Discussion Document for Suggestions to the URS

Consideration for changes

The topics below were suggested by stakeholders (named) and were not directly adopted in the URS document. An explanation is given for each suggestion. The UR numbering refers to URS version 4.0 dated 16 March 20126.

UR	Proposed	Suggested by	Analysis
Overall	Many Requirements are Functional rather than User Requirements.	D. Palmer	The specifications in this document cover user, system and quality/regulatory requirements.
Overall	Will the unique requirements for other Life Sciences industry segments be included, such as Medical Devices, Cosmetics, etc?	O. Gendrin	Initially, the URS is focused on Pharma and Biotech but a future version might include specifics for other Life Sciences segments.
UR-1.6	Editing on small mobile devices is difficult to use. Also, breaks SYS-2.	D. Palmer	Users will choose if they utilize small mobile devices or not. The functionality is optional.
UR-1.7	Generalize to allow for biometric and other identification. Text messaging to verify access to the system should be allowed.	D. Palmer	Biometric identification is accepted. Texting verification is another method but not mainstream.
UR-1.9	Use the tem "search and filter by attributes and metadata"	M. Bellero	Metadata is another word for attributes. Rather than confuse the reader, we have stuck with one term. "search and filter" has been inserted.
UR-1.9	Can the system search based on common metadata?	K. VanLouvanee	Yes, search on metadata must be included.
UR-1.9	Would suggest that this can and should be broadened to reflect two requirements. First, system must be navigable in some visual way (specifying "folders" may be too restrictive) and a second requirement (probably as a nice to have) related to search.	K. VanLouvanee	We've made this requirement as flexible as possible.
UR-1.10	Is full-text search required?	K. VanLouvanee	Requirement is made optional. Each vendor will stand on their merits.
UR-1.11	Date and time in the users local environment should be displayed	D. Palmer	Server will record on the audit trail the UTC and users will see local date & time
UR-1.16	Internal links support?	O. Gendrin	Internal links capability is inherent in MS WORD. Interlinking (between different documents) is a

Discussion Document for Suggestions to the URS

			publishing function but must work within the system.
UR-1.18	Font substitution may not be able to resolve	D. Palmer	Font substitution can cause serious problems during rendition. Embedded fonts can resolve the issue.
UR-1.17	PDF rendering is NOT a function of document management.	K. VanLouvanee	Yes, PDF is required and the format or version of PDF required varies by country.
UR-2.1	Users fulfilling multiple roles are not able to perform those roles under the same ID.	D. Palmer	It is our opinion that the capability for a user performing multiple roles to log in once and their capabilities will be combined.
UR2.8	Is auto-population of attributes required?	K. VanLouvanee	Some document types require this function, e.g. records (GMP).
UR-3.1	Is the required lifecycle a suggestion?	D. Palmer	This is a standard lifecycle taking into account all functions.
UR-3.1	Process for Archiving?	O. Gendrin	Archiving process is beyond the scope of this URS.
UR-3.1	Automated workflows not needed	K. VanLouvanee	Yes, automated workflows are required. However they can be a power-override.
UR-3.2	There is no definition of how a document is edited (e.g. in native application)	O. Gendrin	We have chosen not to proscribe how a vendor provides this capability and have chosen to remain neutral to allow new technologies (e.g. SCA)
UR-3.2	Why follow the version scheme of 0.1, 1.0, etc?	K. VanLouvanee	The major/minor version scheme has been well tested and ratified by the industry common practices.
UR-3.2	Is it necessary to force versions to always increment?	S. Belina	We have found that users that have the option to save as the same version will abuse it. The overhead of creating a new minor version is minimal compared to the risk of loosing valuable audit trail of changes.
UR-3.6	Are we mandating a "For Approval" state of a document?	K. VanLouvanee	Yes, according to the document lifecycle. This will allow for protection against editing while a document is being reviewed/approved.
UR-3.9	Purge minor versions upon approval	M. Bellero	This must be a business decision. Vendor should offer as a configuration option.
UR-4.4	Manifestation of e-signatures	D. Palmer	Currently in most solutions. The implications of Digital Signatures have not been considered.
UR-6.1	Is there a difference between someone who has "review"	K. VanLouvanee	Yes, these are two different levels of access. Review access implies

Discussion Document for Suggestions to the URS

	access and "view" access?		annotation capability.
UR-6.1	External users?	K. VanLouvanee	Business dictates the need to possibly virtualize various business functions. These external organizations will require restricted access.
UR-7.1	External groups need to approve and manage their own users.		Functionality should be "role-based" rather than "group. Role gives functionality; Group sets access limitations.
UR-8.1	Does this refer to Controlled Printing?	K. VanLouvanee	Yes. GMP Requirements are within scope of this URS.
UR-8.1	Document watermark with just one day valid?	S. Belina	Yes, this is a GMP requirement for specific controlled documents that are printed without control logs.
UR-9.1	Attributes visible to users with Consumer access	K. VanLouvanee	READ access is provided to all Consumers. External Partners who have ANY access to the repository, will have an NDA on file and should have access to the documents allowed under the agreement.
UR-10.1	Why is a Change Request necessary	K. VanLouvanee	Change Requests are a requirement for GMP documents.
SYS-2	Why are performance thresholds included?	K. VanLouvanee	These are basic systems capabilities where a user might be concerned. We have added a maximum recovery time.
SYS-3	Should system time be configurable?	K. VanLouvanee	We set a standard time as a recommendation. It may become practical if the company later merges.
SYS-G	What about accessibility?	K. VanLouvanee	See S-10.
Mig-1	What about migration from other sources such as file shares, hard drive or other non-compliant locations.	K. VanLouvanee	The actions desired are considered Import functionality for a validated system.
Mig-2	Restrict migration to only certain versions?		System must be allowed to move all. Selection is a business decision.
Appx-C,D	These sections do not belong in a URS	K. VanLouvanee	We have included Appendices C & D as educational material for a small Pharma (our target audience).