OMNITEK CONSULTING

Business Analysis Techniques For Pharmaceutical System Requirements Gathering:

WHITE PAPER

A Regulator-Aware Guide to Eliciting and Managing Requirements in Life Sciences

Abstract

This white paper examines business analysis techniques that help pharmaceutical and biotechnology organizations gather and manage system requirements in highly regulated environments. It highlights the importance of aligning requirements with scientific workflows, compliance frameworks, and regulatory expectations. The paper focuses on three techniques: stakeholder analysis and discovery workshops, process and data modeling, and risk-based elicitation with traceability. These methods are supported by industry standards and guidance from the International Institute of Business Analysis (IIBA), the Project Management Institute (PMI), the United States Food and Drug Administration (FDA), the Medicines and Healthcare products Regulatory Agency (MHRA), the International Council for Harmonisation (ICH), and the International Society for Pharmaceutical Engineering (ISPE). It also outlines best practices for requirements quality and explains OmniTek Consulting's hybrid Agile and Computer Software Assurance (CSA) aligned approach to delivering regulator-ready systems.

Executive Summary

Pharmaceutical and biotechnology organizations operate in complex and highly regulated environments where system requirements must align with scientific workflows and compliance obligations. Inadequate requirements gathering often leads to delays, rework, and compliance issues that can affect both timelines and inspection readiness. This paper focuses on three high-impact techniques for eliciting and managing requirements in Good Practice (GxP) settings. The discussion draws on guidance from the International Institute of Business Analysis (IIBA), the Project Management Institute (PMI), the United States Food and Drug Administration (FDA), the Medicines and Healthcare products Regulatory Agency (MHRA), the International Council for Harmonisation (ICH), and the International Society for Pharmaceutical Engineering (ISPE).

Regulatory Context for Requirements

In regulated life sciences environments, understanding the foundational regulatory and scientific context is essential before requirements are captured. System requirements must be rooted in established standards, guidelines, and good practices to ensure compliance and audit readiness. These regulatory anchors inform both what is captured during elicitation and how requirements are validated.

Requirements must reflect:

- Good Practice (GxP) principles, including Current Good Manufacturing Practice (cGMP), Current Good Laboratory Practice (cGLP), and Current Good Clinical Practice (cGCP), along with Good Documentation Practices that ensure accuracy, completeness, and reviewable records[i].
- Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available (ALCOA+) data integrity attributes, which are required to ensure the reliability and trustworthiness of records[ii].
- Electronic records and signature controls outlined in Title 21 of the Code of Federal Regulations Part 11 (21 CFR Part 11), which cover audit trails, authentication, and retention requirements[iii].
- International Council for Harmonisation (ICH) E6(R2) Good Clinical Practice guidelines, which emphasize patient safety, data quality, and protocol adherence[iv].
- Food and Drug Administration (FDA) Computer Software Assurance (CSA) principles for risk-based testing and evidence gathering, which direct assurance activities toward areas that most affect patient safety and product quality[v].

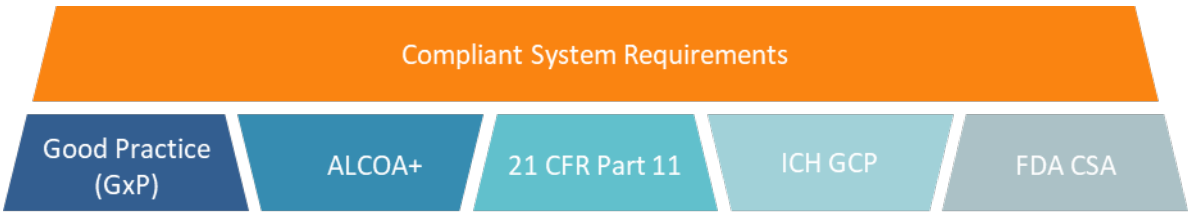

Figure 1: Foundation for compliant system requirements

Together, these requirements frameworks form the backbone of compliant system design and operation. Business analysts who integrate these standards into requirements gathering not only reduce the risk of regulatory findings but also support efficient validation and long-term system sustainability.

