PERSPECTIVE PAPER

Radiopharmaceutical facility design – supporting commercial viability

How half-life, emission types and a double regulatory burden influence how a radiopharmaceutical reaches routine, compliant manufacture.

A perspective paper from Scitech-EKIUM
Engineering of GMP and radiation-compliant radiopharmaceutical facilities since 2003

August 2026

Scitech EKIUM

What this paper covers

Written for project directors, engineering leads and executives responsible for delivering radiopharmaceutical manufacturing capacity.

A radiopharmaceutical facility must satisfy two principal regulatory frameworks at the same time:

- Pharmaceutical GMP protects the product, using a positive-pressure cascade to keep dirty air out of the clean space.
- Radiation protection protects people and the environment, using negative pressure to keep radioactive contamination in.

Those two requirements pull in opposite directions, in the same spaces, at the same time.

This paper sets out where that conflict arises, what governs the design decisions that follow and the delivery lessons that separate programmes which reach qualified operation from those that stall.

Radiopharmaceuticals with demonstrated clinical benefit have not reached their full commercial potential.

The risk now sits in the facility, the logistics and the supply chain.

Contents

The Supply Gap

Proven benefit has never been enough on its own

Bexxar and Zevalin demonstrated this at considerable cost to the companies that developed them.

Zevalin (Y-90 ibritumomab tiuxetan) and Bexxar (I-131 tositumomab) were radiopharmaceuticals approved for non-Hodgkin lymphoma. Both demonstrated clinical benefit.

Commercially, both fell short. The reasons lay largely in how they had to be manufactured, handled and administered.

The science was not the limiting factor. The infrastructure and coordination required to deliver it were.

The Bexxar Illustration

THE CLINICAL CASE
The science held up

Bexxar reported response rates of around 95% in previously untreated follicular lymphoma. These were effective agents with a sound therapeutic rationale, approved by regulators and supported by published clinical evidence.

THE DELIVERY MODEL
The system did not

Every dose needed specialist equipment, trained staff and close coordination between nuclear medicine, radiation oncology and haematology. Referral patterns and reimbursement rules worked against the specialists who controlled the product.

THE COMMERCIAL RESULT
From thousands to dozens

Bexxar fell from an estimated 2,000–3,000 patients a year at its peak to roughly 75 in 2012, with sales declining around 30% annually from 2006. GSK withdrew it from the market in February 2014.

In fairness: the picture was not purely logistical. A later trial showed no survival edge over CHOP-R, and simpler competing agents arrived without the coordination burden. But the infrastructure and logistics burden is what left these products exposed to those pressures.

The Supply Gap - Radioligand therapy

The same problem, a different order of magnitude

Radioligand therapy has moved from the margins of oncology to its centre and has taken the supply problems with it.

The pipeline has turned

Therapeutic radioligands are now a mainstream oncology modality rather than a third-line treatment. Lu-177 and Ac-225 programmes dominate current development, and the companies running them are scaling from single clinical batches toward routine commercial supply.

The volumes have changed

What was R&D-scale production against a trial protocol becomes manufacturing against a patient schedule. Batches are often timed and dated to individual patients, dose calibration is time-critical, and a missed batch is a missed critical treatment.

The industry is attempting, at commercial scale and under time pressure, exactly the thing that defeated Bexxar and Zevalin twenty years ago.

The difference this time must be the facility.

The Supply Gap - Radioligand therapy

Radioligand therapy is transitioning from a last hope treatment to frontline therapy, but the supply challenge remains.

The bottleneck has moved

The binding constraint is no longer whether the molecule works.
It is whether a compliant facility can be designed, licensed, built, qualified, staffed and operated quickly enough, and close enough to the patient, to supply it reliably.

The risk has moved out of the laboratory and into the facility, the logistics and the supply chain.

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The Central Tension

Two regulators. Two opposite instincts. One facility.

This is one of the problems that makes radiopharmaceutical facilities unlike both conventional pharma and conventional nuclear.

