BioPhorum

USER REQUIREMENTS SPECIFICATION (URS) FOR A KNOWLEDGE MANAGEMENT SYSTEM FOR USE IN A BIOPHARMACEUTICAL SETTING

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About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum now comprises over 90 manufacturers and suppliers deploying their top 3,500 leaders and subject matter experts to work in seven focused Phorums, articulating the industry's technology roadmap, defining the supply partner practices of the future, and developing and adopting best practices in drug substance, fill finish, process development and manufacturing IT. In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

BioPhorum Technology Roadmapping

BioPhorum Technology Roadmapping establishes a dynamic and evolving collaborative technology management process to accelerate innovation by engaging and aligning industry stakeholders to define future needs, difficult challenges and potential solutions. The Phorum involves biomanufacturers, supply partners, academia, regional innovation hubs and agencies, serving to communicate the roadmap broadly while monitoring industry progress.

For more information on the Technology Roadmapping mission and membership, go to https://biophorum.com/phorum/technology-roadmapping/

1.0

Introduction

This user requirements specification (URS) document will provide a starting point for the biopharmaceutical industry to build true knowledge management (KM) capability. It is intended to help solutions providers innovate in the area of relevant tools and systems by providing guidance on the specific needs of operating companies. The design, implementation and maintenance of a comprehensive KM platform, solution or system is a complicated undertaking — this is because it should ultimately span many functions, disciplines, business processes and all products over their respective lifecycles. To be effective, a KM capability must also address all the components of an enterprise: people, process, content and technology. The biopharmaceutical industry has been slow to adopt KM practices largely because of this multi-dimensional challenge combined with the inherent complexity of biopharmaceuticals, including therapeutic effect, product chemistry and manufacturing technologies.

This URS document has been developed from the BioPhorum KM paper[2] which was written with a focus toward control strategy development. However, the user requirements in this document are intended to be broadly applicable to all applications of KM.

For more background, general concepts and assessment methods, refer to the *First Edition Biomanufacturing Technology Roadmap* (TRM)[1] and the paper recently published by the Biophorum TRM — KM Working Group[2]. In the latter, an assessment of knowledge flow revealed that there are significant challenges with both explicit and tacit knowledge flow across a single organization, much less so in multiple sites, organizations or institutions. While there has been an increasing awareness of KM among biopharmaceutical manufacturers over the past several years, KM is already recognized by regulators around the globe as a key enabler of a science- and risk-based approach to assuring quality medicines[1]. For example, the International Conference on Harmonization (ICH), highlights KM as a foundation to Pharmaceutical Development (ICH Q8), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Risk Management (ICH Q10).