Three Key Business Analysis Techniques

Before selecting specific techniques, it is important to recognize that business analysis in pharmaceutical environments must navigate both scientific complexity and regulatory rigor. The methods outlined here have been chosen because they balance stakeholder engagement, clarity of documentation, and compliance alignment. Each technique offers a practical path to uncovering detailed, testable requirements while also ensuring they stand up to audit and validation scrutiny. Together, they form a targeted toolkit for delivering systems that meet both operational needs and regulatory obligations.

1) Stakeholder Analysis and Discovery Workshops

Stakeholder analysis is often the starting point for business analysis in regulated pharmaceutical projects. Identifying and engaging the right individuals ensures that requirements reflect not only system functionality but also scientific workflows, compliance obligations, and operational realities. Mapping roles across Research and Development (R&D), Clinical Operations, Quality Assurance (QA), Information Technology (IT), and Regulatory Affairs allows the analyst to see where requirements intersect and where handoffs may occur. This process provides a foundation for inclusive decision making and ensures that both end users and compliance owners have a voice.

Structured discovery workshops expand on this foundation. They bring together cross-functional groups to:

- Walk through process scenarios and map potential system touchpoints.
- Capture compliance and scientific needs that might otherwise be overlooked.
- Record decisions and requirements in real time to promote transparency and reduce rework.

Figure 2: Stakeholder alignment focus

These sessions help bridge gaps between technical and scientific language. By providing a common forum, they encourage dialogue between laboratory scientists, IT specialists, and quality staff. This makes it easier to develop requirements that are both technically feasible and compliant with regulatory expectations[vi].

2) Process and Data Modeling

Once stakeholders are aligned, process and data modeling helps clarify workflows and data relationships. Process maps, including swimlane diagrams, provide a visual representation of activities, handoffs, and segregation of duties. This is particularly important in environments subject to 21 CFR Part 11, where user roles and system access must be carefully defined.

Data modeling complements process analysis by defining key entities, metadata, and controlled vocabularies that support standardized reporting. For example, identifying master data such as study identifiers, sample types, or batch numbers prevents inconsistencies that could compromise regulatory submissions. Including data lineage shows how information moves across systems and demonstrates control over regulated information, which is essential during audits and inspections[vii].

3) Risk-Based Elicitation and Traceability

Risk-based elicitation emphasizes requirements that most directly affect patient safety, product quality, or data integrity. By applying Computer Software Assurance (CSA) principles, analysts can prioritize high-impact areas and reduce unnecessary effort in lower-risk domains. This ensures that limited project resources are focused where they matter most.

A Requirements Traceability Matrix (RTM) strengthens this process by linking requirements to associated risks, test cases, and validation evidence. Traceability provides confidence that every high-priority requirement has been tested and documented appropriately. It also makes change control more efficient by showing the impact of a proposed change on compliance obligations and risk assessments. In inspection scenarios, this level of transparency demonstrates control and readiness to regulators (FDA, ISPE).

Table 1: Sample CSA RTM

Req ID	Requirement Description	Risk / Potential Impact	Test ID	Validation Method
SYS-REQ-001	The system must ensure that all batch records are captured and stored securely for 20 years.	Loss or corruption of batch records; regulatory non-compliance.	TC-001	Test execution report confirming batch record creation, retrieval, and secure storage. Evidence: Screenshots, audit trail logs.
SYS-REQ-002	The system must restrict user access based on roles (e.g., QA, Manufacturing, Admin).	Unauthorized access could lead to data integrity issues or regulatory violations.	TC-002	Access control verification test; Evidence: User access matrix, test screenshots, audit logs.
SYS-REQ-003	The system shall automatically log any changes to critical data fields.	Data integrity risk; audit trail gaps could trigger FDA inspection observations.	TC-003	Change logging test; Evidence: Audit trail review, screenshots of logged changes with timestamps.

Best Practices for Requirements Quality

In order to ensure requirements are actionable, compliant, and resilient throughout the project lifecycle, it is important to adopt a set of best practices grounded in recognized standards. These practices help align diverse stakeholders, reduce misinterpretations, and ensure audit readiness in regulated environments.

- Write requirements that are Specific, Measurable, Achievable, Relevant, Time-bound, Verifiable, and Evidence-ready. This ensures each requirement is clear, testable, and linked to validation evidence, reducing ambiguity and supporting compliance[viii].