What GMP asks for: protect the product

A positive-pressure cascade, with air flowing outward from the cleanest space so that nothing enters it. The threat model is particulate and microbial ingress; the defended asset is sterility and product quality. Every instinct in cleanroom design pushes air away from the core.

What radiation protection asks for: protect everyone else

A negative-pressure regime, with air drawn inward and held at source so that nothing escapes. The threat model is dispersal of activity; the defended assets are the operator, the public and the environment. Every instinct in containment design pulls air toward the core.

The resolution to these conflicting drivers must be settled at concept stage.

The Central Tension

How the conflict is resolved

Not by compromise. A compromised cascade satisfies neither regulator.

It is resolved architecturally.

ASSIGN THE DUTIES SEPARATELY

Give the two duties to different barriers rather than asking one barrier to do both.

ROOM ENVELOPE CARRIES GMP

The room envelope carries the GMP cascade; The hot cell, shielded isolator or glovebox carries the radiation containment and runs at negative pressure relative to the room it sits in.

AIRLOCKS STEP THE REGIME

Airlocks step the regime across boundaries so both conditions hold at once, and the extract is designed as a radiological system that serves a cleanroom, not the reverse.

Concept-stage lockdown of operational workflows, area adjacencies, area GMP and radiation classifications and HVAC zoning are critical to credible layout and engineering development.

What determines the facility

Two properties of the radionuclide set the facility

The product being diagnostic or therapeutic is a clinically meaningful distinction but, for engineering purposes, is of limited value.

01 Property one: half-life sets time

How quickly the radionuclide decays governs manufacturing velocity; the adjacency of synthesis, QC, dispensing and dispatch; whether product can be released before testing completes; how much decay storage the site needs; and the geographic radius a single facility can serve.

02 Property two: emission types set the barriers

Most radionuclides emit more than one type of radiation, and at more than one energy. Together those emissions govern the engineering of mass shielding and contamination containment, the operator dose model, waste classification and what load the structure must carry.

Layout, structure, HVAC, waste and licensing all cascade from these two properties.

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Why the clinical split misleads

Grouping radionuclides by clinical use creates risk of specifying the wrong engineering.
For example:

F-18 — DIAGNOSTIC
A diagnostic agent, but its 511 keV annihilation photons demand serious structural shielding.

Ac-225 — THERAPEUTIC
A therapeutic alpha emitter that needs comparatively little shielding but rigorous containment discipline.

I-131 — BOTH
Both beta and gamma and so needs to be engineered for both at once.

Grouping radionuclides by half-life and emissions instead enables the facility to be designed properly.

What determines the facility

The decay chain is the design case, not the product

Radioactive decay rarely results in single emission. It is a sequence, and every radionuclide in that sequence is an engineering input.

Two radionuclides both described as alpha emitters can place very different demands on a facility. What matters is the full span that the site actually handles: the production parent, every daughter and every branch.

It is usually one member of the decay chain, rather than the product itself, that drives the design.

So, the shielding, the containment, the extract and the waste route are specified against the whole chain that the site holds, and against any generator inventory that outlives every batch.

An alpha therapy can still be a gamma shielding problem.

The solution is for the chain, not the product.

What determines the facility

Three chains, three different design cases

Ac-225

Th-229/Ra-225 generator, or Ra-226 targets

Th-229 → Ra-225 → Ac-225 → Fr-221 → At-217 → Bi-213 → Po-213/Tl-209 → Pb-209 → Bi-209 (quasi stable).

WHAT DRIVES THE DESIGN

- Five alphas and three betas across the chain from Th-229 (4 alphas from Ac-225),
- Bi-213 at 440 keV gamma sets hot cell shielding
- No gaseous daughter, so contamination control rather than extract abatement
- The Ra-226 target route adds Rn-222 (t½ 3.8 d) to the site inventory

Ra-223

Ac-227/Th-227 generator

Ac-227 → Th-227 → Ra-223 → Rn-219 → Po-215 → Pb-211 → Bi-211 → Tl-207 → Pb-207 (stable).

