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All Systems Go?!

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All Systems...Go?

In the rapidly evolving field of life sciences, **innovation is driven not only by groundbreaking research but also by the digital tools that enable it**.

As laboratories and research institutions increasingly rely on sophisticated software to manage data, run experiments, and ensure regulatory compliance, the concept of *software readiness* has taken center stage.

But **what does it mean for software to be "ready" in a life science** context? It's more than just functionality – it's about reliability, validation, security, and scalability in environments where precision can mean the difference between discovery and delay.

So, let's explore **the critical role of software readiness in supporting scientific progress, regulatory success, and operational excellence** across the life sciences landscape.

What is Software Readiness?

Software Readiness Levels (SRLs) and Technology Readiness Levels (TRLs) **are methods used to assess the maturity of a system or technology**.

These are key to articulating the client expected requirements or phases of development during a project.

TRL was developed at NASA during the 1970's and has been used by various government agents over the last 20 years.

It is now published by the International Organisation for Standardisation (ISO) in ISO 16290:2013. The stages of TRL are show in the table[1]:

TRL	Description
1	Basic principles observed
2	Technology concept formulated
3	Experimental proof of concept
4	Technology validated in lab
5	Technology validated in relevant environment
6	Technology demonstrated in relevant environment
7	System prototype demonstrated in operational environment
8	System complete and qualified
9	Actual system proven in operational environment + hyper-care

BUT WHAT DOES THIS MEAN IN LIFE SCIENCE?

In an article written by Mr. Tetley and Prof. John, the article discusses how system readiness and system maturity are linked, but not the same and describe two different parts of the overall system development and lifecycle[2].

In the Tetley and John article, the TRLs are mapped against the **V-model project management tool**, showing that system readiness is the validation aspect of the system development and overall lifecycle within system maturity model. In this model, **a system is only mature once it has been defined by user requirements and is commissioning, qualified and validated in operations**, making it fit for purpose.