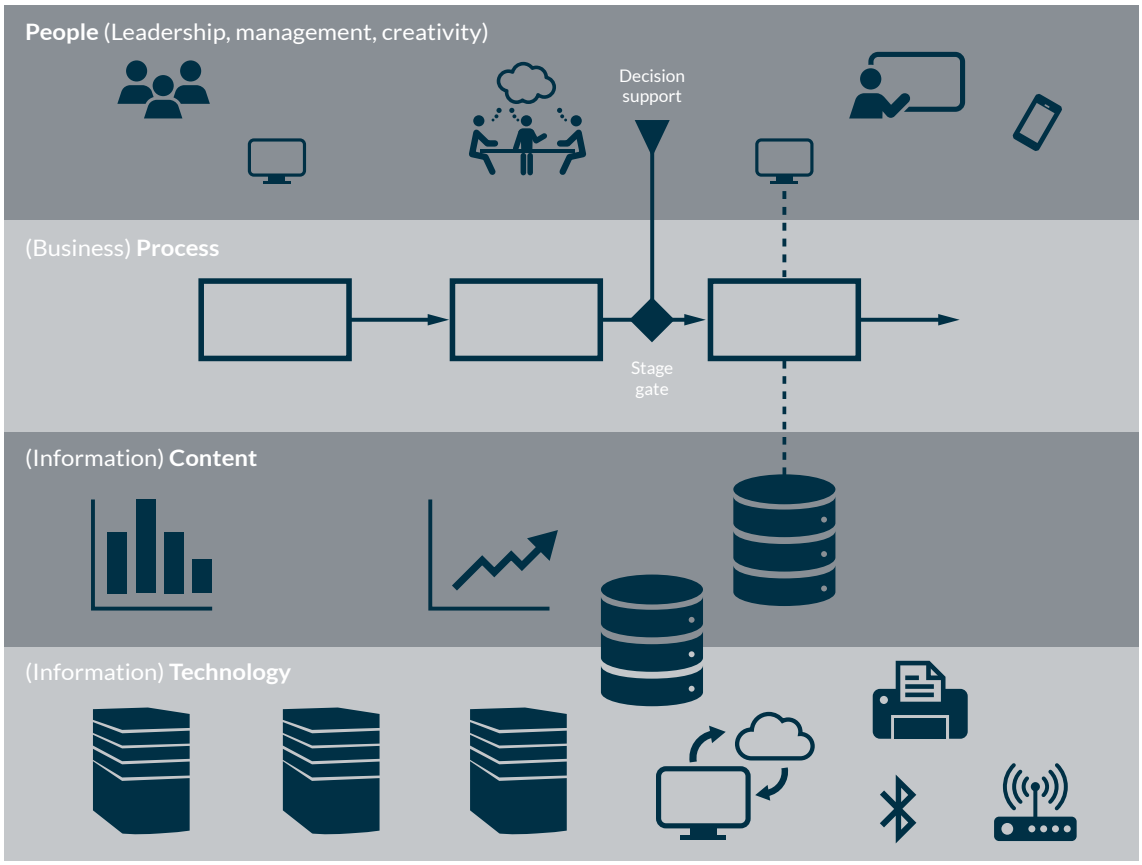
Because of the scope and complexity of KM, a single organization is unlikely to be able to address all aspects of KM at once. It is also unlikely that a single KM solution can address all aspects. KM is perhaps more accurately described as an integrated set of systems, behaviour and culture rather than a single system. So to establish a comprehensive KM capability, a phased approach is likely to be required. However, to achieve a truly comprehensive KM capability, each system or component must be designed with the end in mind. To enable connectivity to existing and future elements of the architecture, each subsystem must be designed to fit into a grand architecture or 'eco system' and be implemented with the appropriate links.

For this reason, this URS document addresses the broader system requirements of KM but also includes more detailed user requirements for some example individual subsystems that are more specific to the needs of the given application. Subsystems or specific business processes that may be part of a KM superstructure are shown in, but not limited to, the following list:

- product development history and platform development
- process development history and platform development
- quality-by-design (QbD) and risk assessments
- control strategy construction (and history)
- preparation for regulatory filings
- regulatory filings
- answering agency questions
- product/process lifecycle management
- commercialization stage gates and decision support
- technology transfer
- change control
- deviations
- manufacturing investigations.

This URS document has been created by the Biophorum TRM — KM Working Group to reflect high-level generic requirements for a KM system and to show that requirements for specific applications can be derived or identified in associated documentation such as a Request for Information (RFI) or a Request for Proposal (RFP). Alternatively, someone using this URS document as a starting point or template is free to revise the content to suit their specific needs. The features required are likely to be unique to the application/organisation and may have differing emphases on the people, process, content, and/or technology components of KM. The applications are too numerous to include them all in a single coherent URS document. Which of these areas to address depends on the individual needs and current deficiencies of a given organization. It is recommended that each organization constructs a roadmap to prioritize and indicate the sequence in which these are to be addressed. Of the processes listed above, commercialization stage gates are overarching and so individual gates are likely to be included in many parts of the product lifecycle and can serve as good anchor points for knowledge collection and consumption. The roadmap should also address the presence of legacy systems and how they are to be integrated and eventually phased out and replaced with more modern solutions. Figure 1 helps to visualize the various components of KM and suggests that these components may represent a hierarchy of information and knowledge, all of which should eventually be addressed by any potential solution. However, in a staged approach, specific subsystems may address only parts of the overall solution.

Figure 1: Suggested hierarchy of KM components



2.0

Purpose and scope of this document

The purpose of this document is to define the user requirements (expectations for the operation and performance) for a generic KM system. However, it is acknowledged that any KM system will ultimately need to connect to information and data management systems. An effective KM system will provide a method of trending, reporting and analysis of continuous and discrete data at a generic biopharma manufacturing facility. The document is designed to:

- increase process understanding
- enable more thorough and timely investigation of unusual event or faults
- identify opportunities for process improvement (yield, cycle time, robustness)
- provide a mechanism for collecting and trending (monitoring) of key performance indicators (KPIs) as part of a compliance process.