WHAT DRIVES THE DESIGN

- Five alphas and three betas from Ac-227
- Rn-219 is a noble gas: capture, delay and decay in the extract
- Pb-211 at 405 and 832 keV gammas sets hot cell shielding
- Ac-227 as parent at t½ 21.8 y dominates waste classification

Pb-212

Th-228/Ra-224 generator

Th-228 → Ra-224 → Rn-220 → Po-216 → Pb-212 → Bi-212, → Po-212 / Tl-208 → Pb-208 (stable).

WHAT DRIVES THE DESIGN

- Five alphas from Th-228 (four from Ra-224), plus two betas
- Rn-220 (thoron) is a gas: capture, delay and decay before discharge
- Tl-208 at 2.615 MeV gamma is the dominant shielding case on the chain
- Th-228 generator inventory at t½ 1.9 y long outlives the product

What determines the facility

What each property determines.

Half-life determines where the facility can be

MINUTES

O-15 ~2 min
C-11 ~20 min

Production must be on site, adjacent to the point of use. Cyclotron, chemistry and scanner are effectively one machine distributed across rooms.

HOURS

Ga-68 ~68 min
F-18 ~110 min
Tc-99m ~6 h

Regional, same-day distribution. The achievable delivery radius, not the market, defines the catchment a single facility can serve.

DAYS

Lu-177 ~6.6 d
I-131 ~8 d
Ac-225 ~9.9 d
Ra-223 ~11.4 d

Centralised manufacture and international shipping become viable, but decay storage, waste hold-up and transport licensing all grow with it.

What determines the facility

What each property determines.

Emission types determine what the barrier is

ALPHA

Ac-225 · Ra-223
Th-227 · Pb-212

Containment-led. Stopped by a glove, but severe if released. Assess the full chain: Ac-225 yields four alphas, Ra-223 five, plus a gaseous daughter. Also, high gamma progeny to consider, needing dense shielding

BETA

Lu-177 · Y-90
I-131 (β and γ)

Low-Z absorbers first. High-Z shielding alone generates bremsstrahlung, so the build-up is acrylic or aluminium backed by a thinner lead layer.

GAMMA / POSITRON

F-18 · Ga-68
Tc-99m · Cu-64

Penetrating radiation stopped only by dense mass — lead, tungsten, concrete — in quantities heavy enough to drive floor loading and lifting provision.

01

LESSON ONE — HALF-LIFE

The physics is immutable and sets the production schedule

A decay constant is the one project constraint that cannot be escalated, resourced or contracted around.

For short-lived radionuclides, the process and facility are a race against the product. Every delay in batch throughput and every metre between synthesis and dispensing is time loss, and every minute of time is yield loss. The process and its timeline dictate equipment and adjacency, and the building is arranged around it.

It also changes what quality assurance can be. When a product decays faster than sterility testing completes, batches ship before all results are available. Parametric and real-time release are therefore engineering requirements rather than quality preferences, and they dictate QC layout, instrumentation and data architecture.

Process and facility design determines how much of every batch is lost to decay before it reaches the patient.

01

LESSON ONE — HALF-LIFE

Half-life in practice

WHAT THIS MEANS IN PRACTICE

- Plan synthesis, QC and dispensing as a single adjacency, not three departments
- Fix the release strategy at concept; it drives QC layout and instrumentation
- Treat transport time as a design input: the delivery map defines the plant
- Plan decay storage for the longest-lived radionuclide in the portfolio, not the lead product

PROJECT REFERENCE

Hammersmith Imanet · GE Healthcare

Cyclotron, GMP radiochemistry and piped radionuclide distribution

Design and installation of a new self-shielded cyclotron with R&D and GMP radiochemistry laboratories, custom hot cells and radioisotope handling systems.

Scitech-EKIUM designed and installed a bespoke system for piped transfer of radioisotopes between the cyclotron, hot cells and laboratories - the practical answer to half-lives measured in minutes. Risk and safety management covered O-15 and F-18, and the project achieved an MHRA 'specials' license.