System Readiness V-Model

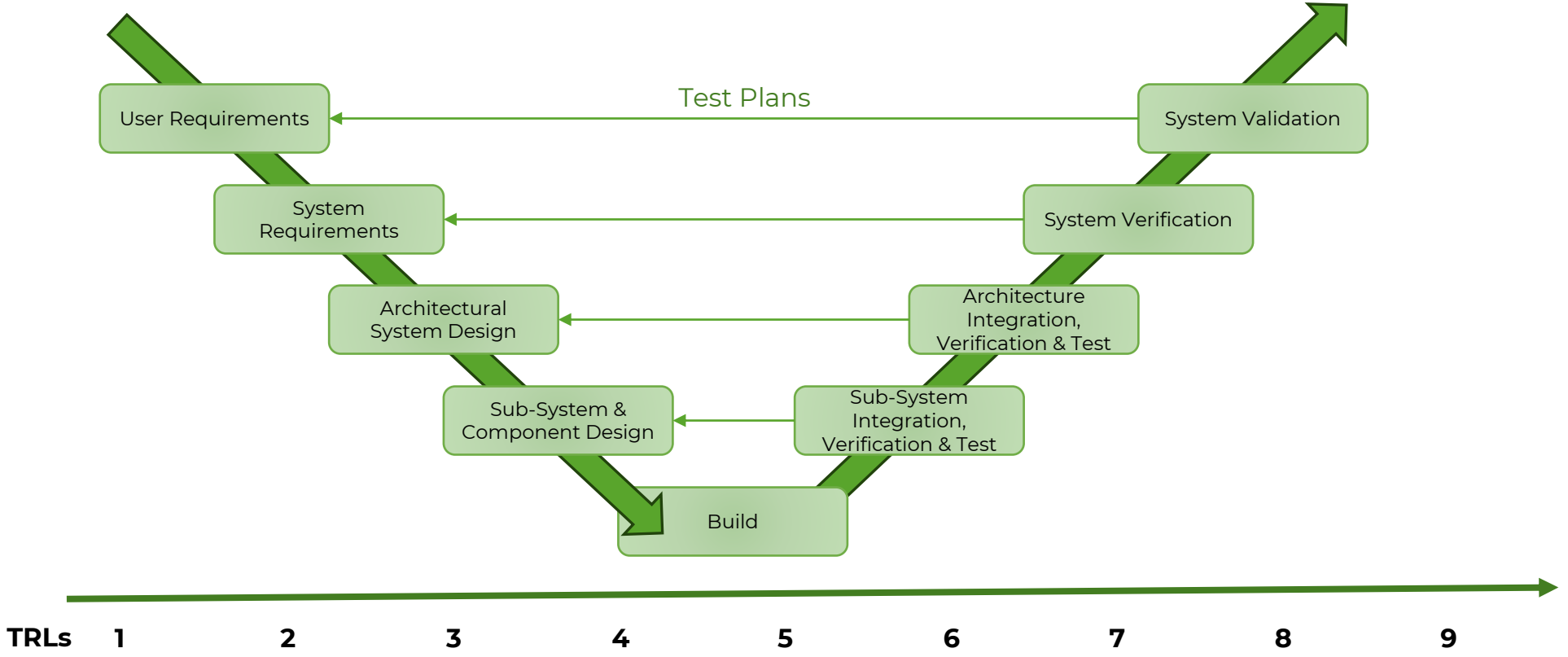


Figure 1: Augmented V-Model with TRLs

In life science, this model **aligns with how GMP projects are commission, qualify and validate facilities, utilities or assets**, preparing them for both the client and licensure.

And, by aligning each stages of the Tetley & John model with the ISPE Baseline Guide Volume 5 – Commissioning & Qualification First Edition[3] V-Model, as shown in Figure 2, you can see how closely the models marry up, ensuring project and technical readiness occur simultaneously.

System Readiness vs CQV V-Model

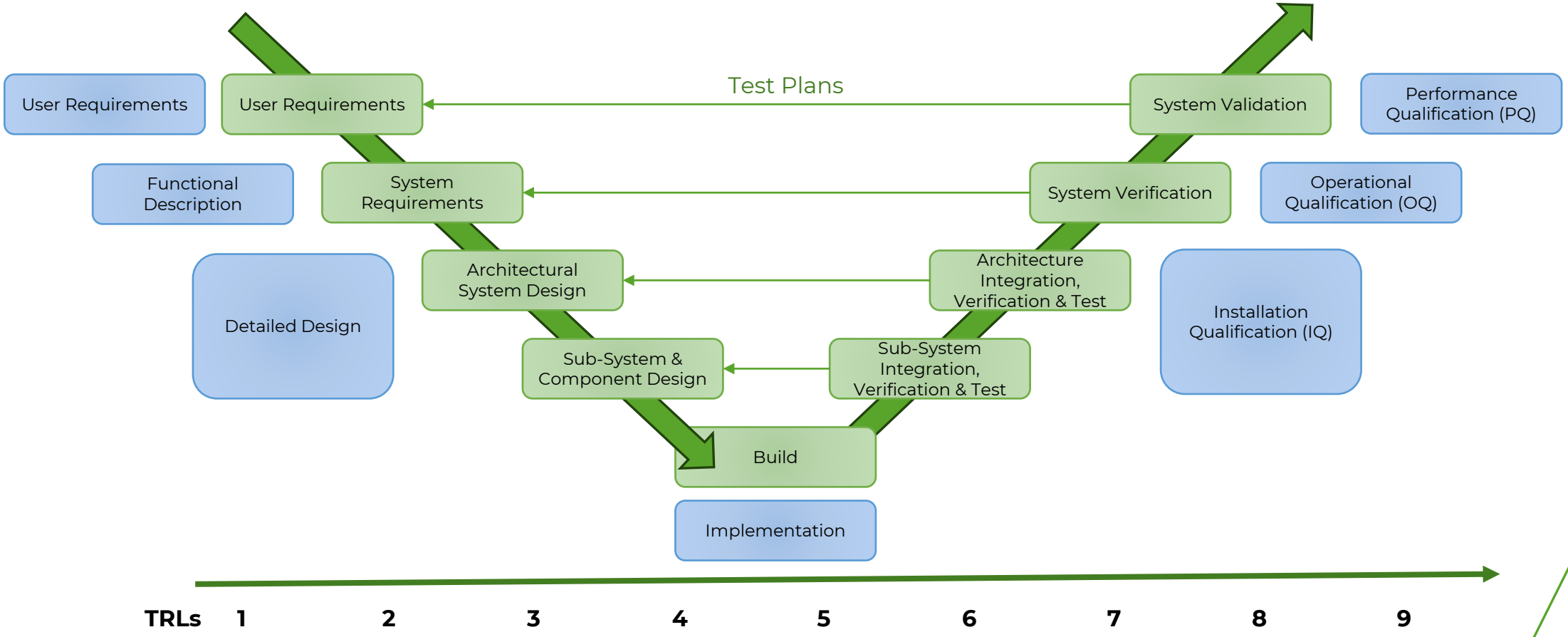


Figure 2: Alignment of V-Models

However, **these models still don’t consider is being operationally ready**.

