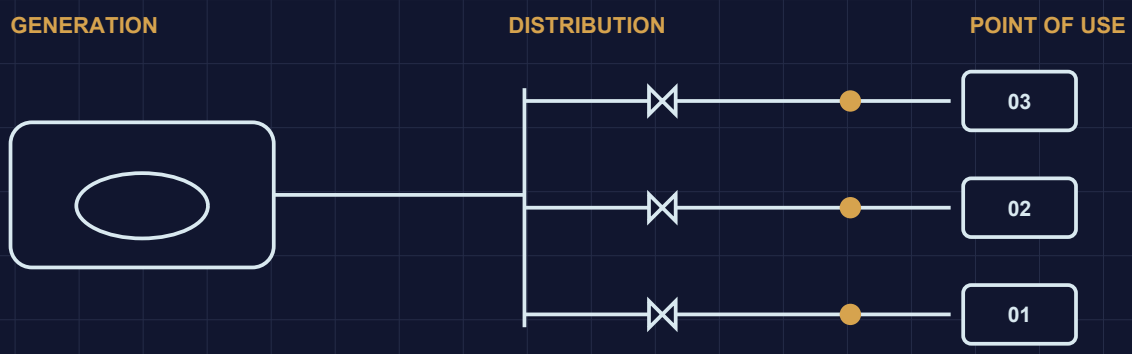
GUIDEGXP / PHARMA ENGINEERING

CRITICAL UTILITIES SYSTEMS

Clean steam, compressed air and process gases in GMP facilities

PRACTICAL GUIDE + EDITABLE TOOLKIT



Boundaries • treatment • sampling

24 CHAPTERS · 24 TOOLS

REV 1.0 / OCTOBER 2026 / ENGLISH EDITION

GuideGxP

guidegxp.com

A practical guide to critical utilities

Clean and pure steam, compressed air, process gases, distribution, qualification and lifecycle management in pharmaceutical facilities.

Edition control

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Publisher	GuideGxP · Pharma Engineering
Revision and print period	Rev 1.0 · October 2026
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Format	PDF guide and editable Word / Excel toolkit

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This guide helps structure decisions, documents and verification. Application requires suitable competence, current requirements and approval under the site quality system. A completed form or calculated result does not replace engineering judgement, system qualification or an authorised product decision.

Scope and intended readers

The guide is written for Engineering, CQV, QA, QC, manufacturing, maintenance, technical procurement and project owners. Its organising thread follows the utility from its source to the actual point of use: requirements, architecture, quality evidence, operating behaviour and maintenance of the approved state.

The principal scope is manufacture of human medicinal products. Readers determine the jurisdiction, product and process before applying a requirement. Provisions specific to sterile manufacture retain that context. Where Annex 1 principles are applied to non-sterile processes, the choice and implementation are documented; not every provision automatically extends to every use of air or gas.

Reference: EudraLex Volume 4: Good manufacturing practice (GMP) Guidelines; EU GMP Annex 1 · Annex 1 · Scope

Product boundaries

Included	Interface to coordinate	Separate assessment
Clean / pure steam and its point-of-use evidence	Feedwater, receiving process and sterilisation cycle	Complete water/WFI-system design and validation of every SIP cycle
Compressed air and process gases	Product, environment, final connection and safety	Medicinal-gas manufacture and specialist oxygen-service or pressure design
Networks, vacuum, monitoring and control	Automation, IT infrastructure, support utilities and rooms	A complete HVAC guide, functional-safety assessment or construction code
Qualification, maintenance, changes and suppliers	PQS, process documentation and product decisions	Replacement of approved site procedures

Criticality is not assigned solely by the name of the fluid. Contact with product, ingredients or relevant surfaces, indirect effects and failure consequences inform the assessment. The guide separates the judgement on the utility system from disposition of a batch or receiving process. The owners proposed in the cases are a working structure to adapt, without automatically transferring responsibilities reserved for other functions.

Reference: EU GMP Annex 1; EU GMP Annex 15 · Annex 1 §§6.1–6.2; Annex 15 §8

The Aurora site, its identifiers and every commercial offer used in the examples are fictional. An illustrative value is not a design recommendation, a pharmacopoeial specification or a preapproved acceptance criterion. The cases keep assumptions, units, reference conditions and the limits of the conclusion explicit.

