



QUALIFICENCY
CONSULTING

The User Side of Radiopharmaceutical Facility Design

Why process reality, user requirements and operability
must be mature before engineering is frozen

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About Qualificiency

01

Executive perspective

CORE POSITION

Engineering can only integrate the process that has been defined for it. Our role is to help make that user-side definition operationally true, sufficiently mature and testable before important design and purchasing decisions are frozen.

Engineering can only integrate the process that has been defined for it.

Qualificency works on the user side of radiopharmaceutical projects. We bring future operators, engineering partners, specialist equipment suppliers, QA, Validation and Radioprotection into one connected process so that process reality, GMP, qualification, operability and performance shape the project from the beginning.

A radiopharmaceutical process can be described in a few boxes on a flow diagram. The real operation is richer: operators intervene, equipment needs cleaning and maintenance, samples and waste move through the facility, dose accumulates, information arrives at different times, suppliers need to support systems for years, and a short-lived product keeps decaying while the project team resolves an assumption.

Across radiopharmaceutical projects, a large proportion of the work is repeatable. Qualificency uses 80/20 as a working principle. The Pareto principle is well established in quality improvement as a way to focus attention on the relatively few causes that create a disproportionate share of effects [7,8]. Our standardised systems therefore use repeatability deliberately: establish the recurring core correctly and quickly, then protect project time for the smaller proportion that requires real judgement.

That decisive layer contains the interfaces, operating scenarios, organisational realities and lifecycle decisions that make the solution fit the actual process. It may represent a smaller part of the final document or project, yet it deserves a disproportionate share of the thinking, challenge and coordination. Maintainability, support, recovery, documentation usability, training, change management, obsolescence and the way the organisation will own the solution after handover all sit here. Published industrial-project and process-industry evidence supports the underlying concentration effect: in nine fast-track industrial projects, design deviations represented 78% of deviations and 79% of deviation costs; process-industry studies report that thorough design review can remove 80–95% of design errors before operation, while design-related causes still appear in 20–50% of studied incidents and accidents [9,10].

That is the subject of this paper: how to standardise intelligently, identify the decisions that genuinely require judgement, connect them to the wider pharmaceutical quality and contamination-control system, and translate user needs across the companies and disciplines that have to deliver the facility.

80%

of operational
consequences
after handover

20%

project-specific
judgement

80%

operational
consequences



Smaller proportion

Complex interfaces, scenarios and lifecycle decisions require real judgement.



Disproportionate consequence

These decisions drive the majority of operational effects after handover.

01

Facility design starts before engineering

The most expensive design decisions are often made before the project feels detailed. Room adjacencies, equipment locations, transfer concepts, shielding interfaces, penetrations, HVAC concepts, service zones and maintenance routes can become difficult to change long before an operator has seen a final operating sequence.

A project can be technically well engineered while still missing important parts of the future operation. Engineering can solve the requirements it receives exactly; user-side maturity determines whether those requirements describe the future process at the level needed for the decisions being made.

The most expensive design decisions are often made before the project feels detailed.

The process is more than the chemistry

In radiopharmaceutical manufacturing, the process includes the complete operating system around the chemistry: receipt and staging; synthesis or labelling; purification; sterile filtration or aseptic transfer; filling; in-process controls; QC sampling; packaging; waste; cleaning and decontamination; line clearance; radiation surveys; environmental monitoring; maintenance; calibration; batch review; release; and the flow of information needed to make decisions in time.

It also includes the operator, the organisation and the business constraints. A strong operational solution protects product quality while remaining staffable, maintainable, recoverable and supportable. We therefore test design input against Safety, Quality, Delivery and Cost (SQDC) alongside technical compliance.



A requirement is a decision boundary

A good user requirement tells the design or supply team what capability, constraint or outcome must be protected while leaving the detailed technical solution with the party that owns the design. Over-prescriptive requirements can freeze an inferior solution too early; vague requirements can shift critical user decisions toward suppliers whose expertise lies elsewhere. The objective is better decisions, expressed early enough to matter and clearly enough to verify.