Hammersmith, UK · Design, engineering, procurement, construction management and validation

02

LESSON TWO — EMISSION TYPES

Shielding and containment are not the same problem

They are commonly conflated, and the cost of conflating them is designed into the structure.

Gamma and positron emitters produce penetrating radiation that only dense material will attenuate. In practice the shielding becomes a weight problem: a gamma hot cell carries tonnes of lead, tungsten or concrete, and the floor slab, wall build-ups and lifting equipment must all be designed around that load.

Alpha emitters present the opposite problem. The radiation is stopped by a glove, so shielding mass is largely irrelevant, but losing containment is severe. The controlling risk is contamination, and the design effort moves into sealed handling, airflow, monitoring and decontamination.

Beta emitters sit between, with a subtlety regularly missed: shielding beta with lead alone generates high bremsstrahlung. The correct build-up is a low-Z absorber first, backed by a thinner high-Z layer.

Alpha containment is not beta shielding is not gamma shielding. Specifying the wrong one is a structural mistake, not a detailing one.

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02

LESSON TWO — EMISSION TYPES

Emission types in practice

WHAT THIS MEANS IN PRACTICE

- Assess the full decay chain and the production route, not just the product radionuclide – different production stages have different needs
- Specify the barrier(s) from the emissions accordingly
- Model operator dose against the actual handling sequence, not room averages
- Build up beta shielding low-Z first, then back it with a thinner high-Z layer

PROJECT REFERENCE

Algeta · Bayer

Xofigo production — Oslo and Indianapolis

Scitech-EKIUM designed and engineered the original Xofigo (Ra-223) production line in Norway for Algeta and Bayer - the world's first FDA-approved alpha therapeutic.

The bulk manufacturing process was subsequently tech-transferred from Oslo to Indianapolis for the second-generation commercial line. Scitech-EKIUM developed the concept and basis of design, then held overall design and engineering responsibility for the production hot cells: built and factory tested in Italy, then shipped, re-assembled, SAT'd and IOQ'd in the USA.

Oslo, Norway 2010–13 · Indianapolis, USA 2014–16

03

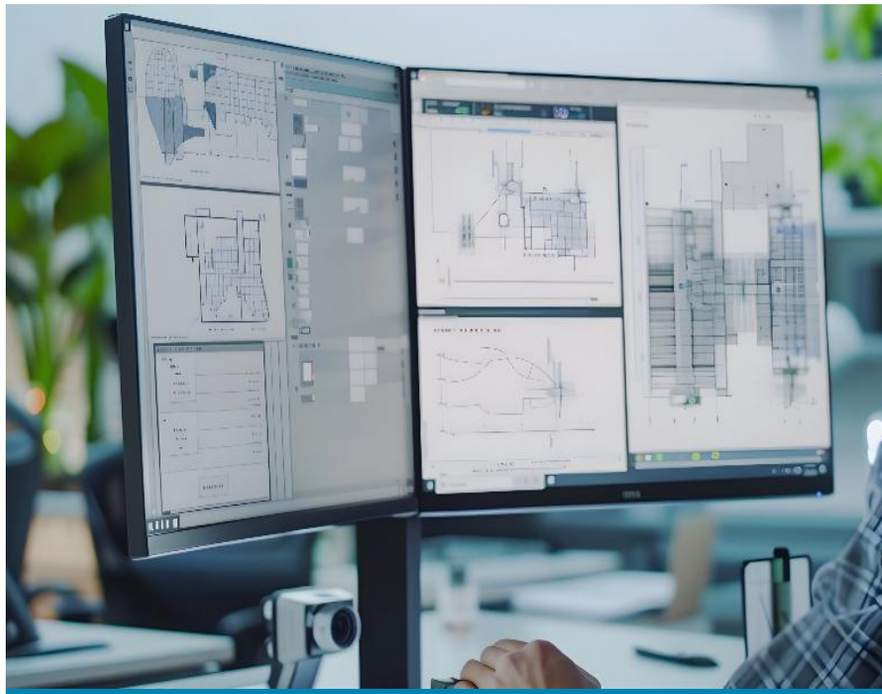
LESSON THREE — IRREVERSIBILITY

You cannot value-engineer physics back in later

Shielding is a civil decision – don't mistake it for a services decision, and it locks earlier than most programmes expect.