Using the guide and toolkit

For a new project, start with Parts I–IV to define use, requirements and architecture; use Part V to build qualification evidence and Part VI for operation, changes and procurement. For a deviation, start at chapter 21 and return to the technical chapters describing the mechanism to investigate. The contents and bookmarks provide direct access.

From the question to the record

Working question	Guide route	Initial tools
What should the system demonstrate?	Chapters 1–4	TL-001, TL-002, TL-003, TL-004, TL-005
What evidence distinguishes steam problems?	Chapters 5–8	TL-008, TL-009, TL-010
How should air and gas quality be defined and controlled?	Chapters 9–12	TL-011, TL-012, TL-013, TL-014
How should networks, measurements and signals be interpreted?	Chapters 13–16	TL-006, TL-007, TL-015, TL-020
How can requirements, tests and release be connected?	Chapters 17–20	TL-017, TL-018, TL-019
How should events, changes and investment be managed?	Chapters 21–24	TL-016, TL-021, TL-022, TL-023, TL-024

Each tool retains the same TL identifier in both languages. The toolkit contains 12 Word tools and 12 Excel tools: documents, protocols and reviews in Word; registers, matrices and calculation models in Excel. Complete master files and individual modules are both provided. There are 24 distinct tools: masters and modules are two ways of accessing and using the same content.

Read the tool instructions, identify the owner and inputs, and then work from the clean form marked TEMPLATE. The EXAMPLE version is a separate completed case. Copy the working file into the site document system, assign its identifier and revision, and replace examples with approved data. Normal local document-control rules apply to the Word and Excel records.

Excel input areas are identifiable and formulas are protected against accidental edits. Logic codes remain consistent between languages; the display text explains the returned state. “Incomplete” does not mean compliant. A numerical comparison does not automatically authorise utility use. Before using a model for a GMP decision, verify its suitability, configuration and the controls required by the site.

Reference: EU GMP Annex 15; EU GMP Annex 11 · Annex 11 · Principle and §4; Annex 15 §2.4

Official references are clickable. Appendix B records source status and access limitations; Appendix C links all 24 tools to chapters. Preserve the distinction between the source requirement, the operational interpretation and the site-approved choice when adapting a template.

Source status and reading rules

The evidence cut-off is 10 October 2026. The register identifies the edition, authority, scope and limits of verification. A catalogue listing does not demonstrate access to the complete normative text. Before setting a specification or contract, the site confirms the applicable edition and obtains the authorised documents it needs.

Principal references at the cut-off

Family	Version / status	How to read it
EU GMP Annex 1	2022 revision, fully applicable from 25 August 2024	Apply provisions within the particular sterile-manufacturing context and stated conditions.
EU GMP Annex 15 / Annex 11	Final texts from 2015 / 2011	Revision initiatives have not replaced the final texts at the cut-off.
PIC/S	PI 006-4: 1 October 2026; PE 009-18: 24 September 2026	Recommendations and a guide with national implementation to verify; no automatic amendment of EU texts.
USA	Applicable CFR and cited final FDA guidance	Distinguish regulatory requirements from nonbinding guidance recommendations.
ISO 8573	Part 1:2010; Part 5:2025 and other parts in the register	Classes and methods do not select one universal GMP class for every user.
ASME BPE	BPE-2026 listed by the publisher	2026 effective/transition dates and clauses not verified; the linked contents still show 2024.
Pharmacopoeias	Obtain and assess current monographs for the relevant use	Public previews or proposals do not replace the applicable official text.

Reference: EudraLex Volume 4: Good manufacturing practice (GMP) Guidelines; EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; Recommendations on Qualification and Validation; Compressed air — Part 1: Contaminants and purity classes; Compressed air — Contaminant measurement — Part 5: Oil vapour content; Bioprocessing Equipment; Guide to Good Manufacturing Practice for Medicinal Products — Annexes

The text distinguishes applicable requirements, official guidance, technical standards, drafts and GuideGxP recommendations. Original operational methods explain how to organise the work; they do not turn an editorial proposal into a regulatory obligation. Technical standards are discussed within their scope and accessible information, without reproducing protected tables or reconstructing unverified numerical criteria.

