

Project Success Two-Ring Model

Downloadable reference document generated from the live page model code

This document lists the full content of the Project Success two-ring model. The outer ring covers External context. The inner ring covers Project flow. Each numbered item below reproduces the node title and associated explanatory text from the code supplied.

Outer Ring - External context

Important considerations intended to inform optimal project / strategy definition and outcome.

1. Market and product trends

In our targeted therapeutic areas: who are current and emerging competitors; how do they compete (speed, price, outcomes, access); which presentations and formats are gaining traction; how are segments being differentiated; which therapeutic or disease areas are attracting attention; what are the market sizes and growth; which geographies are competitors targeting and how that is changing.

2. Process and technology trends

What is changing in processes, technologies, materials, and equipment. Which lessons from related fields could apply. What additions would enhance learning, enable simulation, improve interactions, or assure quality of output.

3. Expectations of transferred-in processes and their impact

Define what the receiving site should expect: process knowledge and control strategy, CPPs and ranges, analytics and data packages, comparability and validation status, training materials, and readiness to run at target scale. Identify gaps early and quantify their impact on start-up, quality, and resourcing.

4. Trends in design of work and expectations of potential employees

How do the best companies maximise the intellectual contribution of employees, realise advantage, and create the most effective environments; what do employees and potential hires expect of their workplace?

5. How do organizations (and the facilities they build) create flexibility to respond to inevitable but unknown change

How does the facility contribute to dynamic capability - the ability to sense, seize, and reconfigure. How does it help attract and connect the right people, and provide an effective canvas that can be reconfigured quickly in response to opportunity.

6. Sustainability

What is best practice; what drives the carbon footprint in a facility like this; what are others doing to improve their carbon footprint - can we model options and their environmental impact in design?

7. Data - how it is used

If we want maximum predictability, process robustness, and effective use of resources, and we want to maximise people's intellectual contribution, what is the role of data. How have others used data effectively, what is best in class, what further opportunities exist, and how is effort justified.

8. Regulatory requirements (real and imagined)

What are agencies looking for in this type of facility, what is their view on developing technologies, what areas are others challenging and to what end, where might we gain advantage through atypical or novel approaches and how would we justify and defend these, and do we have a clear view of risk and of regulatory perception of risk.

9. Financials and timelines

There needs to be a credible and agreed critical path. Assess financials through two lenses: COGs - define how these are built and clearly state COGs that a successful project is required to deliver; unambiguously define rules on depreciation and on how excess capacity is to be treated. Before proceeding compare anticipated COGs to CDMO / 'other source' options - understand and document rationale if higher. Project cost - benchmark against similar projects making sure compared costs are built in similar ways (i.e. include / exclude the same things).

Inner Ring - Project flow

Project execution elements intended to show how context should inform sequential decision-making.

1. Corporate Strategy (as applies to project)

The vision: how value will be created, how people will work, how data will be used, and how sustainability commitments will be met.

2. Site Rationale

Why this site should exist: which strategic gaps it fills, the constraints that apply, the expectations/targets set, and how success will be measured including capital effectiveness and COGs.

3. Site Objectives

Define the target mix - technologies, scales, integration/automation, products, and sustainability goals - and set measurable outcomes, benchmarks, and agreed estimation methods.

4. Operational Vision

How the site will operate and differentiate itself: its capacity, capability and flexibility, operating model, how it complements other sites, its ability to evolve, and how it is future-proofed.

5. Site Selection

Define selection criteria and weightings - talent availability (to support design + build, subsequent operations and site growth), cost, infrastructure, supply chain, utilities, incentives, environmental and other regulation, and risk - plus key constraints and the site's future expansion path.

6. Definition of project approach (Roles and responsibilities)

Set how the project will run: governance and decision rights; who does what (internal / partners / SMEs); how contributors complement each other and which dependencies shape interactions; the collaboration cadence and forums; and how effectiveness will be measured.

7. Appoint key members of internal project team

Identify empowered client leads and critical contributors; set clear accountabilities and time commitments; give them authority to challenge, audit, and if needed call a halt; ensure that authority is understood by all stakeholders; and define the quality-systems approach required of contractor(s).

8. Main Contractor Appointment

Choose a partner that complements the client team and works in a cross-discipline, non-siloed way to deliver the most effective solutions; commits to open challenge, shared data, and joint problem-solving; and in design prioritizes long-term, robust operational performance and site viability.

9. Implementation Framework (outline plan)

Set the outline plan so work happens in the right order: requirements set to requirements challenged, to design to design challenge, to build and verification. The span of decision impact should narrow as the project advances. Document the rationale for key decisions at every stage and use it to underpin regular gated design and implementation reviews. Establish a clear, realistic critical path that all stakeholders commit to, and a cadence that ensures timely involvement of the needed resources and experts.

10. Core design (what is plant built around)

Define the core manufacturing concept that everything else serves and that will, more than anything, determine long-term success and viability. The design must handle current needs and plausible future scenarios, considering scale, technology mix, redundancy, containment levels and environmental classification, as well as the likely evolution of processing and data technologies, regulatory expectations, and product mix. Build on a clear view of risk and what can be justified in audit.

11. Site Concept

How the site is expected to develop and how buildings and the campus should reflect corporate strategy. Define the design principles for laying out envisaged buildings and the relationships between them. State clearly what the site design must deliver and document the rationale for the choices made.

12. Outside -> In Design [Req't-> Design -> Design Challenge -> Next aspect or revise current & "re-challenge"]

Size the envelope first, then work inward so corridors and rooms neither choke future choices nor bloat the site. Define requirements that reflect real need and process physics, are clear to suppliers, capture parameter dependencies, and feed risk assessment and qualification.