, then the request is more a wish than a requirement. A column in the URS for user test topics is essential in order to ensure that only genuine requirements and no wishes find their way into the URS.

A white paper has been produced containing a list of essential requirements for a URS for serialization software solutions (available on request, please contact info@atlanticzeiser.com).

Some simple examples to avoid in an URS

- "The system must be user friendly."
  – Cannot be measured or verified.
- "All screens must appear on the monitor quickly."
  – Not clear and concise.
- "When the power supply is lost, the battery backup must support normal operations."
  – Details of the desired duration would be advisable.
- "As soon as a batch-order is completed, a corresponding production report and a deviation report must be generated."
  – This is not traceable in case the deviation report will be skipped later.
  - Better:
    - UR 3.1: As soon as a batch-order is completed, a corresponding production report will be generated.
    - UR 3.2: The system generates a deviation report when a batch-order is completed.
- "The recovery of the system on Level 1 and 2 should be possible without interruption in the production process."
  – Simply not feasible in practice.
- "All workstations running the software must be configured with 512MB of memory, a DVD ROM/CD-RW multifunction drive, and a 21-inch flat screen monitor."
  – Very detailed and specific and possibly not necessary.
- "After five unsuccessful attempts to log in, a Java script routine starts and locks the user out of the system."
  – Too specific, an URS should not define implementation details.