The scope of this document includes the user requirements for the management of knowledge, the types of analysis required and the requirements for the access and sharing of information.

2.1 Key assumptions

1 Biopharmaceutical companies are gathering prior knowledge for future product development, and learning across the lifecycle of a product or manufacturing platform. This needs to be in a GMP/GLP environment (CFR 21/11).

2 The KM system will have the ability to interface with all industry-standard source systems.

3 Primary users (and anyone else who needs to be able to customize their reports), will be recipients of a standard report.

2.2 Automation

A key assumption is that automation is an important factor in the robustness and sustainability of the KM system. Any technology being applied should:

- ensure that all data are stored in a validated secure format and process decisions may be made using the data
- provide a platform that will contain (or have access to) all the data necessary to support decision making, investigations and troubleshooting issues
- reduce the numerous work-hours that can be spent reconciling data from various sources and incorporating all these data into a single report
- reduce the time spent compiling data for KM management and reporting, resulting in reduced time to transfer technology, decreased batch-release times, improved audit support and improved process robustness.

The KM system will follow a system lifecycle development process. The computer systems selected should be widely used in the industry and vendor support should be available. The systems should allow for expansion and provide flexibility for future process changes. The system's lifetime expectation is 20 years.

A schedule will be provided that identifies maintenance items and duration intervals.

Installation, operation, and maintenance instruction documentation for the system will be developed to a level that can be understood by a high school graduate.

3.0

Operational requirements

3.1 Knowledge assets

It is critical that key knowledge assets are appreciated in the development and delivery of a KM system. As part of the KM mapping exercise conducted by the KM Working Group, several key knowledge assets were mapped for the purpose of identifying how knowledge was created and how it flowed for a particular activity.

An example of a knowledge asset table is provided in Appendix 1.

4.0

Personae

The personae involved in KM activity are suggested in Appendix 2. These personae have been defined so that the KM system can be designed to take into consideration the various sources and needs of the different functions that interact with it. These suggestions are based on the KM Working Group's experience and may be modified by users to suit their own purpose.

4.1 People

The system will have a user interface and customization that allows entry and visualization of knowledge assets.

The user interface includes all tools and entry methods for knowledge assets.

Users should be able to create a template for capturing specific information across the lifecycle. This information may have required fields at one stage that are expanded to include additional required fields at another stage in the development and commercialization process. It could also be the case that an existing system may be the source of the data and information, which will not need to be replicated in the KM system, but may need to be summarized in the KM system to become knowledge that can be shared.

4.2 Process and technology

Where knowledge assets already reside in existing IT systems or are reported through current business processes,the KM system does not need to replicate these processes, but simply access and capture the knowledge assets for combination with the full set.

This section specifies the personae for a KM system. Requirements are categorized into three principal areas of focus:

- people
- process
- technology.

Requirements have been divided into these three areas of focus for the purpose of clarity but in reality they are not wholly independent of each other. Solutions for one requirement may address requirements in another section either wholly or in part. It is accepted that for specific use cases derived from a whole system architecture, not all requirements will need to be met and this is indicated in the examples in Tables 1 to 4. These example requirements are not exhaustive and are intended for guidance only. Further insight as to how these example requirements were derived may be found in the BioPhorum KM white paper[2].

People

Table 1 shows likely requirement for users in the biopharmaceutical industry who need to manipulate and report on a wide range of knowledge assets to meet stringent internal and external reporting needs.