Read each statement together with its condition of application. For example, a provision for gases in aseptic processes does not become an indiscriminate rule for all plant air. Similarly, utility steam quality, validation of a cycle and product disposition answer different questions.

Reference: EU GMP Annex 1; EU GMP Annex 15 · Annex 1 §§6.17–6.19; Annex 15

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PART 01 / CHAPTER 01

Utility governance, scope and lifecycle

Define responsibilities and boundaries between generation, distribution, process and quality.

RELATED TOOLS TL-001 · TL-002 · TL-003 · TL-004 · TL-019

A utility becomes a quality matter when its behaviour can affect the product, the surfaces that receive it or the process's ability to operate under the intended conditions. The system's name does not settle this assessment: two use points on the same header may have different exposures, operating modes and consequences. Before comparing generators and quotations, establish which service is being governed, for which process and through which connections. An incomplete boundary leaves unresolved precisely the decisions that will emerge during a failure or change.

Reference: EU GMP Annex 1 · EU GMP Annex 1

This chapter proposes a GuideGxP method for making those boundaries visible and assigning decisions. The intended outcome is an agreed project charter linking the production objective, technical responsibilities, quality assessment and acceptance evidence. The charter does not replace the URS: it gives it a stable foundation. A useful opening question is specific: who will demonstrate that the service reaches the use point as required, and who may authorise its use when only part of the documentation is available? The answer needs to precede equipment selection.

Reference: EU GMP Annex 1; EU GMP Annex 15; ICH Q9(R1); SRC-0050 · EU GMP Annex 1; EU GMP Annex 15; ICH Q9(R1); GuideGxP operational recommendation

Establish applicability before selecting documents

The guide primarily considers utilities for manufacturing medicinal products for human use. The applicable route depends on jurisdiction, product and the site's role. Active substance manufacture requires identification of its GMP context; finished medicinal product manufacture requires its own. Supplying gas to a process does not automatically constitute medicinal gas manufacture. Similarly, the presence of a steriliser does not extend the guide's scope to the entire medical device framework. Record these distinctions rather than leaving them to participants' familiarity with a similar installation.

Reference: EudraLex Volume 4: Good manufacturing practice (GMP) Guidelines; EU GMP Annex 1; EU GMP Annex 15; Part II: Basic Requirements for Active Substances used as Starting… · EudraLex index; EU GMP Annex 1; EU GMP Annex 15; EU GMP Part II

For sterile manufacture, Annex 1 links utility control to the risk to product quality and the contamination control strategy. Its provisions must not become an indiscriminate statement about every non-sterile service. Where a manufacturer chooses to apply its principles to products not intended to be sterile, it must document which principles it adopts and demonstrate their application. The project can therefore share a management foundation while applying different requirements to particular use points, provided that the distinction is understandable and verifiable.

Reference: EU GMP Annex 1 · EU GMP Annex 1

Document status also matters. At the verification date of 10 October 2026, the official European index retains Annex 11 from 2011 and Annex 15 from 2015. Revision consultations belong in regulatory surveillance; they do not automatically constitute adopted requirements. PIC/S PE 009-18 is dated 24 September 2026, and PI 006-4 came into effect on 1 October 2026 within its own context. These dates do not, by themselves, represent amendments to European legislation or uniform dates for national implementation.

Reference: EudraLex Volume 4: Good manufacturing practice (GMP) Guidelines; EU GMP Annex 15; EU GMP Annex 11; Recommendations on Qualification and Validation; Stakeholder consultation on Chapter 4, Annex 11 and new Annex 22; Concept paper on the revision of EU/PIC/S GMP Annex 15 —…; Publications; Guide to Good Manufacturing Practice for Medicinal Products —

Annexes · EudraLex index; EU GMP Annex 15; EU GMP Annex 11; PIC/S PI 006-4; EU GMP consultation; Annex 15 revision concept paper; PIC/S publications index; PIC/S PE 009-18

Three applicability questions to resolve in the charter

Question	Evidence to retain	Resulting decision
Which activity and product?	Description of the receiving process and the site's role	Identify the relevant GMP route, avoiding implicit extensions.
Which uses are sterile or aseptic?	Map of exposures and operating modes	Link specific requirements to the affected use points.
Which text is current or adopted?	Edition, scope, verification date and applicability rationale	Separate applicable requirements, proposed revisions and site choices.