Wall build-ups, floor loading, penetration geometry, door and plug arrangements and lifting provision are all consequences of the shielding assessment. They are fixed when the structural grid is fixed, which can be long before the process is fully defined.

When shielding is added later, the change is seldom local. The structure needs re-analysis, space is compromised, services need re-routing through new penetrations, the construction sequence needs revisiting, and everything the change touches needs re-qualification. On a GMP facility that last item is the expensive one: a late containment or grade change can have major consequences.



The cheapest hour on a radiopharmaceutical project is the one spent on the shielding and containment assessment before the grid is frozen.

03

LESSON THREE — IRREVERSIBILITY

Irreversibility in practice

WHAT THIS MEANS IN PRACTICE

- High cost, time and spatial impact of change
- So, get it right at Concept stage
- Know the process
- Shielding and containment per production step
- Area classifications and zoning for radiation and GMP
- Area adjacencies for contamination control and efficient workflows
- Waste and emissions strategy – abatement, storage
- Design for validation, maintenance, future equipment changes, regulatory developments

PROJECT REFERENCE

Guy's & St Thomas' · King's College London

PET production facility in a sub-basement conversion

Conversion of an emptied basement PET/CT suite into a new PET production and R&D facility: a GE PETtrace cyclotron, vault plug door, 26 hot cells, and QC and R&D analytical laboratories.

Scitech-EKIUM delivered the concept study, scheme and detailed design for facility, utilities and HVAC. Scitech-EKIUM managed the equipment scope and carried out GMP qualification from VMP to OQ.

Lambeth, London, UK · Design, engineering, construction, validation

04

LESSON FOUR — WASTE AND EFFLUENT

Everything that leaves the building is regulated too

Waste routes are commonly the last system designed and the first to constrain how the facility can operate.

A radiopharmaceutical facility has three outbound streams and all of them require permits. Solid waste needs decay storage sized by half-life and inventory, a requirement that consumes significant floor area. Liquid effluent needs delay, hold-up and monitoring before it can be discharged. Gaseous release needs filtration, abatement and stack dispersion under an environmental permit that is separate from, and on a different timetable to, the GMP approvals.

For alpha programmes in particular, the daughters matter as much as the product. A nuclide that is straightforward to handle in itself can sit in a chain that produces a mobile gaseous daughter, and that daughter becomes the governing design case for the entire extract system.

The extract stack and the decay store are not back-of-house. They are front and centre in the design.

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04

LESSON FOUR — WASTE AND EFFLUENT

Waste and effluent in practice

WHAT THIS MEANS IN PRACTICE

- Understand your waste generation and waste disposal routes from the outset, and design them in
- Size decay storage from inventory and half-life at concept, not at detailed design
- Design the extract as a radiological system that serves a cleanroom, not the reverse
- Model the decay chain for gaseous or mobile daughters before fixing abatement
- Align the discharge permit timetable with the GMP programme early

PROJECT REFERENCE

Bayer · Algeta

Radon gas abatement system

Development and implementation of a complete radon abatement system to capture, delay, decay and filter radon generated during radiopharmaceutical manufacturing - a direct consequence of the decay chain rather than of the product itself.

The solution integrated with an existing exhaust system serving hot cells used for parent radioisotope production. Scitech-EKIUM delivered a full turnkey package engineered for a nuclear-licensed environment, containerised so that fabrication and FAT happened off site, then managed site integration and a successful SAT within a tightly controlled shutdown.