Table 1: People

Category	Section	Requirement	Element	Primary requirements	
People	**1**				**Sub-requirements**
People	1	1		**Users will be able to access and visualize all knowledge assets associated with the process of interest.**	
	1	1	1		Knowledge assets can be defined and categorized by the user
	1	1	2		The user interface includes entry methods for knowledge assets
	1	1	3		The user can create record templates for capturing specific information across the lifecycle
	1	1	4		Existing records can be expanded to include additional fields to add information and context
	1	1	5		The system allows users to switch languages without affecting original content
	1	1	6		Knowledge assets may exist in multiple languages
	1	1	7		The system can identify and connect contributing subject matter experts (SMEs) for knowledge assets
	1	1	8		The solution can leverage external resources for knowledge understanding
	1	1	9		Meeting notes and records can be captured
	1	1	10		The solution will allow communication and collaboration that can also be captured as part of the knowledge assets
People	1	2		**Users can view data, conduct analytics, generate reports and automate reporting.**	
	1	2	1		Users can create and save filters and dashboards
	1	2	2		End-users can save configured views and reports as templates for later reuse
	1	2	3		Users can export data from configured views and reports
	1	2	4		When recalling a previous view/report, data will be refreshed to prevent use of obsolete information
	1	2	5		Users must have the ability to access knowledge assets generated across functions/departments as appropriate, forwards and backwards across the lifecycle of a product
	1	2	6		The solution can view information and knowledge across the lifecycle of the product including previous versions of changed data
People	1	3		**The system allows SME-user interactions and users to define roles and responsibilities for specific activities.**	
	1	3	1		Users can search for SMEs by qualifications and responsibilities
	1	3	2		The solution can provide information about SMEs' qualifications and responsibilities
	1	3	3		User roles can be configured to define accessible assets and change management responsibilities for knowledge assets
People	1	4		**The system allows users to identify, categorize, associate and manage/control knowledge assets and connect external references.**	
	1	4	1		Users can connect to external references in the open literature
	1	4	2		Users can connect to external references in other organizations
	1	4	3		The solution allows external organizations to connect and share knowledge
	1	4	4		When a single piece of data is used in multiple systems, an owner of the data must be defined to ensure a single version of the truth (i.e. CPP must be tracked and used from development to production, along with change history — should the KM system 'own' it?)

4.3 Process

The KM system must have workflow governance processes to cover stage gate processes that are used for any specific applications of knowledge across product lifecycles and platforms, and other relevant business processes.

Table 2: Process

Category	Section	Requirement	Element	Primary requirements	
Process	2				Sub-requirements
Process	2	1		**Users need to define business processes which include workflow governance for knowledge assets to support decisions and enable rapid retrieval of these assets.**	
	2	1	1		Templates can be created that define generic stage gates for the various types of products and/or platforms
	2	1	2		A process for harvesting platform-specific knowledge can be defined — this may be separate from the product stage gate process or another KM business process
	2	1	3		A knowledge element such as a risk assessment can be updated throughout the stage gate process
	2	1	4		A standard process, e.g. risk management can be configured as a template in the stage gate process
	2	1	5		The stage gate process can be specified to enforce (or make optional) the capture of specific types of data, information, knowledge and summaries — these can include various knowledge elements such as aggregated product, platform and process knowledge or another KM business process
	2	1	6		Decisions in the stage gate process can be enforced with linkages to supporting information and data and the rationale behind the decisions
	2	1	7		A workflow process can be configured to proactively provide or suggest visibility of knowledge assets for appropriate functions, e.g. R&D and manufacturing at the right stage in the lifecycle of the knowledge asset or stage gate process
	2	1	8		Stage gate actions and responsibilities can be assigned to users and user roles
	2	1	9		Required details and data captured should be commensurate with the stage gate so that additional data can be added to knowledge elements during the various stages
	2	1	10		As appropriate over the course of the product development lifecycle, stage gate processes or another KM business process, steps for data reporting can be included, e.g. design of experiments data. This may include links to data in source systems or aggregation of data or reports
	2	1	11		Users should be able to promote the assets or aggregation of assets, e.g. product with its KM assets, from one development stage to the next in the lifecycle, based on the established stage gate rules that may be specific to a KM business process and may also be specific to an organization
Process	2	2		**The system provides a general governance process to define KM elements and associated properties including standardization, criticality, change management/change history/tracking, etc.**	
	2	2	1		Knowledge element types can be defined in the system
	2	2	2		Knowledge elements must use standard terminology, definitions and nomenclature to capture data, information and knowledge — these standards can be defined in the system
	2	2	3		The system allows inputs for impact assessments of a knowledge element
	2	2	4		Criticality rankings will be defined as a data set
	2	2	5		Control elements will be rated for criticality using the criticality ranking data set
	2	2	6		Criticality rankings of process elements can be adjusted across the lifecycle
	2	2	7		Data, information and knowledge elements can be shared across the lifecycle (e.g. lifecycle of products and across platforms or another KM business process) as per the associated stage gate process
	2	2	8		Data and information ownership is defined as part of a stage gate process