Reference: EudraLex Volume 4: Good manufacturing practice (GMP) Guidelines; EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; Stakeholder consultation on Chapter 4, Annex 11 and new Annex 22; Concept paper on the revision of EU/PIC/S GMP Annex 15 —…; Part II: Basic Requirements for Active Substances used as Starting… · EudraLex index; EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; EU GMP consultation; Annex 15 revision concept paper; EU GMP Part II

GuideGxP recommends assigning maintenance of this applicability register to a competent function. A bibliography is insufficient: each reference used in the URS needs an explanation of the decision it supports. If two participants interpret the scope differently, make the conflict visible before ordering. Resolution may involve further investigation, internal consultation or a restriction on the intended service. Adding a generic phrase such as compliance with all GMP to the specification is unhelpful, because nobody could translate it into a conclusive test.

Reference: SRC-0050 · GuideGxP operational recommendation

Draw the boundary that the process actually uses

A skid's commercial boundary is only one useful boundary. Governing the service means following the path from generation or delivery to the actual process connection, including distribution, local regulation, filtration, flexible hoses and relevant temporary configurations. Then look in the opposite direction: which process conditions could affect the service or other use points? The GuideGxP proposal is to describe these paths through an inventory of uses and operating modes, giving each interface an owner and associated evidence.

Reference: EU GMP Annex 1; EU GMP Annex 15; ICH Q9(R1); SRC-0050 · EU GMP Annex 1; EU GMP Annex 15; ICH Q9(R1); GuideGxP operational recommendation

In sterile manufacture, Annex 1 requires a lifecycle perspective: design, installation, qualification, operation, maintenance and monitoring must support the utility's intended function. This perspective prevents control from being considered complete when the generator passes its acceptance tests. The service can change when a user is added, a connection is modified or the standby mode is revised. Documentary continuity allows these changes to be compared with the original scope and helps establish whether existing evidence remains relevant to the configuration actually used.

Reference: EU GMP Annex 1 · EU GMP Annex 1

Map of responsibilities along the path

Section or interface	Proposed responsibility	Verification question
Source or generator	Technical system owner	Who documents inlet conditions and the service operating range?
Header and branch	Distribution owner	Who knows all the use points and alternative configurations?
Final connection	Process owner with maintenance	Who controls the component, assembly and conditions of use?
Receiving process	Process owner with the Quality function	Who interprets the effect on the process and distinguishes utility authorisation from the product decision?

Reference: SRC-0050 · GuideGxP operational recommendation

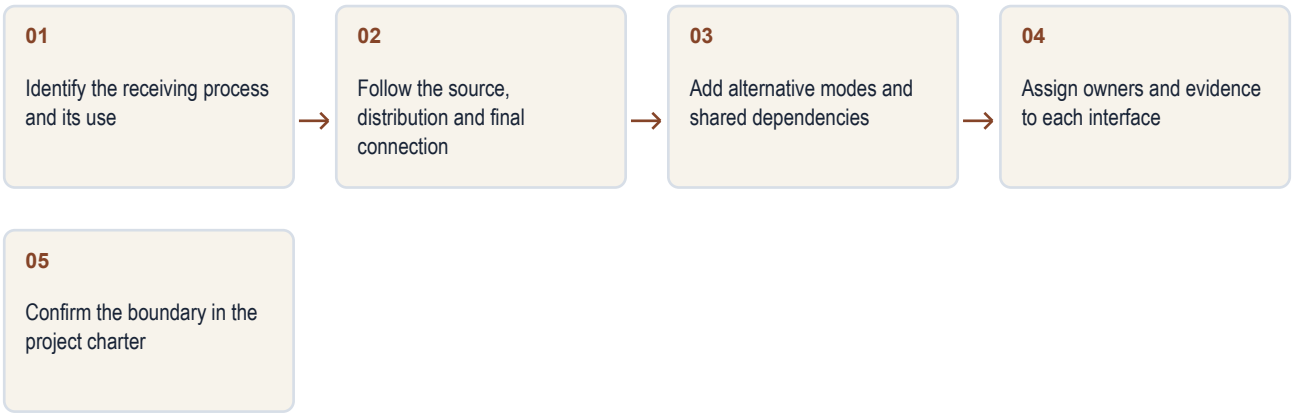
The map needs to include dependencies excluded from the supply but necessary for the service. Electrical power, cooling, instrument air, feedwater or shared control may have different owners. Describing them as interfaces enables precise questions without turning the utility project into a redesign of the entire site. For each dependency, the charter should state the required condition, who confirms it and the consequence of unavailability. A requirement assigned to another team remains a service requirement: contractual exclusion does not make it irrelevant.

