

Planning New Builds and developing business cases –

.....what I wish I'd known at the beginning

Linda Hardy

The first stop for professional medicines advice

Background – why was new guidance needed?

Lots of activity UK wide over the last 5 years

>60 schemes in England

Annex 1 update – compliance now required

Current YCD (2010) – needs update

What did we do?

Writing Team assembled:

Experience of new builds

Experience of business case writing

Annex 1 & GMP knowledge

Writing and webpage skills/Project Management

Opinions from some Chief Pharmacists who've had recent builds

Aims of the new guidance:

Develop web articles to provide a set of guidance updating and expanding on previous Yellow Cover Document

Signpost to standards and other resources

Provide and link to templates and examples

Resources summary

Fundamentals

- ✓ Appointing the right team
- ✓ Meeting Annex 1

Planning

- ✓ Designing and building clean rooms
- ✓ Planning the new build
- ✓ Writing the business case
- ✓ Writing the User Requirement Specification
- ✓ Agreeing a design specification & DQ

Qualification

- ✓ Qualification of aseptic clean room suites
- ✓ Installation qualification
- ✓ Operational qualification
- ✓ Performance qualification

Plus:

Links to other PQAC/SPS documents

Annex 1 gap analysis

Links to NHS & UK gov resources

Business case writing advice

Templates and examples

URS

Business cases

Fundamentals - Assembling the right team

Project Board

The Project Board ensures engagement with **relevant stakeholder groups** e.g. pharmacy, estates, finance, and clinical teams to encourage **joined-up thinking and socialisation** of the plan.

Implementation/Commissioning Team

Crucial to the project and includes **Principal Designer, Project Manager, Validation experts** and the Aseptics Managers.

External Specialist advisors e.g.

- RQA's
- **Independent GMP experts**
- MHRA
- **Project Management** firms

Specialist clean room builder

A Specialist Clean room Contractor is recommended.

Projects with separate teams of non-specialist architects and building companies are often more difficult to manage and can be subject to delay.

Planning – Considering your Options

General considerations

Define the **scope and purpose** of the new aseptic suite

- ✓ Engage clinical users early to **assess future service needs**
- ✓ Determine if the suite will continue existing services or expand capacity
- ✓ Clarify licensing requirements (e.g. **MHRA license or Section 10**)

Product Range & Delivery Capacity

What products will be manufactured and **expected production volume**?

Will new **product types** (e.g. ATMPs, biologicals) be included?

Is collaboration with other providers anticipated?

Location, Location, Location – who and where are the product users?

Meeting Annex 1 standards

Principle - focus on the protection of the product

Consider:

- what are the **critical processes**?
- What are the **contamination risks**?
- How does the facility and equipment provide protection?

Describe in the **Contamination Control Strategy**

SPS previously published resources (log-in required)

<https://www.sps.nhs.uk/articles/responding-to-annex-1-eu-gmp-changes/>

✓ Gap analysis to Annex 1

✓ Q&As with MHRA on some key points e.g.

- Can negative pressure isolators be used for cytotoxics?
- Do I need to have active air hatches?
- Background environment for isolators?

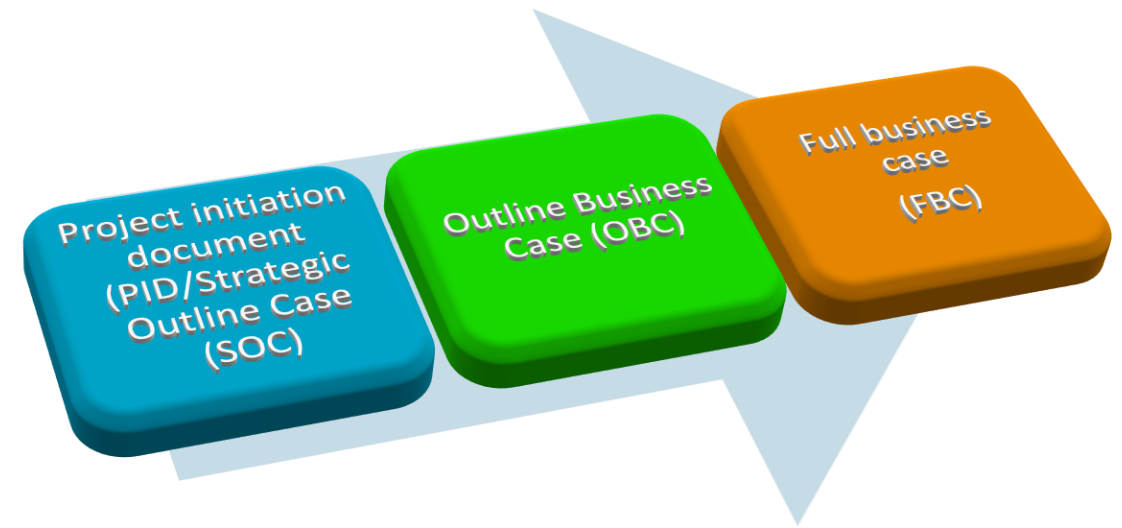
Writing the business case

The NHS has some excellent resources on the structure and content of business cases.