European nuclear-licensed site · Design engineering, construction, commissioning

05

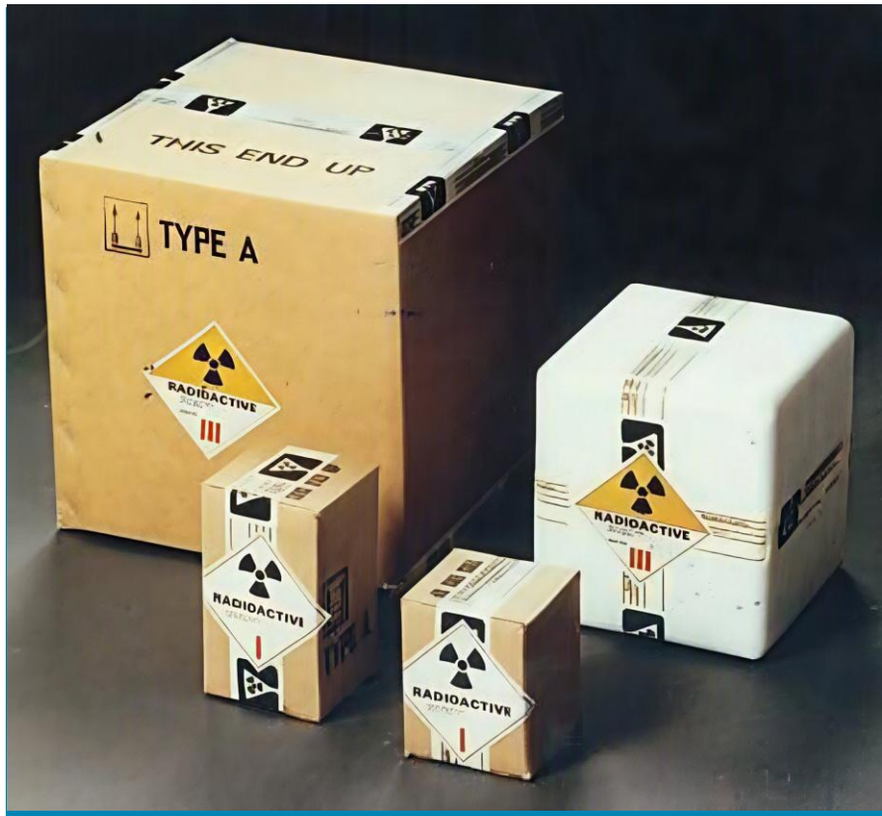
LESSON FIVE — THE REGULATORY INTERFACE

Two rules shape the building. A third governs what exits

Programmes rarely stall inside a regulatory framework. They stall in the gaps between them.

The two frameworks set out at the start of this paper shape the building itself: pharmaceutical GMP, enforced by a medicine's regulator, and radiation protection, enforced by a radiation and environmental regulator. At the point of distribution, a third joins them - the transport regime governing shipment of active product.

Each has its own vocabulary, evidence expectations and timescale, and none of them owns the interfaces between them. A GMP change control triggers a permit variation nobody scheduled. A licensing submission needs design detail that the design programme has not yet reached. A transport classification constrains a packaging decision that the process team considered settled. These are not compliance failures; they are interface failures.



Nobody is accountable for the interfaces unless you make somebody accountable for them.

05

LESSON FIVE — THE REGULATORY INTERFACE

The regulatory interface in practice

WHAT THIS MEANS IN PRACTICE

- Map all approval paths onto a single programme, with named owners at each interface
- Identify which decisions are irreversible under each regime, and when they lock
- Sequence submissions against design maturity rather than calendar convenience
- Engage regulators with people who have presented this class of facility before

PROJECT REFERENCE

GE Healthcare · Royal Victoria Hospital

PET production facility

Design of a new PET production facility within an existing space, incorporating a GE self-shielded cyclotron, an ISO Class 8 QC laboratory, an ISO Class 7 clean production room with hot cells and an ISO Class 5 dispensing isolator.

Future flexibility for alternate products was built in, within a challenging budget and contract programme. Scitech-EKIUM supported detailed discussions with the Environment Agency and presented the project to the MHRA through its in-house specialists - both regulators, one programme.