Reference: SRC-0050 · GuideGxP operational recommendation

A simplified drawing is often more useful than a very long list. It does, however, need references that allow controlled details to be retrieved: system identifiers, responsibility handover points and connections awaiting confirmation. GuideGxP suggests checking the drawing with process operators as well as the designer. A dashed line can mark a path to be confirmed, but it must not become a permanent graphical answer to missing knowledge. Uncertainty calls for an assigned closure activity and an explicit consequence for the project.

Reference: SRC-0050 · GuideGxP operational recommendation

From the commercial boundary to a governed service



Reference: EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); SRC-0050 · EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); GuideGxP operational recommendation

Distinguish those who perform, assess and authorise

Annex 15 places qualification within the lifecycle and requires trained personnel, defined responsibilities and appropriate quality oversight. It does not require identical organisational arrangements for every activity or every technician to report hierarchically to QA. Adapt the proposed structure to the site's quality system. An owner may coordinate work without having the expertise to judge every result; an expert may assess its correctness without delegated authority to authorise production start-up. Making this distinction explicit prevents signatures with ambiguous meanings.

Reference: EU GMP Annex 15 · EU GMP Annex 15

In the charter, GuideGxP recommends describing responsibilities through observable decisions. The designer prepares the technical rationale; the process representative confirms uses and modes; the laboratory evaluates its assigned analytical aspects; competent experts examine assumptions; the authorised function approves under the quality system. Not everyone needs to sign every document. What matters is knowing which verification precedes a particular authorisation and where it is recorded. A RACI matrix is useful only if its letters correspond to activities understood by those assigned to them.

Reference: SRC-0050 · GuideGxP operational recommendation

Questions that make a responsibility executable

- Which decision does this function need to make, and with what information?
- Which expertise enables it to assess the evidence, and which delegated authority enables it to approve?
- Who manages a conflict between production needs and the limits of available evidence?
- Who receives the system after the project and keeps the references current?
- Which function decides on potentially exposed product, separately from the utility's technical availability?

Reference: SRC-0050 · GuideGxP operational recommendation

Handover deserves a specific responsibility. The future operator needs to be able to retrieve the qualified boundary, permitted uses, open commitments and conditions requiring reassessment. Handing over a folder full of files without explaining these points transfers documents but not control. The future owner should participate in decisions affecting maintenance, sampling access and recovery from shutdown. Their observations are particularly valuable when a solution works during testing but calls for unrealistic actions in everyday operation.

Reference: SRC-0050 · GuideGxP operational recommendation

Technical approval and the product decision need to retain distinct meanings in project language. The former may confirm that a particular modification has been installed and verified within a defined boundary. The latter requires evaluation of the specific product exposure and responsibilities under the quality system. In the GuideGxP model, the charter identifies the interfaces between these decisions without assigning new regulatory authority to the signatory of the technical document. Clear wording prevents a signature from being reused for a purpose different from the one actually assessed.

Reference: SRC-0050 · GuideGxP operational recommendation

Manage assumptions and priorities throughout the lifecycle

ICH Q9(R1) links risk decisions to scientific knowledge and patient protection, with proportionate effort and formality. Uncertainty, importance and complexity help determine the level of formality; limited resources do not justify reducing the necessary rigour. For a project, this means recognising what is not yet known. An apparently precise score built on an unobserved use point or an undescribed operating mode does not make the analysis more reliable. The method's value lies in the quality of the information and the decisions that follow.