Table 2: Process (continued)

Category	Section	Requirement	Element	Primary requirements	
Process	**2**				**Sub-requirements**
Process	**2**	**3**		**Users need to know the change history of the knowledge.**	
	2	3	1		Changes are routed for review as defined by the overarching stage gate process
	2	3	2		Versions of relevant information aggregated from data (e.g. product information change history — versions of product information) can be managed with supporting change justification and data
	2	3	3		All changes made since the last round of approvals are available for viewing during the review and approval process
Process	**2**	**4**		**Users need to be able to relate, capture and categorize knowledge assets.**	
	2	4	1		Knowledge assets can be identified and are searchable in the context of our business processes, i.e. stage gate process
	2	4	2		Knowledge assets are manageable and can be updated in a timely manner to support business decisions
	2	4	3		Content — A master data knowledge asset has properties associated with it, e.g. criticality and impact assessment information
	2	4	4		Key decisions can be recorded and linked clearly with the version-supporting information and data as part of the stage gate process
	2	4	5		The system can 'snapshot' data, e.g. a report of all appropriate data at a specific time and in relation to decisions in the stage gate process
	2	4	6		Data/information context and comments can be provided by data sources or captured by users in the system where the data are entered in the system by users if not available in source systems — this enables users to turn data into information and knowledge
	2	4	7		Design of experiment data can be captured within a plan for product development and transfer into manufacturing
	2	4	8		Observations can be captured within the context of the platform, process and product as part of the process development and control strategy development process
	2	4	9		A method is provided to create an association between two sources of data
Process	**2**	**5**		**Knowledge assets can be linked with data, other assets and other systems. Users need to find easily the source of their knowledge assets and relate the assets.**	
	2	5	1		Current investigations can be linked with knowledge elements, such as previous risk information or failure modes
	2	5	2		Documents can be aggregated, e.g. standard operating procedures (SOPs) and guidelines, and these can be connected as references
	2	5	3		Equipment and materials supplies can be linked with the risk management process
	2	5	4		The system may require an entry for dependencies or relationships between knowledge elements (design strategies, plans, protocols, tech reports, etc.)

Table 2: Process (continued)

Category	Section	Requirement	Element	Primary requirements	
Process	**2**				**Sub-requirements**
Process	2	6		**A feedback loop is possible within and across stages, e.g. manufacturing back to development. Users also need to be able to use historical knowledge (including failures) to support their current project.**	
	2	6	1		History about successes and failures regarding the product or platform or another KM business process can be made accessible at certain points in the stage gate process
	2	6	2		The ability to capture data, information and knowledge (including reports) about successes and failures for a product or platform or another KM business process is included as a workflow process
	2	6	3		The ability to capture performance history of the manufacturing process is included — deviations, investigations, failure modes including CQA (critical quality attribute)/CPP(critical process parameter), changes in control, ranges
	2	6	4		The ability to capture equipment performance history is included
	2	6	5		Notification or indication when required information is missing is included
Process	2	7		**Users need to have access to process design, analytics, dashboards and alerts capabilities for product and process information.**	
	2	7	1		The system can provide views of real-time and historical data on-line
	2	7	2		The system can provide a batch alignment methodology to receive the data with the context for batch phase(s)
	2	7	3		The system can provide an alert status page, summarizing process alerts for the current batches, most recent batches and historical batches
	2	7	4		The system can provide a batch alignment context for batch phase(s) as an overlay for visualization
	2	7	5		The system can provide a means to visualize multiple Y-axis parameters, each with an independent, user-configurable scale — the Y-axis parameters may be process measurements or user-derived parameters
	2	7	6		There is a way to view who has worked on the various stages of the product in order to gather additional knowledge that may not have been captured
Process	2	8		**The system includes integration and knowledge asset linkages from multiple sources to enable reporting on knowledge assets throughout the product lifecycle stage gate process. Users need one system where they can query and generate both knowledge and reports (whether ad hoc, standard, visualizations, etc.).**	
	2	8	1		At a minimum, users can query data based on date/time, batch ID, campaign ID or equipment numbers
	2	8	2		The system can generate reports compiling information from various data sources. Information from multiple sources such as DeltaV historian, QLIMS, SAP, and TrackWise will be correlated by information such as batch ID
	2	8	3		The system has preconfigured reports which display lists of deviations per piece of equipment, unit operation, batch or campaign
	2	8	4		Summaries can be queried and reviewed as part of the process for new, existing or still in development products
	2	8	5		The system can generate a product history/genealogy and version report by compiling information from one or more connected data sources
	2	8	6		Generated reports and report templates cannot be modified without appropriate access
	2	8	7		Editable reports are used throughout the product lifecycle to query the available knowledge about platforms, products and processes
	2	8	8		Key documents (key knowledge assets) are clearly recognizable in the system
	2	8	9		The system provides a display or report on relationships between knowledge elements (design strategies, plans, protocols, technical reports, etc.)