QUALIFICENCY PRINCIPLE

Design input should describe the process as it will be operated, maintained, supported and improved, with drawings translating that reality into technical form.

02

Radiopharmaceutical design is a multi-constraint problem

Radiopharmaceutical facilities sit at the intersection of pharmaceutical GMP, sterile processing, radiation protection, specialised equipment, short half-lives, logistics, occupational exposure, waste management, quality systems and often very small batches. These constraints interact and change one another.

EU GMP Annex 3 recognises that risks depend on radiation type, energy and radionuclide half-life and calls attention to cross-contamination, radionuclide contaminants and waste. EU GMP Annex 1 requires sterile manufacture to be managed using quality risk management and suitable process, engineering and microbiological knowledge. [1,2]

The design challenge is to make GMP, radiation protection and operational performance work together as one system. Each control has an objective, and the complete facility has to protect those objectives simultaneously. This requires decisions that connect technical design to the future operating system. The regulatory architecture reinforces the same point: GMP and radiation protection are not one regulatory framework and they do not have the same accountable owners. EU GMP Annex 3 explicitly requires radiopharmaceutical manufacture to adhere to radiation-protection regulations, while Council Directive 2013/59/Euratom establishes the European basic-safety framework for occupational, medical and public exposure and covers the manufacture, handling, storage and disposal of radioactive material. [2,15] The project therefore does not need one regulation; it needs one operating model in which requirements from different frameworks are visible, traceable and mutually workable.

Multiple constraints. One operating system.

Constraint	What it influences	User-side question
Decay and time	Batch sequence, proximity, transport, QC and release	Where can time be lost, and where can it not?
Radiation protection	Shielding, handling, access, monitoring, occupancy	What requires shielding, what requires containment, and when must a person intervene?
Asepsis / contamination control	Barrier strategy, transfers, interventions, cleaning, EM	Where is the critical boundary and what crosses it during the real process?
Process chemistry	Materials, hold-up, transfer paths, temperature and compatibility	Which details materially affect yield, purity, cleanability or robustness?
Waste and residual activity	Segregation, decay storage, removal routes and capacity	What leaves the process, when, and under what radiological condition?
Maintenance and lifecycle	Access, modularity, spares, service model and obsolescence	Can the system be kept in a controlled state after handover?
People and organisation	Reach, staffing, training, responsibilities and workload	Can the future organisation operate and own the solution reliably?

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03

The user gap in capital projects

Most engineering methodologies assume that a user exists who can define what the process needs. In practice, that user may be the least available person in the project.

- The future operating organisation may still be forming while major project decisions are already being made.
- Current operators may be running production and have limited capacity for design workshops, document review and vendor clarification.
- Process-development knowledge may sit with scientists while routine production knowledge sits elsewhere.
- The project representative may know the programme objectives while daily interventions, cleaning, recovery and handover still need deeper operational definition.
- Equipment suppliers know their platforms; the customer-side process definition determines how those platforms must work within the intended operation.
- Engineering teams may correctly avoid making user decisions, leaving assumptions unresolved until late design reviews.

This creates a predictable gap: workshops may have taken place and a URS may exist while the user-side information is still too immature to expose the operating constraints that matter.



THE GAP WE FILL

Qualificency can act as an experienced user-side partner while the future organisation is still forming, when operational teams have limited project capacity, or when lived process knowledge needs translation into design, supplier and qualification decisions.

Why lived experience changes the questions

People who have lived radiopharmaceutical production tend to recognise where apparently small design choices become daily constraints: visibility at a connection point, recovery from a difficult transfer, a cleaning sequence that changes dose or contamination risk, a sample route that interrupts flow, or a maintenance task whose real execution differs from the theoretical access model.

Lived process experience strengthens the problem statement that engineering and suppliers receive, complementing the calculations and specialist design work that follow.



THE GAP WE FILL

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04

Standardise the URS - preserve the judgement

A mature URS should benefit from standardisation. Common requirement families can be maintained, improved through experience and applied quickly. The repeatable 80% should therefore consume relatively little project effort, leaving most of the thinking capacity for the 20% that genuinely changes the outcome.