When introducing a new system or software into a business, as per the TRL model, **project teams focus on the system requirements and system, or technical, readiness**. This means they build the framework and hand the client an empty picture, which is not operational. This leads to projects over budget and overdue, as, in many cases now the data needs to be collected, uploaded and verified.

To avoid future disappointment, we need to define what system or technical readiness is verses business readiness.

So, what does **System, or Technical, Readiness** vs **Business Readiness** really mean?!

Before we dive into technical vs business readiness, **let's define operational readiness**. Operational readiness is **"a process that ensures a project in prepared to be operated and maintained efficiently and safely.** It involves **addressing operational risks, developing mitigation strategies and ensuring the operations team has the skills and tools** to do their jobs."

When implementing a new facility or asset, companies often consider projects in a few stages – design, construct and commission. However, there are the supporting function which prepare the client for an asset.

When either operational readiness is not considered at the start of a project, **there are a few risks** the project manager and client may encounter:

- Project closure delays
- Operational start / go-live delays
- Resource dissatisfaction and departures
- Hidden costs – in the project, operations or both

In this case, the last risk is key. **Systems are not always considered up front.** There are the standard systems most project managers consider – for example, BMS, lighting control, security system, EWIS etc.

However, **when it comes to operating a building or asset, there are additional systems that are required**. For example, asset management software, procurement software, documentation management and in some cases, like in life science, deviation and change management.

When these **systems are forgotten**, **hidden costs emerge, driven by two factors**:

1. Hidden project costs to implement a team, develop the architecture and deploy the system

2. Hidden operating costs to establish and maintain the data in the system

Aside from costs, these projects also take time. Often, time that impacts operations. **Let's consider an example.**

A client has built a new lab, the lab contains an HVAC system, water system and 40 pieces of equipment, including biological safety cabinets (BSC). When handed the keys, the client asks about on-going maintenance of the BSC and HVAC.

In this case, the project team has allowed for **an asset management software system, but the system doesn't contain any data.**

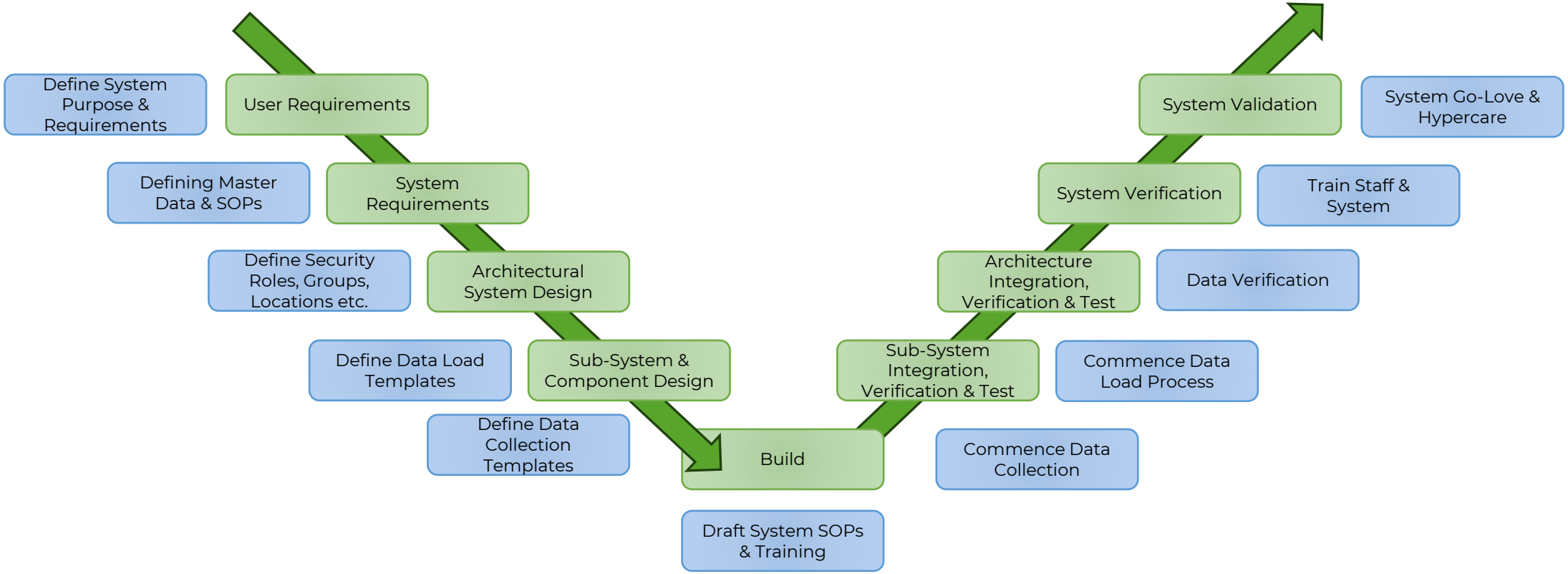
When the lab operator is ready to maintain the BSC, there is no asset maintenance data in the system meaning they can't complete maintenance, meaning the BSC will need to be put out of service until the service can be complete.

