Automation Integrator Evaluation Checklist

An automation integrator evaluation checklist for future-focused life sciences manufacturers.

Automation integrators in regulated life sciences directly impact validation effort, inspection readiness, and system performance. The right partner embeds GMP and compliance into engineering decisions from the start.

Use this checklist to align teams, reduce validation risk, and evaluate integrators.

1. GMP and validation readiness

- ☐ Demonstrates practical experience with GAMP 5 and Annex 1
- ☐ Produces full validation documentation (protocols, reports)
- ☐ Applies a risk-based validation approach in project execution
- ☐ Engages QA and validation input during design

2. Documentation and data integrity

- ☐ Documentation is created throughout the project lifecycle (not at closeout)
- ☐ End-to-end traceability from requirements to testing is maintained
- ☐ Version control and change management are clearly defined
- ☐ Systems support audit-ready data integrity

3. Life Sciences experience

- ☐ Proven delivery in pharmaceutical, biotech, or medtech environments
- ☐ Understands cleanroom, batch processing, and regulated production constraints
- ☐ Balances operational performance with validation requirements
- ☐ Anticipates compliance impact of design decisions early

4. Systems integration capability

- ☐ Experience integrating SCADA, MES, PLC, and ERP systems
- ☐ Strong understanding of ISA-95 / IEC 62264 architecture
- ☐ Ensures clean data flow across OT and IT layers
- ☐ Maintains validated state across integrated systems

5. Change management and lifecycle support

- ☐ Formal change control process with validation impact assessment
- ☐ Clear approach to revalidation and documentation updates
- ☐ Post-Go-live support for troubleshooting and optimization
- ☐ Lifecycle strategy beyond initial project delivery

6. Scalability and delivery model

- ☐ Supports multi-site or global deployment strategies
- ☐ Can standardize systems while maintaining compliance consistency
- ☐ Clear execution methodology aligned with validation requirements
- ☐ Flexible delivery model (custom or standardized approaches)

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