The useful question is: which requirements are stable enough to standardise, which need a project-specific overlay, and which operational or lifecycle expectations need to be added because regulations, generic templates and supplier quotations only cover them partly?

Start with operating scenarios, then translate them into equipment requirements



Routine
production



Setup /
loading



Sampling



Cleaning /
decontamination



Maintenance /
recovery

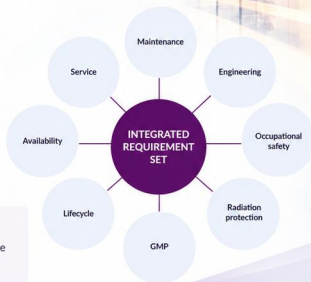
Start with operating scenarios, then translate them into equipment requirements

Before detailed requirements are finalised, we reconstruct the scenarios the equipment and facility must support: routine production, setup, material loading, sampling, cleaning, decontamination, waste removal, maintenance, calibration, interventions, recovery and foreseeable abnormal conditions. Where multiple products or radionuclides are expected, we test the intended operating envelope rather than one ideal batch.

Then build a requirement set that is testable at the right level. Some needs belong in a reusable core. Others belong in the project overlay. Still others relate to lifecycle ownership: serviceability, support and escalation expectations, training, spare parts and obsolescence, documentation and data availability, change notification, recovery and the transfer of knowledge to the future organisation.

The same principle applies to requirements that come from different disciplines. GMP, radiation protection, occupational safety, engineering, maintenance, service, availability and lifecycle requirements can retain their own regulatory sources and accountable owners while still being managed as one traceable requirement system. Separating them too early into independently developed discipline documents risks hiding exactly the interfaces that later become design constraints.

This approach connects URS, supplier selection, design review, DQ, FAT/SAT, IQ/OQ and process qualification without forcing every requirement into every protocol. The line of evidence should be proportionate to the decision it supports.



INTEGRATION PRINCIPLE

Different sources. Different owners. One integrated requirement set.

05

A standard core. A project overlay. What sits on top.

Hot cells illustrate the model particularly well. Detailed hot-cell design and fabrication normally belongs to a specialist supplier. The user defines what the equipment must enable, the engineering partner integrates it into the facility, and qualification demonstrates that the installed solution performs as intended.

Much of the URS can be standardised deliberately. That is a strength: it reduces variability, speeds specification and makes supplier responses easier to compare. The standard core starts the conversation; the project-specific and lifecycle overlays complete it.



Reusable core

Examples: Standards and documentation; general containment and shielding expectations; materials and finishes; alarms/interlocks; utilities; data/calibration expectations; FAT/SAT and qualification support.

Why it matters: Provides a proven baseline, reduces variability and accelerates specification.



Process-specific overlay

Examples: Radionuclide and activity envelope; exact manipulations and transfer strategy; sterile boundary; product-contact pathway; cleaning/decontamination; waste and sampling; intervention and recovery scenarios.

Why it matters: Determines whether the platform truly fits this process and operating model.



Operational and lifecycle overlay

Examples: Maintainability; support and escalation model; operator and maintainer training; spare/obsolescence strategy; software/data dependencies; change management; documentation usability; organisational ownership; major-maintenance access; activated-component handling; decommissioning assumptions.

Why it matters: Determines whether the solution can remain available, controlled, supportable and ultimately removable or retired safely after the project team leaves.

The '80/20' formulation is our Qualificency working principle. Published evidence across quality, industrial projects and process industries repeatedly shows the same concentration pattern: relatively few causes, design decisions or unresolved issues can account for a disproportionate share of downstream rework, cost or risk.[7–10] We therefore use standardised systems to complete the repeatable majority correctly and quickly, then spend the majority of project judgement on the smaller set of requirements and interfaces that carry disproportionate consequence.