4.4 Technology

While this URS cannot anticipate the starting point for an organisation's technology, these requirements will to help understand whether to develop existing platforms, or apply new technology to deliver them.

Table 3: Technology

Category	Section	Requirement	Element	Primary requirements	
Technology	**3**				**Sub-requirements**
Technology	**3**	**1**		**The system allows users to define the source of knowledge assets, allow for intelligent linkages between assets and extract knowledge asset content with context from their source.**	
	3	1	1		There is an option to integrate with and capture data from communication systems, e.g. Yammer, email or Skype
	3	1	2		The sources of the knowledge assets can be linked together within a common context, e.g. find all related knoweldge assets at product level.
	3	1	3		There is readily available access to all related knowledge assets identified through links
	3	1	4		There is an enhanced interface to improve interoperability between source systems
	3	1	5		All knowledge assets are accessible from a central location
	3	1	6		Additional data sources are supported as needed through common interfaces
	3	1	7		Application program interfaces (APIs) exist for the components
	3	1	8		It is possible to obtain and utilize both time-series and discrete data — these data must appreciate validation and audit trail expectations of regulatory authorities
Technology	**3**	**2**		**The system allows users to form queries in the natural language of the defined knowledge sources and to utilize structured data for querying and keyword search.**	
	3	2	1		Querying is possible
	3	2	2		Users can filter search results, create structured queries and save previously run queries
	3	2	3		Based on prior searches, search results and saved searches, intelligence can provide predictive search options
	3	2	4		Users can retrieve knowledge assets by querying through natural language
	3	2	5		Users can query data in both structured and non-structured ways
	3	2	6		As an aggregation engine, the aggregated knowledge assets can be queried through a standard protocol to then drive other tools
	3	2	7		Semantic enrichment is used in querying
	3	2	8		Options to use the system in local languages are available
Technology	**3**	**3**		**Industry standards are used to connect sources of knowledge assets and no customized or proprietary technology or methodology is used.**	
	3	3	1		Users can master data according to agreed standards
	3	3	2		Users can retrieve knowledge assets through a standard taxonomy
	3	3	3		Aggregated data sets can be saved and exported in a commonly accepted structured format
	3	3	4		Users can build in structured execution workflows

Table 3: Technology (continued)

Category	Section	Requirement	Element	Primary requirements	
Technology	**3**				**Sub-requirements**
Technology	3	4		To provide and enable insights, users need to be able to intelligently consume knowledge assets from source systems through artificial intelligence (AI) or learning systems, aggregation, trending or correlation of data, etc.	
	3	4	1		Users can introduce new AI functionality and algorithms
	3	4	2		Users can interact, configure and design analytics pages, e.g. dashboards or queries
	3	4	3		Users can visualize and intelligently consume knowledge assets
	3	4	4		There is an enhanced interface to improve interoperability between source systems
Technology	3	8		Users need automation of an updating functionality to refresh and identify new knowledge assets within defined sources	
Technology	3	9		Accessibility of knowledge assets incorporates existing security protocols including tiered access permissions if required	

4.5 Systemic and other requirements not specified in Tables 1 to 3

Table 4: Systemic and other requirements

Category	Section	Requirement	Element	Primary requirements	
Other	**4**				**Sub-requirements**
Other	4	1		Sufficient training is available for individuals to enable them to create or engage with the KM systems.	
	4	1	1		

5.0

Use cases

Use cases, e.g continued process verification, or the investigation of manufacturing deviations, are not presented in this document. Specific requirements or amendments or points of clarification are included in any accompanying RFI.

6.0

Constraints

No explicit constraints are expressed at this time.