Reference: ICH Q9(R1) · ICH Q9(R1)

GuideGxP proposes keeping an assumptions register separate from conclusions. A row should distinguish the assumption, its reason, missing information, planned action and the impact if it proves incorrect. For example, assuming that two users do not operate together calls for verification of the production schedule and how that separation is maintained. If it cannot be demonstrated, the project needs to consider concurrent operation or explicitly manage the limitation. The register allows an individual assumption to be discussed instead of reopening the whole project each time with incomparable opinions.

Reference: SRC-0050 · GuideGxP operational recommendation

Three governance errors and their correction

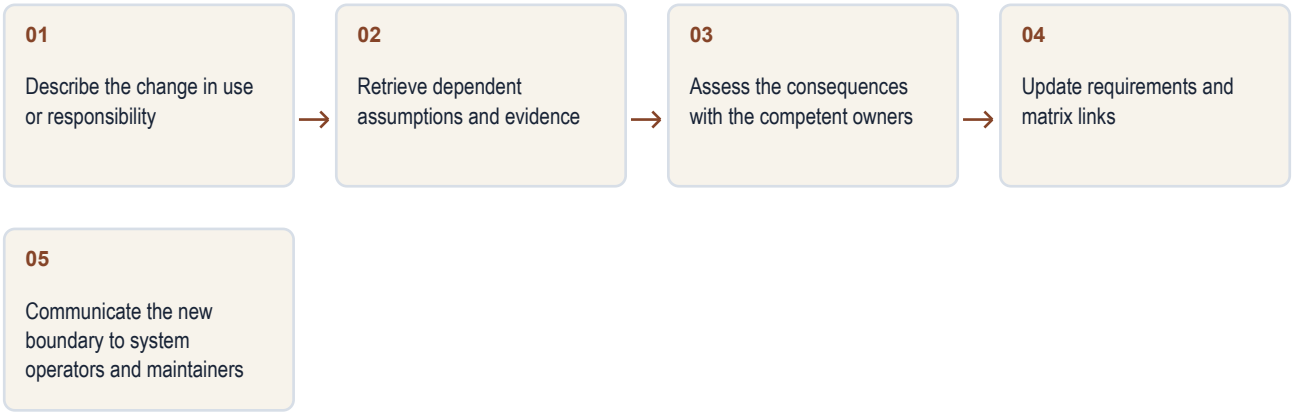
Error	Observable sign	Proposed correction
Connection without an owner	The supplier stops at the header and the process team assumes the hose is included	Assign the boundary, component and verification before closing the URS.
Technical completion mistaken for production availability	An installation record is used as the sole authorisation	Define separate decisions and the evidence needed for each.
Shared dependency overlooked	Main and standby supplies depend on the same unevaluated service	Add the scenario to the register and assign verification of the dependency.

Reference: SRC-0050 · GuideGxP operational recommendation

Charter revisions need to respond to identifiable events: a new product, an additional operating mode, a change of responsibility or a new supply route. Risk review must take acquired knowledge into account, including product availability. The project should not wait for its scheduled review to address an already evident change. Equally, updating the document does not mean restarting every activity: identify which decisions depended on the changed assumption and review them to a justified extent.

Reference: ICH Q9(R1) · ICH Q9(R1)

Bringing a change into the charter



Reference: EU GMP Annex 15; EU GMP Annex 11; SRC-0050 · EU GMP Annex 15; EU GMP Annex 11; GuideGxP operational recommendation

Aurora case: the new nitrogen branch

WORKED CASE · Original case CU-CASE-A — from a piping project to an agreed charter

The fictional Aurora site intends to add POU-N2-03 to header HN-01, supplied by GN-01. A standby route, BN-01, is also planned. The project manager receives a quotation ending at a valve on the header and a proposed installation date. Production interprets the quotation as making gas available at the new machine; the supplier considers final regulation, the flexible connection and verification of the standby path excluded. No numerical acceptance values have yet been set: the initial issue is the service to describe and the responsibilities for demonstrating it.

During the charter review, the process representative explains how nitrogen will be used and points out that the connection will be disconnected during some activities. The maintenance technician shows a possible standby configuration different from the drawing. The team avoids calling these observations mere installation details: they change the boundary to be controlled. The utility owner adds the final connection to the drawing and distinguishes the normal path, the BN-01 path and the disconnected state. Each section receives a representative and a link to information still to be obtained.