The 80/20 effect continues after handover

The allocation of attention during the project becomes visible in routine operation. The repeatable majority should disappear into normal ownership because it was resolved through proven requirements and standard methods. The smaller project-specific portion continues to shape how easily people can operate, maintain, clean, recover, release, change and support the process. Front-end planning research has reported cost differences of 6–25% and schedule differences of 6–39% between projects with differing levels of effective front-end planning, reinforcing the value of resolving definition early.[11]

When that decisive portion is rushed, the consequences can recur for years as workarounds, extra handling, avoidable interventions, downtime, deviations, retraining, requalification effort, supplier dependence, unnecessary waste, lost capacity and other forms of operational friction. Pharmaceutical operational-excellence examples show how strongly design and operating-system choices can affect later performance: reported results include 38% shorter lead times and more than US\$13 million in savings at Abbott Longford, an 87.5% reduction in changeover time on a Johnson & Johnson packaging line, and more than 20% improvement in OEE at Bayer SOLIDA-1.[12–14] These examples demonstrate scale of effect.

Our working principle is therefore deliberately direct: the 20% that deserves the greatest attention during the project is often the same 20% that causes 80% of the operational problems, inefficiencies and losses afterwards. The exact ratio will vary by project; the evidence supports the concentration of impact rather than a fixed mathematical law. Standardisation should save thinking, not replace it.

80/20 PRINCIPLE

The repeatable 80% should be completed correctly and quickly through proven systems. The decisive 20% deserves most of the project judgement and focus. When that 20% is rushed, it is often the same 20% that causes 80% of the operational problems, inefficiencies and losses afterwards.



20% decisive / project-specific

80% repeatable core

06

What decides whether the process can actually be operated

Activity profile and source geometry

A nominal maximum activity is only one part of the requirement. Location, distribution, duration and movement of activity through the process can drive shielding, monitoring, manipulator use, maintenance strategy and occupancy assumptions. User input therefore describes the operating sequence alongside the design-point number.

Manipulations, interventions and APS

An intervention is an operating scenario as well as a geometric one. The project has to ask whether it can be performed safely and repeatedly, whether the contamination-control strategy supports it, and - for aseptic processing - whether the intervention strategy can be represented and challenged through aseptic process simulation. Annex 1 expects APS to include aseptic manipulations and interventions that occur during normal production as well as relevant worst-case situations. [1]

This changes the design conversation. An acceptable intervention combines technical access with a workable sequence, suitable tools, visibility, operator position, time, contamination control, dose management, recovery and the ability to train and qualify people for the way the process is intended to run.



Cleaning and decontamination

"Cleanable surface" becomes a meaningful user requirement when it is connected to the expected contamination, cleaning and disinfection agents, relevant residues, reachability, disposable components, effectiveness evidence and the way radioactive contamination changes the acceptable sequence.

Waste, recovery and abnormal conditions

Waste and recovery are part of the manufacturing process. Failed transfers, dropped items, blocked lines, alarms, power interruption, failed manipulators and rejected batches all create requirements for safe state, access, segregation, investigation and restart. Good design input anticipates credible failure while keeping the response proportionate to realistic scenarios.

Design the release system, not only the manufacturing process

In radiopharmacy, release is an operating pathway that the facility and process must enable. Short radionuclide half-lives mean that sampling, QC testing, data availability, review, certification and dispatch can sit directly on the critical path to the patient. Annex 3 recognises that some radiopharmaceuticals may need to be distributed and used before all chemical and microbiological tests are complete, provided the staged release procedure and responsibilities are precisely defined. Annex 16 provides the wider QP certification and batch-release framework, while Annex 17 provides the EU GMP framework for Real Time Release Testing and parametric release where these approaches form part of the authorised control strategy. [2,16,17]

This means release should be designed together with manufacture. Sample routes and volumes, QC proximity and capacity, information flow, automated data, review responsibilities, decision timing, quarantine and status control, recovery from atypical results and the consequences of delay all influence whether the product can be released while it is still clinically useful. A technically correct production sequence can still fail operationally if the release system cannot keep pace with it.

DESIGN PRINCIPLE

Design the release system, not only the manufacturing process.