- Maintain a clear distinction between user needs (URS), functional details (FRS), and design or configuration specifications. This separation supports traceability, minimizes scope creep, and allows clear validation planning.
- Keep traceability up to date as requirements evolve. Maintaining a Requirements Traceability Matrix (RTM) ensures that changes are evaluated for impact on risk, validation, and compliance, which is critical for inspection readiness.
- Incorporate risk ratings into each requirement. Linking requirements to risk levels helps prioritize development and validation activities in line with CSA guidance, ensuring high-risk items receive appropriate scrutiny[ix].
- Use controlled terminology and standard data definitions. This practice improves data consistency, reduces integration issues, and supports accurate reporting for regulatory submissions.

Collectively, these practices create a structured, transparent approach to requirements management. They facilitate collaboration between technical teams and scientific or regulatory stakeholders while ensuring that compliance, quality, and business value remain central throughout the project lifecycle.

OmniTek Consulting's Approach

OmniTek Consulting recognizes that pharmaceutical and biotechnology organizations face the challenge of balancing innovation with strict regulatory oversight. Our approach is designed to give clients a structured yet flexible path to requirements gathering and validation that meets both operational needs and compliance expectations.

OmniTek uses a hybrid Agile approach to capture requirements early, validate them through prototypes, and maintain compliance with Computer Software Assurance (CSA) aligned testing. Agile principles encourage collaboration and iterative delivery, while CSA guidance ensures risk-based evidence collection. Together, this creates an approach that is both efficient and regulator ready.

Our consultants:

- Conduct cross-functional workshops that bring together scientific, IT, quality, and regulatory stakeholders, ensuring requirements are captured from every perspective.
- Build validation-ready artifacts such as User Requirement Specifications (URS), Functional Requirement Specifications (FRS), and Requirements Traceability Matrices (RTM) that support inspection readiness.
- Integrate regulatory compliance into every project phase by embedding best practices for risk assessment, documentation, and change control.

This combination of methods allows OmniTek to deliver systems that align with scientific workflows, withstand regulatory scrutiny, and provide long-term business value.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

Effective system requirements gathering is the cornerstone of successful pharmaceutical operations—whether you're implementing a new clinical system, optimizing manufacturing processes, or ensuring regulatory compliance across global sites. OmniTek Consulting applies proven business analysis techniques to help organizations capture precise, actionable requirements that reduce risk, align workflows, and accelerate system adoption. Our structured approach ensures that requirements are traceable, stakeholder-aligned, and designed to support validation and compliance objectives. If your teams are struggling with incomplete requirements, misaligned processes, or slow system adoption, OmniTek is ready to help you turn requirements gathering into a strategic advantage.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.

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Endnotes

[i] U.S. Food and Drug Administration. eCTD Resources. FDA. Accessed 2025. Available at: https://www.fda.gov/industry/electronic-common-technical-document-ectd
[ii] GOV.UK. MHRA GxP Data Integrity Guidance: ALCOA/ALCOA+ Expectations. GOV.UK Assets. Accessed 2025. Available at: https://www.gov.uk/government/publications/data-integrity
[iii] U.S. Food and Drug Administration. eCTD Resources. FDA. Accessed 2025. Available at: https://www.fda.gov/industry/electronic-common-technical-document-ectd
[iv] International Council for Harmonisation (ICH). E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). ICH Database, U.S. FDA. Accessed 2025. Available at: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
[v] U.S. Food and Drug Administration. Computer Software Assurance for Production and Quality System Software (Draft Guidance). FDA, 2022. Accessed 2025.
[vi] IIBA. KnowledgeHub Techniques. International Institute of Business Analysis. Accessed 2025. Available at: https://www.iiba.org/knowledgehub
[vii] International Society for Pharmaceutical Engineering (ISPE). Commentary on Computer Software Assurance and Critical Thinking: GAMP® Perspective. ISPE, 2023. Accessed 2025. Available at: https://ispe.org
[viii] Project Management Institute. Requirements Management and Elicitation Fundamentals. PMI. Accessed 2025. Available at: https://www.pmi.org
[ix] U.S. Food and Drug Administration. Computer Software Assurance for Production and Quality System Software (Draft Guidance). FDA, 2022. Accessed 2025.