This is a common example of where a system is technically ready, but not business ready. So, let's define the two:

- **System / Technical Readiness:** Ensures all technical and system components are in place and function. This focuses on the system itself – i.e. hardware, software, infrastructure, data migration, back-up procedures and disaster recovery.
- **Business Readiness:** Ensures the client – its people, processes and structures – are ready to accept the change, or in this case, system. Additionally, this means that the business has readied the system for operations. This includes developing a master data framework, preparing and uploading all relevant data, developing and implementing documents and training procedures for end users, ensuring all peripherals are accounted for, licenses are purchased etc.

Figure 3 shows how system readiness and business readiness work together.

Technical vs Business Readiness Activities



Let’s focus more on **business readiness and leave system and technical readiness to the experts**.

Being business-ready means the business is ready to accept a system. So, before we accept a system, we need to ask ourselves some key operating questions...

Our considerations...

- How do we collect the data? In templates or in a web application?
- What security / access levels are there? How are these assigned?
- What data is critical to collect? Does the system have a set of minimum entry fields that need to be completed – should these be completed in the data collection forms?
- Do we need to define how the data is structured – i.e. defined or structured nomenclature – to ensure clean and consistent data?
- How is the data uploaded? Do you need to segregate duties – i.e. the person uploading the data cannot approve the data? Do we need a dedicated team or certain skills to upload the data?
- Do the upload templates need to be different from the data collection templates?
- What level of validation do we need when uploading the data? 10% or 100%?
- If we need to add future data or change the data, how do we do this? Do we need a data or systems team? Can this be outsourced?
- Do we need SOP's, so we train staff?
- Do we need classroom or virtual training?
- Who updates the training material when the system is updated?

What's the minimum?

Each of these questions needs to be considered when driving toward business readiness and **can be used to establish a list of minimum requirements that defines business readiness**.

From there, each minimum requirement can be defined with a set of tasks that should be executed prior to readiness.

Table 2 below shows an example set of minimum requirements and associated tasks.

Minimum Requirement	Task
Master Data Nomenclature Defined	Create nomenclature SOP
	Create training program
	Update Templates with pre-filled options / drop down lists
Training Program Established	Create system SOPs
	Create virtual training videos
	Create training program
Upload Data to System	Create a template for data collection
	Create a template for data upload
	Create process flow defining process for data collection and data upload
	Train project team in data collection
	Train operations team to complete data upload