Maintenance, support and organisational ownership

Maintainability includes physical access, competent support, understanding of the installed system, software and configuration dependencies, spares and obsolescence planning, change control and the ability to restore the process within an acceptable operating window. These requirements are often commercially important even when GMP describes them only indirectly.

Lifecycle ownership also extends beyond routine maintenance. For cyclotron facilities, material selection, activation, access strategy, removable components, contamination control and temporary storage can affect eventual dismantling and decommissioning. IAEA TRS 471 explicitly recommends planning for decommissioning when the facility is built and links early choices such as vault materials, activation and service access to the difficulty and cost of later removal. [18] A project does not need a detailed end-of-life method at concept stage, but it should avoid design decisions that make future maintenance, component removal or controlled retirement unnecessarily difficult.

7. CCS as a holistic control strategy

A Contamination Control Strategy connects the technical, organisational and quality systems that together control contamination. Annex 1 expects the CCS to consider design, premises and equipment, personnel, utilities, raw materials, vendor approval, outsourced activities, process risk management, validation, maintenance, cleaning and disinfection, monitoring, CAPA and continual improvement. It should also connect the interactions between those systems. [1]

The CCS therefore belongs across functions. It connects physical design with the Pharmaceutical Quality System, organisational responsibilities, hiring and competence, process controls, suppliers, maintenance, monitoring, validation and routine management review.

Radiopharma adds another dimension: radiation-protection decisions can alter access, pressure relationships, intervention methods, cleaning, maintenance and waste handling. A useful CCS therefore combines pharmaceutical contamination-control expertise with radiopharmaceutical operating reality so the complete system can be evaluated as one strategy.



QUALIFICIENCY PRINCIPLE

The CCS should explain how the organisation controls contamination as a system. The document provides the visible evidence of that integrated strategy.

08

Clear roles and strong translation across interfaces

Successful projects work when each party owns the decisions it is competent and accountable to make, while the interfaces are actively translated and coordinated across the team.

Party	Primary ownership	Critical interface
User / manufacturer	Intended process, operating model, quality objectives, acceptable risk and business priorities.	Makes process and operating decisions; remains accountable for the manufacturing system.
Qualificency	User-side process definition, requirement maturity, operability, GMP/QMS integration, supplier and verification challenge.	Translates needs across user, engineering, equipment suppliers, QA, Validation and Radioprotection; keeps the full operating system connected.
Engineering partner	Facility and system engineering design and multidisciplinary technical integration.	Converts mature requirements into a coordinated design and identifies technical trade-offs.
Hot-cell / equipment supplier	Detailed proprietary equipment design, manufacture, vendor testing and technical documentation.	Demonstrates how its solution meets requirements and provides evidence for integration and verification.
QA	PQS governance, quality oversight, quality-risk acceptance routes, deviation/change/CAPA governance.	Ensures quality decisions remain controlled and appropriately owned.
Validation / qualification	Lifecycle strategy, traceability and execution of qualification/validation evidence.	Turns critical requirements and risks into proportionate verification while QA retains quality-system ownership.
Radioprotection	Radiological risk assessment, dose/contamination controls and applicable radiation-safety responsibilities.	Ensures shielding, access, monitoring, waste and work practices remain radiologically defensible and integrated with GMP.
Operations / technical functions	Routine production, maintenance, QC, logistics, cleaning, training and support realities.	Expose the non-project work needed to meet SQDC after handover.

OUR ROLE

We translate user needs into language engineering and suppliers can act on, then translate proposed solutions back into what they mean for operations, quality, validation, radioprotection and SQDC.



09

Supplier choice should become testable before purchase

Supplier selection is strongest when technical capability, delivery model, documentation, support, lifecycle performance, organisational fit and evidence are evaluated together. This applies across the project ecosystem - specialist radiopharmaceutical equipment, utilities, automation, services and other suppliers that can materially affect Safety, Quality, Delivery, Cost (SQDC). The central question is whether the supplier can deliver, document, support and maintain the required capability in a way that fits the customer's process and operating model.