Belfast, UK · Design and engineering for a turnkey project

06

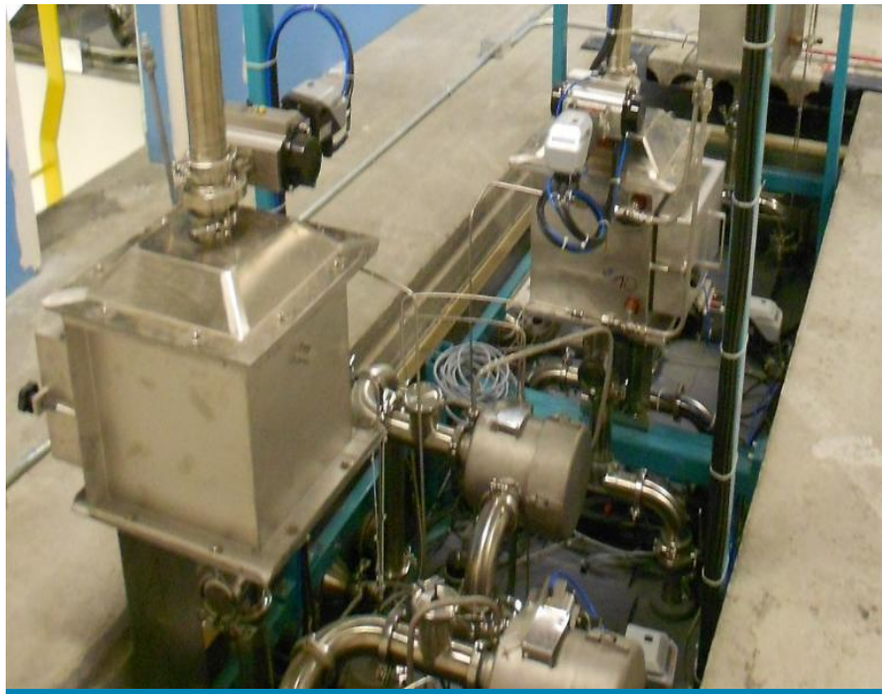
LESSON SIX — LIVE OPERATIONS

This often happens in a building that cannot stop

New capacity is commonly added to a site that is already producing, already licensed and already qualified.

This changes the nature of the engineering problem. The binding constraint is not the design; it is the sequence. Work needs to be phased around live production, segregated from validated areas, tied into existing services during short access windows and handed back without disturbing the qualified state of anything adjacent.

It also changes what good looks like in a design team. Buildability, temporary segregation, out-of-hours tie-ins and the impact assessment on adjacent validated systems stop being construction concerns and become design deliverables. An expansion or remodelling project is won or lost on the phasing plan, and the phasing plan must exist before the detailed design does.



On a live site the phasing plan is the design. Everything else is detail.

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06

LESSON SIX — LIVE OPERATIONS

Live operations in practice

WHAT THIS MEANS IN PRACTICE

- Treat the phasing and segregation plan as a design deliverable, not a contractor output
- Pre-fabricate and factory-test off site so that on-site windows are short and predictable
- Assess the impact on adjacent qualified systems before committing to tie-ins
- Establish at concept stage how the GMP, radiation and engineering change control process will work, and build that into the design process
- Plan out-of-hours working into the programme and the budget from the outset

PROJECT REFERENCE

Confidential client

FDG production facility built inside a live building

When a previous production site proved unsuitable, the client required rapid design and construction of a new FDG production facility to meet critical product delivery commitments.

The facility was built inside an existing live building with full production maintained throughout. Disruption was eliminated through construction technique, material selection and out-of-hours tie-ins. Long-lead items - a self-shielded cyclotron, sliding shield door and four hot cells - were installed within a cleanroom environment before completion.

All completed from start of design to start of OQ in 12 months

Engineering, procurement, construction, validation · Awarded the client's 'Contractor of the Year'

06 Six key things to know from your delivery partner

Less about credentials in the abstract; more about what has been done, and what was learned in doing it.