Table 2: Example Set of Minimum Requirements for Business Readiness

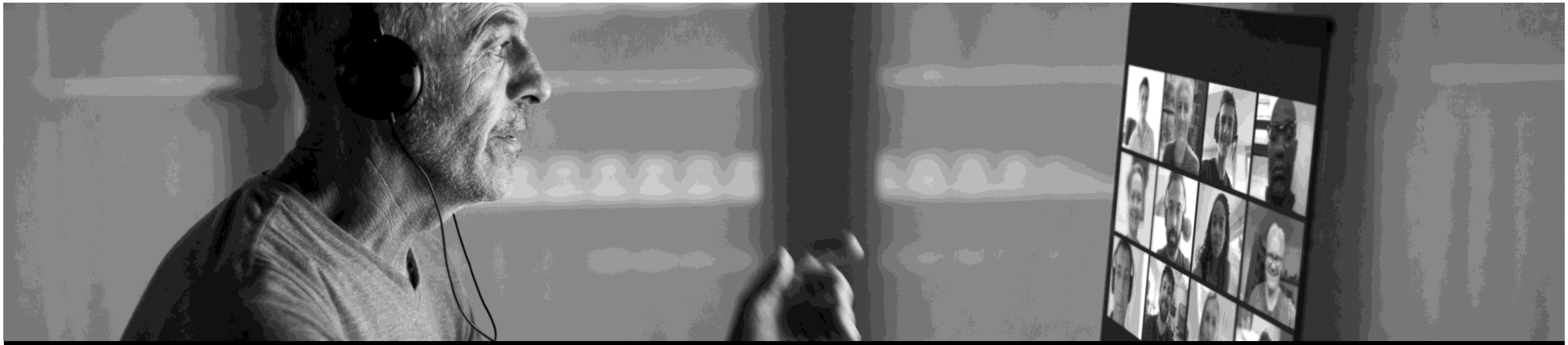
So how do we ensure there is alignment between the project and operational readiness activities?

To ensure alignment between the project and operations, both system and business readiness must be achieved in tandem, as one supports the technical capability, while the other enable adaptation and value realization.

Below we consider some combined success factors:

Factor	System Readiness	Business Readiness
Functional tools & system	☒	☐
Skilled & confident users	☐	☒
Business continuity defined & adopted	☒	☒
Change acceptance	☐	☒
Operational resilience	☒	☒

From here we start considering alignment with project milestones and deliverables.



Previously in Figure 2, we aligned system readiness with the CQV V-model, established by ISPE. If we then overlay out operational requirements, we can map out a project timeline which aligns project and operational milestones.

As shown in Figure 4, we can see that in most cases, operational requirements need to be executed in parallel with project requirements to ensure timelines and milestones are achieved. An example where an operational requirement is needed prior to a project milestone, is in the case of system SOPs. Often to execute and close an OQ protocol, the project team require a draft SOP for the system or equipment item. In this case, a resource (usually from operations) is required to draft an SOP in parallel with the project