A strong selection process therefore converts important needs into comparable evidence before the order is placed. Different technical architectures can still be compared against common outcomes: process fit, quality-system maturity, project execution capability, documentation and qualification support, lifecycle service, change and obsolescence management, integration behaviour, schedule credibility and operational support.

The objective is to make "can they do it?" evidence-based and to preserve a line from supplier claim, through contractual or technical commitment, to the verification evidence expected later in the project.

Need

Supplier claim

Commitment

Evidence

Verification

SUPPLIER PRINCIPLE

A supplier decision is stronger when the reasons for choosing can later be tested against what was actually delivered.

10

Design qualification and validation should protect intended use

Design qualification is most valuable while design decisions can still change. Annex 15 defines DQ as documented verification that the proposed design of facilities, systems and equipment is suitable for the intended purpose. [3] A mature intended purpose allows DQ to function as meaningful design assurance rather than a retrospective consistency check.

DQ is early design assurance

A useful DQ process connects user requirements, process risks, design assumptions and evidence while decisions are still reversible. It identifies where a requirement is satisfied, conditional, accepted with rationale, or still needs evidence during FAT, SAT, IQ, OQ, PQ or process validation.

Qualification follows criticality and intended use

Some requirements can be closed through design review or robust supplier evidence. Others need inspection, calibration, functional challenge, alarm testing, mapping, smoke studies, APS or process-performance evidence. The objective is stronger evidence for the requirements that carry material risk or performance consequence.



User requirements



Risk assessment



QUALIFICIENCY PRINCIPLE

Qualification should confirm both that equipment was installed correctly and that the process can be operated as intended.

11

How Qualificency works

Our way of working is deliberately collaborative. We begin with the process, the users and the intended operating model. That shared understanding allows the right specialist to design each part with fewer hidden assumptions, while we stay close enough to the interfaces to see when one decision creates a consequence elsewhere.

Stage	What we do	Decision enabled
1. Process immersion	Walk the process from receipt to release, including people, cleaning, waste, sampling, maintenance, abnormal conditions and the practical constraints of the future organisation.	Do we understand how the operation is expected to work?
2. Requirement maturation	Apply a proven standard core, then resolve process-specific and lifecycle overlays into testable user requirements.	What must engineering and suppliers protect?
3. Supplier and design challenge	Compare supplier capability against evidence; challenge layouts, equipment concepts, flows, interfaces and maintainability.	Is the selected solution credible and fit for the intended use?
4. CCS / QMS integration	Connect design decisions to the contamination-control strategy, PQS, responsibilities, training, maintenance, monitoring and change control.	Does the wider operating system support the physical design?
5. Qualification strategy	Map critical requirements to proportionate evidence and keep QA, Validation and operational ownership clear.	How will fit-for-purpose be demonstrated and governed?
6. Operational readiness and lifecycle ownership	Connect the installed solution to procedures, training, staffing, support, release, maintenance, requalification, change control, routine SQDC performance and the eventual end of operations.	Can the organisation own, sustain, improve, requalify, adapt and eventually retire the solution safely and effectively across its full lifecycle?

Experience across the lifecycle

Our team brings lived operational experience from across radiopharmaceutical operations and the wider supply chain - from external manufacturers and suppliers through material receipt, production, QC, QP release, storage, transport and dispatch. Within that operating context we also bring Radioprotection, Regulatory Affairs, QC and Validation experience. We complement this core with access to engineering, architecture and (early development / clinical) CMC expertise when the project needs those disciplines. This breadth helps us translate needs across functions while each specialist retains ownership of their own technical and accountable domain.

That allows us to support the full lifecycle: strategy and operating model; process and facility definition; supplier selection; design input and review; CCS and QMS development; qualification and validation; readiness for operation; routine production; periodic review and requalification; optimisation and major change; and ultimately decommissioning and the controlled end of operations. The value is continuity of intent from the earliest strategic decision through every operating state and the final lifecycle decision.