01 Can they evidence delivery under a medicines regulator and a radiation or environmental regulator on the same project - not one or the other, and on how many different projects?

02 How do they resolve the cascade conflict between GMP grade and radiation containment, and at which design stage do they fix it?

03 What is their shielding and containment assessment process, and when in the programme does it lock against the structural grid?

04 Have they engineered for the emission types you are working with, across the full decay chain? Alpha containment, beta absorber build-ups and gamma shielding are different disciplines.

05 Can they show hot cell and isolator delivery across the full lifecycle - URS, vendor management, FAT, site re-assembly, SAT and IQ/OQ?

06 Have they done this inside a live, qualified facility without stopping production, and can they name the project?

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A partner who has met these constraints before will answer with projects. One who has not will answer with process

Track Record

23 years. 81+ projects. 24+ isotopes.

Continuously active in radiopharmaceutical project delivery since 2003, through every development in the field.

81+	23	13	24+	53	54
Radiopharma projects completed or ongoing	Years continuous engagement	Countries	Radioisotopes	GMP production projects	Hot-cell projects

THERAPEUTIC

Ac-225	Lu-177	Ra-223	I-131	Th-227	Pb-212
24	15	7	7	4	3

DIAGNOSTIC

F-18	O-15	C-11	Cu-64	Mo-99	Tc-99m
17	12	12	12	6	4

Specialist focus, backed at scale

Scitech-EKIUM is a radiopharma and life-sciences design and construction specialist within Ekium Group (2,700 people, 16 countries) and Groupe SNEF (16,000 people, 30 countries) - with 50+ in-house commissioning, qualification and validation specialists.

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Selected project references

BAYER

Xofigo bulk manufacturing line

Ra-223 alpha therapeutic. Tech transfer Oslo to Indianapolis; hot cells built and FAT'd in Italy, SAT and IOQ in the USA.

Indianapolis, USA

BAYER · ALGETA

Radon gas abatement system

Capture, delay, decay and filtration integrated into an existing nuclear-licensed hot cell exhaust and discharge stacks.

Europe

BAYER

Radiopharmaceutical QC laboratory

Expansion and re-purposing to increase QC and research capability, including a multi-glove isolator housing an ICP mass spectrometer.

Oslo, Norway

BWXT MEDICAL

Alpha project hot cell line

Technical and schedule recovery consultancy across mechanical and automation scope for a large hot cell suite under construction.

Ottawa, Canada

GE HEALTHCARE

Royal Victoria Hospital PET facility

Self-shielded cyclotron, ISO 8 QC laboratory, ISO 7 production room with hot cells, ISO 5 dispensing isolator. EA and MHRA engagement.

Belfast, UK

GUY'S & ST THOMAS' · KCL

PET production facility

Sub-basement conversion: PET trace cyclotron, vault plug door, 26 hot cells, full GMP qualification from VMP to OQ.

London, UK

HAMMERSMITH IMANET

Cyclotron and GMP radiochemistry suite

Self-shielded cyclotron, bespoke hot cells and a piped radionuclide distribution system. MHRA 'specials' licence achieved.

Hammersmith, UK

CARDIFF UNIVERSITY

All Wales PET Centre

Cyclotron and GMP Grade B production suite with dedicated hot cells, plus R&D hot cells for new tracer development.

Cardiff, UK

UNIVERSITY OF OXFORD

PET research and GMP manufacturing centre

Over 750m² re-purposed and new build across two phases, re-purposing a redundant Linac bunker suite.

Oxford, UK

STFC · UKRI

Precision-engineered building (R132)

Radiation shielding integrated into the building design, with a strict non-magnetic zone at the heart of the structure.

Harwell, UK

The molecule proves the science.
The facility supports the business.

Scitech-EKIUM - a partner for radiopharmaceutical programmes from concept to qualified operation.

Consultancy through to full EPCV. Master planning, process and containment design, hot cell and isolator lifecycle management, construction in GMP and nuclear-classified environments, and commissioning, qualification and validation led by in-house specialists.

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