Users wishing to modify this URS may add constraints here or in an accompanying RFI.

7.0

Milestones and timelines

[example text] The supplier shall provide a written proposal within 3 weeks of receipt of this document at the supplier's local office.

The supplier shall provide a functional specification within 4 weeks of receipt of the purchase order.

The user shall review, comment and/or approve, and return the functional specification to the supplier within 3 weeks of receipt from the supplier.

The factory acceptance test (FAT) shall be executed at the supplier's site on or before ...

8.0

Procedural constraints

8.1 Regulatory compliance

[example text] The supplier shall ensure that the provided solution(s) comply with 21CFR part 11 and appropriate FDA pharmaceutical GMP regulations as may be in place at the time.

8.2 Lifecycle

[example text] The system shall be provided with a lifecycle and maintenance plan that addresses:

- *base operating system requirements (as required)*
- *periodic updates as a result of third-party changes to leveraged platforms (e.g. operating systems, browsers, SSO authentication systems)*
- *disaster recovery procedures*
- *redundancy and back-up scheduling where cloud or hosted solutions are provided*
- *maintenance window definition*
- *etc.*

8.3 Development

[example text] The supplier shall provide a quality and project plan as part of its proposal.

The supplier shall have a quality system in place.

Internal quality procedures shall be available for the user's review.

The supplier shall provide a project manager for the project to provide a single communication point with the user.

The project shall utilize the GAMP methodology when developing the system and documentation.

8.4 Testing

[example text] In order to verify system performance, the supplier shall provide an approved FAT protocol to the user for review and approval 4 weeks before the FAT.

The supplier shall notify the user 2 weeks before the start of this test.

(Would acceptance be based upon simulation, phased roll-out, proof of concept challenge, etc?)

8.5 Delivery

[example text] The system deployment plan will be a deliverable that will be developed with the purchaser.

8.6 Documentation

[example text] The supplier shall use the formats described in the current version of the GAMP supplier guide to produce the documentation.

8.7 Support

[example text] 24/7 support is required with first-level support available in the local language and English. Second- and third-level support requirements tba.

Mean response time for first line support is tbc.

Mean response time for escalation and resolution for routine second level support is tbc.

8.8 Training

[example text] User training shall consist of a combination of classroom, online and on-demand training.

Formal training materials specific to the equipment shall be provided for all administrative users (x seats).

Certificates of training shall be provided for each person completing the training program.

The training shall be given by certified instructors and technicians familiar with the system and developed with the sponsor.

8.9 Post start-up support

[example text] Post-go-live support shall be available as described above and be subject to annual review.

8.10 Technical support

[example text] Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

Post-go-live support shall be available as described above and be subject to annual review.

8.11 User site support

[example text] No on-site support is anticipated for the system.

Appendix 1

Example of key knowledge assets as might be applicable to a CMC process

Table 5: Key knowledge assets

Example step		Examples of key knowledge assets
3.2.S	DRUG SUBSTANCE	Brand name, generic name
3.2.S.1	General information	e.g. drug class, licensed therapeutic usage
3.2.S.2	Manufacture	Cell bank manufacturing history, process development and characterization studies, risk assessments, process description, scale-up/scale-down comparison, process performance qualification
3.2.S.3	Characterization	Analytical characterization, degradation studies
3.2.S.4	Control of drug substance	In-process control strategy, sampling plan, CQAs (critical quality attributes), analytical methods, method validation summaries
3.2.S.5	Reference standards or materials	Reference standard lot selection, testing results
3.2.S.6	Container closure system	Bag leachables/extractables testing
3.2.S.7	Stability	Drug substance stability testing results
3.2.P	DRUG PRODUCT	e.g. variant, strength
3.2.P.1	Description and composition of the drug product	
3.2.P.2	Pharmaceutical development	Process development and characterization studies, risk assessments
3.2.P.3	Manufacture	Process description, scale-up/scale-down comparison, process performance qualification
3.2.P.4	Control of excipients	Vendor and grade of materials, material specifications
3.2.P.5	Control of drug product	In-process control strategy, sampling plan, CQAs, analytical methods, method validation summaries
3.2.P.6	Reference standards or materials	Reference standard lot selection, testing results
3.2.P.7	Container closure system	Stopper/vial studies
3.2.P.8	Stability	Drug product stability results
3.2.A	APPENDICES	
3.2.A.1	Facilities and equipment	Facility validation, vessel hold studies, equipment lists, flow diagrams
3.2.A.2	Adventitious agents safety evaluation	Viral clearance and inactivation study reports and summary of results
3.2.A.3	Novel excipients	
3.2.R	REGIONAL INFORMATION	
3.3	LITERATURE REFERENCES	