Project v Operational Milestones

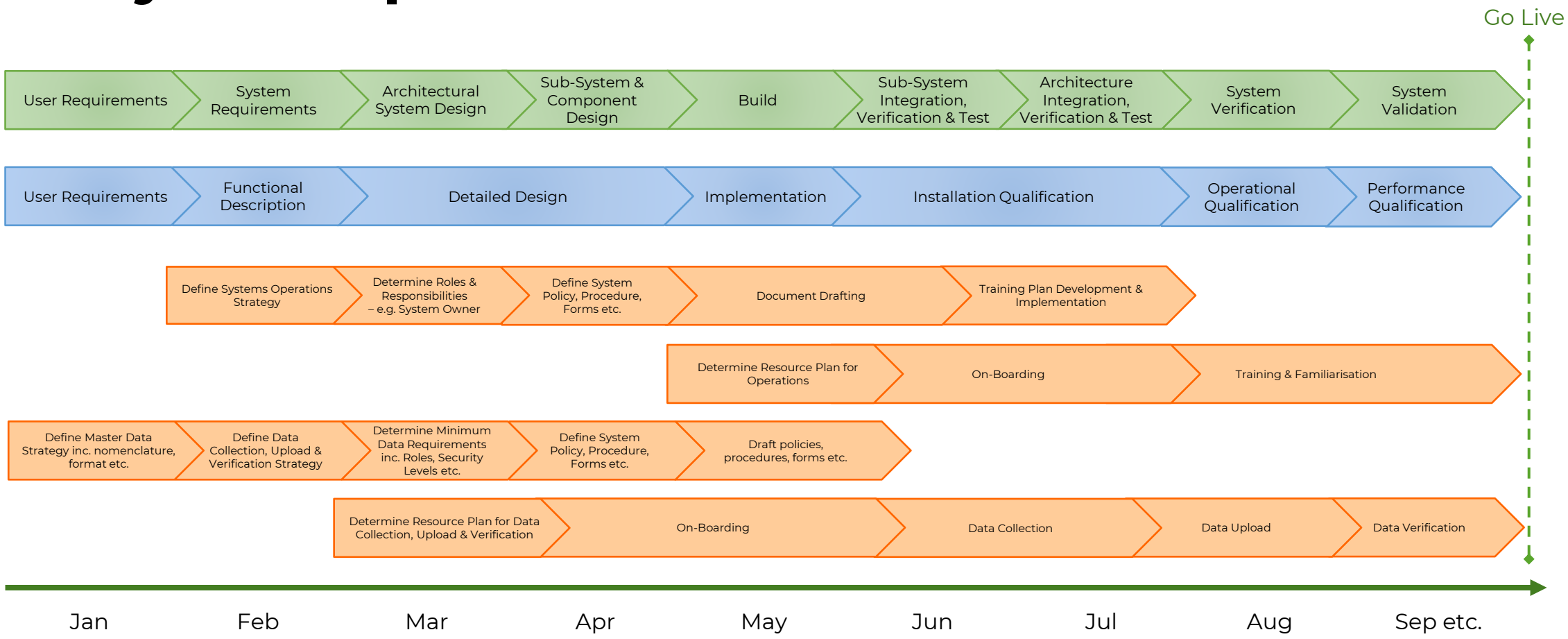


Figure 4: Project vs Operational Milestones

Project Resource Considerations

To ensure all tasks are achieved against project milestones, Figure 4 also considers two types of resources – operational, or BAU, resources and project resources. These project resources are often additional to the ones that have been allocated to completing the project deliverables, as they often require different skills.

Figure 5 shows an example project organizational chart for resourcing the activities shown in Figure 4.

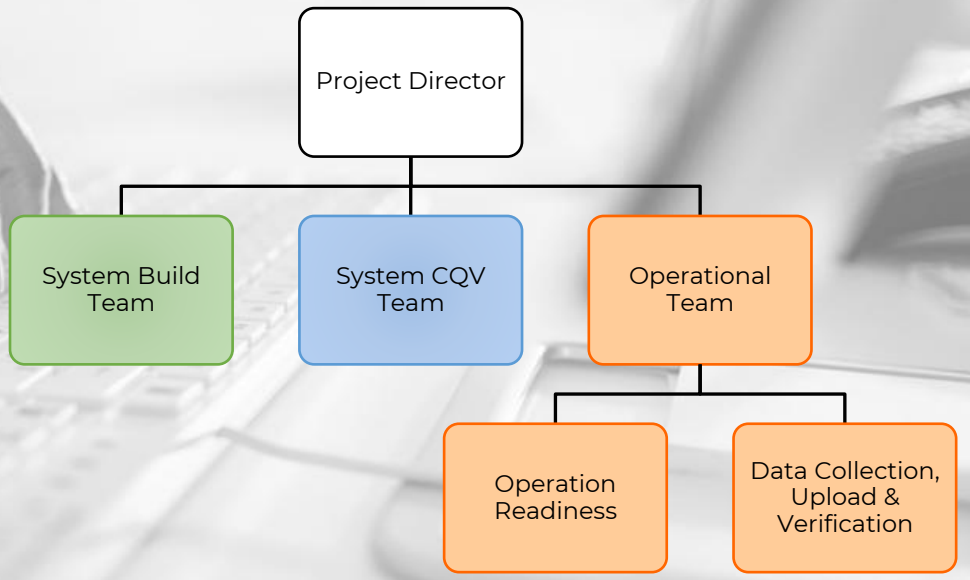


Figure 5: Project Resource Organisational Chart

It all depends...

In this example, we have dedicated resources delivering system build activities, system qualification activities and operational readiness tasks, which are split into two sections – operational readiness (e.g. strategy definition, document drafting, training preparation etc.) and data collection, upload and verification.

For most projects however, resources are not dedicated, and operational readiness activities are assigned to operational staff. This, in many cases, causes delays to operational readiness cases, causing project deliverables to be delayed.