Begin by reading the [NHS Property Services 'Your Guide to building a business case'](#)

The format usually follows the **Five Cases** model to prove the business case is:

- supported by a robust Case for Change – the **strategic** case
- able to deliver Value for Money – the **economic** case
- commercially viable – the **commercial** case
- financially affordable – the **financial** case; and
- capable of being delivered – the **management** case.



The **Strategic** case is where you make your case for change

Discuss the risks and opportunities associated with your existing arrangements:

...age of the aseptic suite and whether it is still GMP compliant

...ability to meet current workload

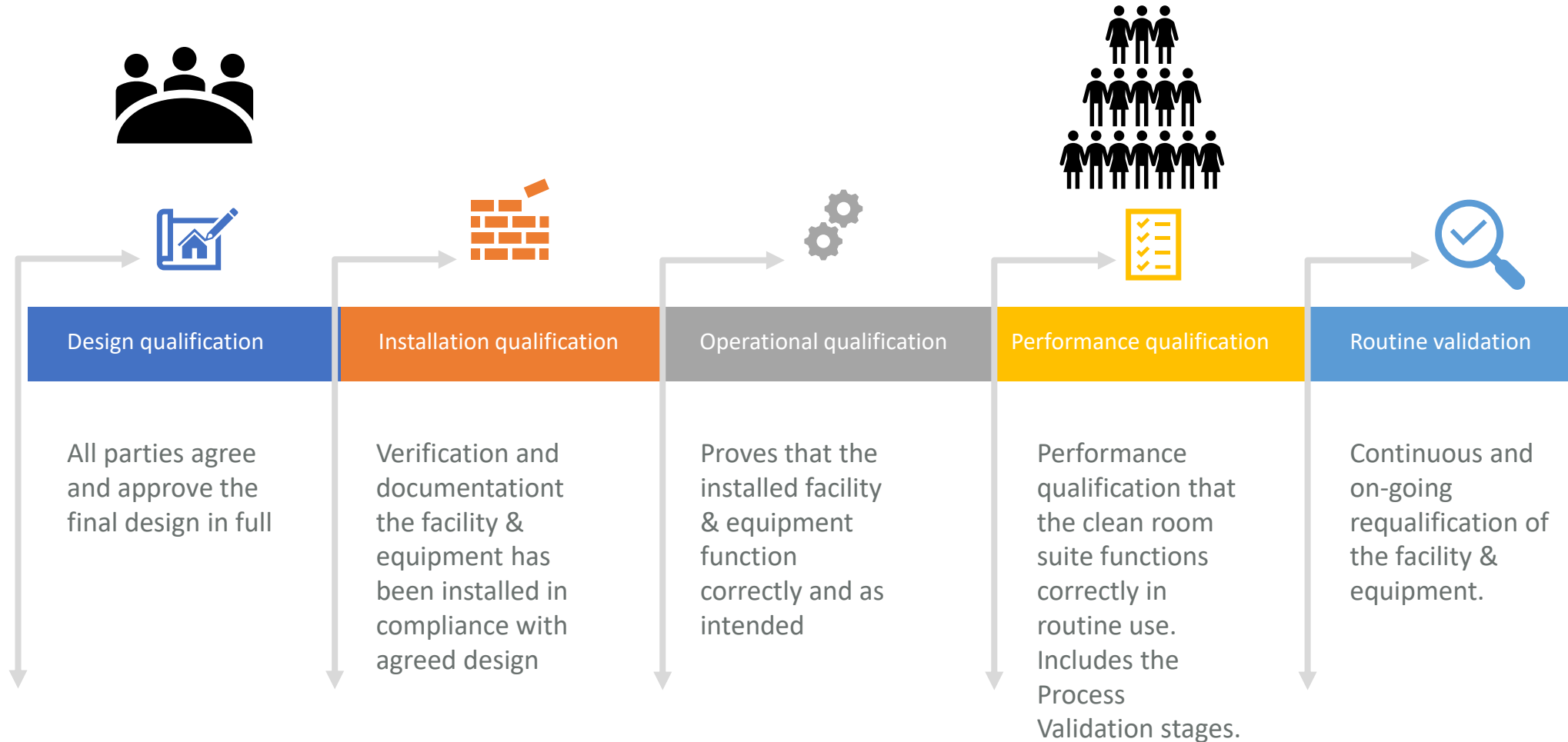
....ability to meet projected demand and Trust's clinical priorities

Do not underestimate.....

- Amount of **time** that will be required
- to deliver the build project alongside the existing service.
- The **cost, time and expertise** required at each qualification stage
- The costs of **enabling and preparatory works**
- The cost of **outsourcing** during any shutdown of the existing facility
- The **cost of microbiological media** required to perform validation including process validation
- Revenue costs for the new unit e.g. upgraded gowning arrangements
- Additional transport and delivery arrangements if different to previous



Planning for Qualification stages



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