We also explain the reasoning behind our recommendations. Users benefit from understanding what a regulation says, how different regulators or inspectors may interpret the same design choice, and how quality, radiation-protection and operational perspectives interact. Our operational-excellence lens connects compliance with SQDC: safety, quality, delivery and cost, together with flow, capacity, maintainability, staffing, reliability, standard work and continuous improvement. Where the project exposes a QMS gap, we can develop or update the required QMS elements so the physical project and the management system mature together.

A scalable service architecture

Projects need different levels of integration. We scale the deliverables through three service levels - Proven Core, Configured Integration and Integrated Programme - based on the decisions and outputs the customer needs. Standardisation makes the lighter levels fast and proven; deeper integration is added where the project needs broader decision support.



Integrated Programme

Typical emphasis: Highly integrated support where process, organisation, suppliers, QMS and readiness must mature together. Illustrative deliverables: End-to-end user-side definition; supplier evaluation; CCS/QMS integration; interface governance; qualification/readiness architecture; decision and evidence continuity.

Configured Integration

Typical emphasis: Standard core plus project-specific configuration and interface challenge. Illustrative deliverables: Configured URS; operating scenarios; supplier/design reviews; targeted risk and CCS interfaces; qualification strategy.

Proven Core

Typical emphasis: Fast, standardised foundation for a well-understood scope. Illustrative deliverables: Proven requirement baseline; focused process confirmation; defined decision list; concise traceability / verification basis.

COMMERCIAL PRINCIPLE

The service level is defined by the decisions and deliverables the customer needs, with effort scaled to the value and integration required.

12

Questions that expose hidden assumptions

- These examples illustrate the kind of questions that connect design to routine work and expose assumptions while change is still practical.

Process and timing

- What is the true critical path, and how much recovery margin exists for each delay?
- Where does material or information wait, and what does that do to yield, dose, release or delivery?
- What information and test results must be available for release, when must they be available, and what happens if they are late?
- Which steps are sequential because of physics and which are sequential because of the current design?

Interventions and people

- Which manipulations and interventions are expected, exceptional or should be designed out?
- Can those interventions be trained, qualified and - where aseptic - represented credibly in APS?
- Can the operator see, reach, recover and document the task under real constraints?

CCS and organisational control

- Does the contamination-control strategy connect design, people, procedures, maintenance, monitoring, suppliers and validation?
- Who owns each control after the project ends, and is that function actually staffed and competent?
- Do QMS processes support the way the facility is intended to operate, or will they need to change?



Questions that expose hidden assumptions - continued

Supplier and lifecycle

- What evidence makes two technically different suppliers genuinely comparable?
- What must remain available after handover for the system to be maintained, changed and recovered?
- Which dependencies could become a single point of failure for delivery or routine operation?
- Which design choices could constrain major maintenance, removal of activated or contaminated components, or eventual decommissioning?

Qualification and evidence

- Which requirement needs an OQ or process challenge, and which can be verified adequately by design or supplier evidence?
- What test would demonstrate both technical function and operability?
- What evidence must remain available for future change, requalification or investigation?



Select › Operate › Clean › Maintain › Recover › Qualify › Release › Improve › **Support**

WHY THESE QUESTIONS MATTER

They force the project to connect design decisions to the full manufacturing lifecycle: select, operate, clean, maintain, recover, qualify, release, improve and support.

13

What Qualificiency brings to the project

Clarity about scope is part of the value. We strengthen the user side of facility and equipment projects and connect it to the wider operating system, working alongside the licensed or competent engineering disciplines that design the facility and specialist equipment.

Typical Qualificiency contribution	Complementary specialist ownership
Process definition, operating scenarios and SQDC-based future-state challenge	Architectural design and statutory engineering responsibility remain with the competent engineering disciplines.
Standardised and configured URS development; user-side requirements challenge	Detailed HVAC, electrical, structural and mechanical calculations remain with the relevant engineering specialists.
Supplier qualification/selection logic and evidence-based comparability	Proprietary equipment design and manufacturer design authority remain with the equipment supplier.
GMP, CCS and QMS integration with facility/process needs	Customer QA, QP and accountable regulatory ownership remain with the manufacturer.
Material, personnel, sample, waste, information and lifecycle-flow challenge	Detailed radiation calculations remain with competent Radioprotection and engineering specialists.
Design review, DQ input, traceability and qualification/validation strategy	Technical, GMP and radiological risk acceptance remains with the accountable customer functions.
QMS development or upgrade where the facility/change creates a real system need	QMS development complements sound design and addresses genuine management-system needs created by the project.
Operational readiness, procedures, training, maintenance/support and handover challenge	Routine operation remains with the manufacturer's organisation, supported by readiness, training and handover.

