

## CHECKLIST · LIFE SCIENCES CAPITAL PROJECTS

# Before Design Freezes

An automation & validation checklist for early-stage Life Sciences capital projects

The decisions that drive automation cost, validation effort, and long-term operability are usually made during conceptual and basic design, often before an automation partner is involved. Use this checklist to confirm each one is made on purpose, not by default.

| 01                           | 02                  | 03                       | 04                  | 05                                | 06                                 | 07                                |
|------------------------------|---------------------|--------------------------|---------------------|-----------------------------------|------------------------------------|-----------------------------------|
| Control Platform & Standards | MES & Digital Scope | Data Integrity & Part 11 | Validation Strategy | OT Infrastructure & Cybersecurity | Lifecycle Ownership After Handover | Project Execution & Partner Roles |

## 01 Control Platform & Standards



**WHY IT MATTERS** Platform choices made early set your spare parts, training, obsolescence exposure, and validation reuse for the next 15 to 20 years.

- ☐ Will you standardize on your existing enterprise control platform, or is the platform open for this project?
- ☐ Are there documented site or corporate automation standards, current enough to hand to designers?
- ☐ Will batch processes follow an ISA-88 model, and is a recipe structure defined?
- ☐ Have you set automation and communication requirements for OEM skids and package equipment (e.g., OPC UA, PackML, MTP)?
- ☐ What is the expected support lifecycle of the chosen hardware and software versions?

**OWNER:** \_\_\_\_\_

## 02 MES & Digital Scope



**WHY IT MATTERS** Adding MES after the facility is built often means rework in the control layer, networks, and validation documentation.

- ☐ Is MES / electronic batch record in scope for Day 1, or planned for a later phase?
- ☐ If it's phased, is the control system being designed now to support it later?
- ☐ Which systems need to integrate (ERP, LIMS, QMS, historian, warehouse), and who owns each interface?
- ☐ Is the goal paper-on-glass, or full review by exception?
- ☐ Has a data model or ISA-95 architecture been defined across sites?

**OWNER:** \_\_\_\_\_

## 03 Data Integrity & Part 11



**WHY IT MATTERS** Data integrity is far cheaper to build into the architecture than to add controls and procedures around after the fact.

- ☐ Has each system been classified as GxP or non-GxP?
- ☐ Are ALCOA+ principles written into user requirements, not just SOPs?
- ☐ How will audit trails, electronic signatures, and time synchronization be handled across systems?
- ☐ Have GxP data flows been mapped from instrument to final record?
- ☐ What are the retention, archiving, and retrieval requirements?

**OWNER:** \_\_\_\_\_

## 04 Validation Strategy



**WHY IT MATTERS** A risk-based approach agreed early can meaningfully reduce documentation and testing effort without adding compliance risk.

- ☐ Will you apply a risk-based approach aligned with GAMP 5 (Second Edition) and FDA's Computer Software Assurance (CSA) guidance?
- ☐ Will commissioning and qualification be integrated (e.g., ASTM E2500), with FAT/SAT testing leveraged into qualification?
- ☐ Who is writing the user requirements, and when will they be approved?
- ☐ Can supplier documentation and testing be leveraged, and what does your quality unit require for that?
- ☐ How will traceability from requirements to testing be maintained?

**OWNER:** \_\_\_\_\_

## 05 OT Infrastructure & Cybersecurity

**WHY IT MATTERS** Network and security architecture is hard to retrofit once walls, panels, and cable trays are in place.

- ☐ Is the OT network designed around zones and conduits (IEC 62443)?
- ☐ How will secure remote access for vendors and support teams work?
- ☐ Where is the line between IT and OT responsibility, and is it documented?
- ☐ Is virtualization, backup, and disaster recovery part of the design?
- ☐ How will patching and vulnerability management work in a validated environment?

**OWNER:** \_\_\_\_\_

## 06 Lifecycle Ownership After Handover

**WHY IT MATTERS** The qualified state has to be maintained for as long as the facility runs. Deciding who owns that before go-live avoids gaps when the project team moves on.

- ☐ Who will own change control for automation and MES after turnover?
- ☐ Who will monitor system health, security, and performance, and will that be proactive or reactive?
- ☐ How will obsolescence and upgrades be planned without disrupting validated operations?
- ☐ Does your team have the internal staff to sustain the systems, or will you need an ongoing partner?
- ☐ What must be in the turnover package for operations to own the system with confidence?

**OWNER:** \_\_\_\_\_

## 07 Project Execution & Partner Roles



**WHY IT MATTERS** Late engagement of automation expertise is one of the most common causes of schedule pressure during commissioning.

- ☐ When will the automation partner be engaged relative to the EPC's design schedule?
- ☐ Is there a clear responsibility matrix across owner, EPC, automation partner, and OEMs?
- ☐ Are automation deliverables built into the overall project schedule, not appended to it?
- ☐ Is there enough spare I/O, panel space, and network capacity for future expansion?

**OWNER:** \_\_\_\_\_

### HOW INFLEXIONPOINT HELPS

## An accountable operating partner, from design through the life of your facility

We help Life Sciences teams answer these questions early, then deliver on them. InflexionPoint designs and builds automation, MES, and IT/OT infrastructure, then stays on as an accountable operating partner to support your team, with proactive managed services that keep systems secure, compliant, and performing long after go-live.

### Design

Automation strategy, architecture, and validation approach shaped early.

### Build

Controls, MES, and IT/OT infrastructure delivered and qualified.

### Manage

Proactive monitoring, OT cybersecurity, and continuous improvement.

## Open items & next steps

---



---



---



---



---



---