Appendix 2

Example of personae and how they might be mapped as contributors in a CMC process

Table 6: Example of personae identified in the URS

	Examples of relevant knowledge assets
Research Scientist	User
Process Development Engineer	User
Analytical Development Scientist	User
Regulatory Affairs	Interface with the health authority
Automation Engineer	User
IT Analyst	Focuses on IT infrastructure/framework
Manufacturing Associate	User
Manufacturing Head (Senior Management Team)	Customer of reports and visualisations
Quality Control and Assurance	Customer of reports, user of investigations and deviations management
Process Technology Engineer	User
Planner	Oversees the fit of demand to production capabilities including materials supply
Supply Chain (Materials/Supplies)	User
Maintenance Supervisor	User
KM Consultant/Team Member (internal)	Enablement/enrichment of system, curators of knowledge business processes
Product Owner/Molecule Steward	Customer of reports for interaction with regulatory authorities and QA
Data Scientist	Analyses data sets and seeks context for signals as part of business process
Licensing and Acquisition	Decides what opportunities fit into the capabilities of the company
Operational Excellence	Leads continuous improvement at the operational level
Program and Project Managers	Users – particularly of prior knowledge
CMC Regulatory	Coordinates function with product knowledge
Contract Manufacturing Organisations (CMOs)	Recipients of technology transfer, providers of manufacturing data on products
Contract Research Organisations (CROs)	Recipients of technology transfer, providers of product and process development knowledge
CDMO Management (Contract Design and Manufacture Organisation)	A combination of CMO and CRO
Development Head (Senior Manager(s))	Champions the need for effective knowledge management (product, process and platform) and ensures if functions well within Development Dept

Note: These roles may change between producer and consumer or may be absent depending on the use case being considered.

Glossary of terms

Term	Definition
AI	Artificial intelligence
API	Application program interface(s)
CAPA	Corrective and preventative action
CDMO	Contract development and manufacturing organization
CFR	Code of federal regulations
cGCP	current good clinical practice
cGLP	current good laboratory practice
cGMP	current good manufacturing practice
cGPP	current good pharmaceutical practice
cGxP	current good x practice where x may be C-clinical, L-laboratory, M-manufacturing, P-pharmaceutical)
CMC	Chemistry Manufacturing Controls a section of the license application; a descriptor supporting this functionality, or the process used to develop this section of the application
CMO	Contract manufacturing organization
Continuous data	Information that can be measured on a continuum or scale. Continuous data can have almost any numeric value and can be meaningfully sub-divided into finer and finer increments, depending upon the precision of the measurement system. (Source: https://www.isixsigma.com/dictionary/continuous-data/)
CPP	Certificate of pharmaceutical product/critical process parameter
CPV	Continuous process verification
CQA	Critical quality attribute
CRO	Contract research organisation
DCS	Distributed control system
DeltaV	A distributed control system (DCS) marketed by Emerson
DeltaV Historian	An event recording structure of the DeltaV distributed control system (DCS) marketed by Emerson
Discrete data	'Information that can be categorized into a classification. Discrete data are based on counts. Only a finite number of values is possible and the values cannot be sub-divided meaningfully ...' (Source: https://www.isixsigma.com/dictionary/discrete-data/)
EBR	Electronic batch record
FAT	Factory acceptance testing
GAMP	Good automated manufacturing practice
ICH	International Conference on Harmonisation
IT	Information technology
KM	Knowledge management

Glossary of terms

Term	Definition
KPI	Key process indicator
LIMS	Laboratory information management system
QLIMS	Quintiles laboratory information management system
R&D	Research and development
RFI	Request for Information
RFP	Request for Proposal
SME	Subject matter expert
SOP	Standard operating procedure
TrackWise	An example of a deviations, change, corrective actions, preventative actions tracking and management system.
URS	User requirements specification

References

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3 ISO, *ISO 30401:2018 Knowledge management systems – Requirements*. ISO Copyright Office (2018).