The practical outcome

When this works well, engineering receives clearer inputs; suppliers compete against more meaningful requirements; the user makes decisions earlier; the CCS operates as a real strategy; QA and Validation retain clear responsibilities; Radioprotection is integrated from the beginning; qualification focuses on true criticality; and the operating organisation inherits a system it understands and can own.



The practical outcome

When this works well, engineering receives clearer inputs; suppliers compete against more meaningful requirements; the user makes decisions earlier; the CCS operates as a real strategy; QA and Validation retain clear responsibilities; Radioprotection is integrated from the beginning; qualification focuses on true criticality; and the operating organisation inherits a system it understands and can own.

14

What good looks like

A good radiopharmaceutical facility is one in which the complete manufacturing system works as one process and each discipline contributes to that shared outcome.

- ✓ The physical layout supports the production sequence and enables efficient, controlled work.
- ✓ The CCS connects design, QMS, people, suppliers, maintenance, monitoring, validation and continual improvement.
- ✓ The release strategy is reflected in sampling, QC capacity, information flow, status control and timing, so the facility supports batch decisions as well as manufacture.
- ✓ Radiation protection and contamination control are integrated at the points where their controls interact.
- ✓ Hot cells and other specialist equipment support the actual manipulations, interventions, cleaning and recovery scenarios expected in routine use.
- ✓ Supplier capability and lifecycle support are understood before purchase and verified through delivery and handover.
- ✓ Maintenance and end-of-life needs are considered early enough that activated or contaminated components can be accessed, removed, stored and ultimately decommissioned under control.
- ✓ User requirements remain traceable to design decisions and proportionate verification evidence.
- ✓ QA, Validation, Radioprotection, engineering, operations and suppliers know what they own and where decisions cross interfaces.
- ✓ The operating organisation understands why the design is the way it is and can manage future change without rediscovering the original assumptions.



Conclusion

"Understand the process first" is easy to agree with. The difficult part is deciding what "understand" means. In our view, it means understanding the process at the level where facility, equipment, people, QMS, suppliers, qualification, radiation protection, release and everyday operational performance meet.

That level is reached by combining P&IDs, process descriptions, regulations and equipment data with lived process knowledge, organisational reality and deliberate interface management. Good projects use standardisation to finish what is already known efficiently, focus judgement on the decisive 20%, and carry those decisions forward into supplier choice, design, verification and routine ownership. The same 20% that deserves the greatest attention during the project is often the 20% that causes 80% of the operational problems, inefficiencies and losses afterwards when it is rushed or insufficiently resolved.

Lived process experience is a distinct expertise that complements engineering, quality, validation and radioprotection. Qualificiency brings that user-side expertise into the project and translates it across the specialists who turn it into a working facility.

OUR POSITION

Qualificiency works on the user side of radiopharmaceutical projects, strengthening process definition and translating it across engineering, equipment suppliers, QA, Validation and Radioprotection so the complete operating system can be designed, verified and owned.

The result we are aiming for is simple: a facility that is compliant, operable, supportable and able to perform - because the decisions were connected before they became difficult to change.

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About Qualificency

Qualificency Consulting supports radiopharmaceutical and pharmaceutical organisations where compliance and operational performance need to work as one system. Our work includes facility and process design support, qualification and validation, GMP and quality systems, supplier qualification, process optimisation and training.

In facility projects, our focus is the user side: turning lived process knowledge into mature requirements, making suppliers and solutions comparable against what matters, connecting design to CCS/QMS and qualification, and preparing the operating organisation to own the solution after handover.

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