Not only does resourcing play a part in ensuring project milestones are achieved, but early commencement of operational readiness planning ensures task prioritization aligns with project deliverables.

Using the previous example, if operational readiness planning does not commence until after the implementation or build phase for the system, this means system SOPs have not commenced therefore OQ protocols cannot be signed off, causing delays to PQ and extension of project resources, adding to project budgets.

By **commencing** operational readiness planning **early**, this allows **appropriate budget planning** for both project and operational resources, ensures that the system, data and business will be ready.

But what does it mean for the data to be ready?

In some of the pervious figures, we have pointed to **master data strategy and defining standardized nomenclature**. These are all **aspects of data readiness**, which refers to the process of ensuring all data necessary – for both the system and operations – is available, accurate and structured correctly.

Some of the **key components to data readiness** includes (but not limited to):

- **Data Availability:** Ensuring the data is available either for collection or migration.
- **Data Quality:** Ensuring the data is clean (e.g. free of errors/duplication), consistent with standardized nomenclature, accurate and consistent
- **Data Migration / Integration (if appliable):** Ensuring the data is appropriately mapped to new system structures, appropriate API's are in place and data validation / performance tests are established
- **Security & Compliance:** Ensuring the data meets appropriate regulatory requirements, both internal to the business and external to regulatory bodies
- **User Acceptance:** Does the data reflect what the end users are expecting? Is there any missing information or misalignment to existing (or new) operations?

Focusing on data quality, master data nomenclature is critical when either setting up a system or migrating old data. It is a standardized way of naming and classifying data for a system.

For example, standardizing equipment or vendor name formatting, location data or product types.

This ensures consistency and avoids duplication or messy data.

When developing your master data strategy, the following should be considered:

- Naming conventions
- Data Definitions
- Data Attributes
- Taxonomies and Hierarchies
- Ownership and Governance

By considering the key components of data readiness, coupled with a tailored master data strategy, this provides additional steps toward wholistic system readiness.

The **final piece to system readiness is the associated hardware** necessary to operate systems.

We have spoken about systems, data and business readiness, but what about hardware?

Often these systems are supplied with a plethora of devices which need to be installed, configured, commissioned and qualified. System peripherals are considered external devices that connect to a software system that expands its functionality.

There are three types of devices we can consider:

- **Input Devices** – these are devices that input into the system, e.g., scanners, iPad or tablets
- **Output Devices** – these are devices that output from the system, e.g., printers or HMI / monitor
- **Input/Output Devices** – e.g. multifunctional printers that both scan (input) and print (output)

Like the system itself, these devices require a level of planning to ensure they are ready for day one, including (but not limited to) procurement (including consumables – e.g., printer ink, stickers etc.), configuration, commissioning or data upload.

Ready System, Success Ready!

Achieving full system readiness is more than just installing software or configuring hardware – it requires a holistic approach that ensures every component is aligned and prepared for day one.

Starting with project and operational readiness align, to preparation of master data and its nomenclature or peripherals commissioning, all elements create a foundation that not only supports technical success but also drives organizational efficiency and user adoption.

Without a wholistic readiness strategy, even the most sophisticated systems can fail to deliver their intended value.

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EngCor brings a rare blend of deep operational insight and full-spectrum project leadership across the life sciences, food and beverage projects – from concept to compliance. With hands-on experience in design, construction, commissioning, and qualification, we bridge the gap between technical execution and regulatory readiness—ensuring that every project is not only delivered on time and on budget, but also fully aligned with regulatory standards and future operational needs.

We have a passion for streamline processes and driving efficient operations. Reach out to us at admin@engcor.com.au to schedule a **free call** or visit our website at engcor.com.au

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Acronym	Definition
API	Application Programming Interface
BAU	Business as Usual
BSC	Biological Safety Cabinet
CQV	Commissioning, Qualification and Validation
e.g.	Example
etc.	Et cetera or ‘and other similar things’
GMP	Good Manufacturing Process
HMI	Human-Machine Interface
HVAC	Heating, Ventilation and Air Conditioning
IQ	Installation Qualification
ISO	International Organisation for Standardisation
ISPE	International Society for Pharmaceutical Engineering
OQ	Operational Qualification
PQ	Performance Qualification
SOP	Standard Operating Procedures
SRL	Software Readiness Levels
TRL	Technology Readiness Levels

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