Two options emerge. The first leaves the final connection within the machine project, requiring a documented interface and coordinated verification. The second includes it in the utility supply. The team does not choose by counting documents: it compares who has the expertise, how changes will be managed and what evidence will be available for the actual assembly. The illustrative choice keeps the component within the process project but assigns a single interface owner to coordinate information and verification between the two teams.

The Quality function also clarifies that signing the charter does not authorise production use of the new point. The document authorises development of the URS within the agreed boundary. The laboratory needs to contribute to defining the necessary analytical information; the technical expert needs to check the consistency of service conditions; the function authorised under the quality system will assess the final evidence for the intended use. The commercial manager revises the quotation comparison because the chosen solution includes coordination activities that the original price did not make visible.

The team records the actual concurrency of POU-N2-03 and existing users as an open assumption. It records standby availability separately: BN-01 appearing on the drawing does not demonstrate that the service can be used as required. Production is assigned to describe operating modes; engineering

collects dependency data; the system owner checks identifiers and future responsibilities. Priority follows the consequence of a wrong decision, not a score selected to justify a conclusion already reached.

The charter is closed for this phase when scope, interfaces, owners and actions are sufficiently defined to write verifiable requirements. Detailed quality and capacity decisions remain open and are addressed in later chapters of the case. The lesson is practical: a project can progress with declared uncertainties if it knows which choices depend on them and when they need resolution. It cannot use installation progress as evidence that those uncertainties have disappeared. Aurora retains the updated charter as a common reference for both teams and the future operator.

Reference: EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); SRC-0050 · EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); GuideGxP operational recommendation

Complete the tools and close the first stage

Before handover, organise a short reconstruction starting from a real question: who needs to be involved if the final connection changes? The operator should find the owner in the charter, the affected use point in the register and the dependent requirements in the matrix. If the trail breaks, the defect is not necessarily a missing document: it may be an inconsistent identifier or a vaguely described responsibility. Correcting the link during the project demands less operational attention than reconstructing it during a shutdown. This readability test can be performed without simulating any production authorisation.

Reference: SRC-0050 · GuideGxP operational recommendation

The coordinator also retains the reasons for rejected decisions where this helps explain the selected boundary. Alternatives, the selection criterion and available evidence are sufficient; there is no need to transcribe every conversation. A successor can then distinguish a deliberate choice from an omission and assess whether the conditions supporting it still exist.

Reference: SRC-0050 · GuideGxP operational recommendation

Use TL-001 as the initiation document: describe the objective, site, product and required service before listing equipment. Link the boundary drawing and record dependencies with their owners. In the decisions section, distinguish what has been agreed from what still needs evidence. The completed toolkit example explains the logic; adapt the blank template to your project and quality system. Names and delegated authorities need to reflect the real organisation rather than being inherited from the example.

Reference: SRC-0050 · GuideGxP operational recommendation

Then open TL-002 to inventory use points and TL-003 to describe contact, consequence and uncertainty. These registers feed TL-004: a useful URS comes from translating uses into requirements and verification methods, not copying generic rows. TL-019 retains the link between requirement, risk, technical decision and evidence. At this stage, the matrix may show activities still to be performed, provided it does not present them as completed tests. The link’s value lies in knowing what is missing and why it prevents a particular decision.

Reference: EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); SRC-0050 · EU GMP Annex 1; EU GMP Annex 15; EU GMP Annex 11; ICH Q9(R1); GuideGxP operational recommendation

Charter closure check

- The receiving process and intended modes are unambiguously identified.
- Every final connection has an owner and a documented interface.
- Functions performing, reviewing and authorising decisions are distinct.

- Open assumptions have an owner, a verification activity and a stated consequence.
- The initial URS and traceability matrix can start from the same boundary.
- The future owner knows which changes will trigger a charter review.

Reference: SRC-0050 · GuideGxP operational recommendation

The chapter’s objective is achieved when a competent colleague can reconstruct the service and decision path without relying on oral explanations. If an answer remains implicit, improve the charter or map rather than adding signatures without substance. This foundation makes the subsequent inventory more precise: each use point can be examined as a concrete use, with a real connection and an identifiable owner. Quality, capacity and qualification discussions will then start from a shared question and remain verifiable as the project moves into operation.

Reference: SRC-0050 · GuideGxP operational recommendation