



SUCCESS FACTORS FOR GMP CONSTRUCTION AND QUALIFICATION PROJECTS.

Robust GMP Projects Begin with Clear Structures.

In GMP construction and qualification projects, one recurring insight becomes evident: the decisive risks in a project do not arise from individual technical misjudgments, but from a lack of structural consistency within the project. When governance, information architecture, qualification logic, and interfaces are not clearly defined and interlinked from the outset, inconsistencies inevitably shift into later project phases – with corresponding impacts on timelines, costs, and compliance.

This whitepaper consolidates practical experience and derives specific fields of action from it. The objective is not to ensure GMP relevance only during qualification, but to anchor it in the project model from the very beginning. The foundation includes insights from a multi-year GMP project in which IE collaborated with the client over three years, with significant support from ecoSPECS in qualification. Following completion, a joint “lessons learned” exercise was conducted, and its results have been incorporated into this whitepaper.

GMP Robustness is Created by the Project Model – Not Only During Qualification.

A recurring pattern in complex projects is the implicit assumption that GMP compliance can primarily be ensured through late-stage testing and documentation activities. In practice, the opposite is true: as soon as project logic, decision structures, and the documentation model are not defined coherently at an early stage, conflicts and ambiguities shift into later project phases – where they have significantly greater cost and schedule impacts.

This becomes particularly critical when qualification requirements are known from a technical perspective but are not visibly embedded in operational project management. In such cases, planning, execution, documentation, and qualification run in parallel instead of being integrated.

Key message:

GMP compliance in complex construction projects is not a downstream verification step, but the result of a consistent project model.



Four Patterns That Typically Reduce Project Stability

1. Lack of Governance Between Project Management, Stakeholders, and Qualification

In complex project constellations, it is not only relevant who is involved, but how areas of responsibility, decision-making authority, and escalation mechanisms are structured. As soon as roles overlap functionally, responsibilities are only assumed situationally, or external stakeholders are not properly embedded in the leadership logic, friction losses, interpretation gaps, and loss of trust arise.

2. Lack of Information Architecture in Documentation and Review

Many projects underestimate that documentation is not only a repository of evidence but an operational management tool. If information statuses, versioning, reviews, storage, and approval workflows are not designed as an integrated system, this leads to an unstructured documentation landscape and a growing administrative parallel system.

3. Non-integrated Qualification Logic Within the Overall Project Lifecycle

A particularly impactful pattern is the insufficient integration of qualification phases into project management. URS, review windows, GMP-relevant changes, documentation statuses, and qualification-related milestones must not only be known, but must be **visibly controllable** within the project.

4. Overloaded Interfaces Between Construction, Site operations, Client, and Qualification

In almost all demanding GMP projects, a significant share of risk lies not in technical planning itself, but in the interfaces between disciplines and organizations. This becomes critical when on-site operational decisions, documentation requirements, client expectations, and qualification logic do not converge within a shared communication structure.

Systemische Einflussfelder in GMP-Bau- und Qualifizierungsprojekten

Verdichtung der Lessons Learned auf Executive-Ebene

● Qualität / GMP-Compliance

● Termin / Ressourcen

● Rework / Kosten

● Teamstabilität / Zusammenarbeit

Einflussfeld	Qualität / GMP-Compliance	Termin / Ressourcen	Rework / Kosten	Teamstabilität / Zusammenarbeit
Governance & Verantwortungsräume Steuerungslogik, Rollenarchitektur, Eskalation und Einbindung externer Akteure	hoch	hoch	relevant	hoch
Informationsarchitektur & Review Versionierung, Reviewfenster, Freigabelogik und belastbare Dokumentationsstruktur	hoch	relevant	hoch	punktuell
Integration der Qualifizierungslogik Sichtbare Verankerung von URS-, Review- und Quali-Meilensteinen im Projektmodell	hoch	hoch	relevant	punktuell
Operative Schnittstellenführung Kopplung von Baustelle, Kunde, Dokumentation, Projektleitung und Qualifizierung	relevant	hoch	hoch	hoch

Lesart für die Darstellung: Nicht einzelne Symptome in den Vordergrund stellen, sondern die strukturellen Hebel, die Qualität, Termine, Kosten und Zusammenarbeit gleichzeitig beeinflussen.



"The more complex the project, the more important it becomes to consciously manage interfaces between project management, site operations, the client, external partners, and qualification."

Ricardo Klering, Hygiene & Cleanroom Expert
IE Industrial Engineering München GmbH



What Works Best in Practice

1. Define a Joint Project and GMP Operating Model at Project Start

Erfahrene Projekte profitieren davon, zu Beginn nicht nur Ziele und Termine, sondern auch das Betriebsmodell des Projekts zu definieren: Begriffe, Entscheidungswege, Rollenräume, Review-Logik, Eskalationsmechanismen und qualifizierungsrelevante Steuerungspunkte.

2. Make Governance Visible Rather Than Assuming It

Role descriptions alone are insufficient. Governance becomes effective only when responsibilities, handovers, substitutions, and decision boundaries are actively managed within the project.

3. Establish Documentation as an Information System

A robust documentation strategy does not begin with the number of documents, but with their architecture: a consistent structure, transparent versioning, clearly defined review windows, unambiguous approval logic, and an information model that is understood and applied by all stakeholders.

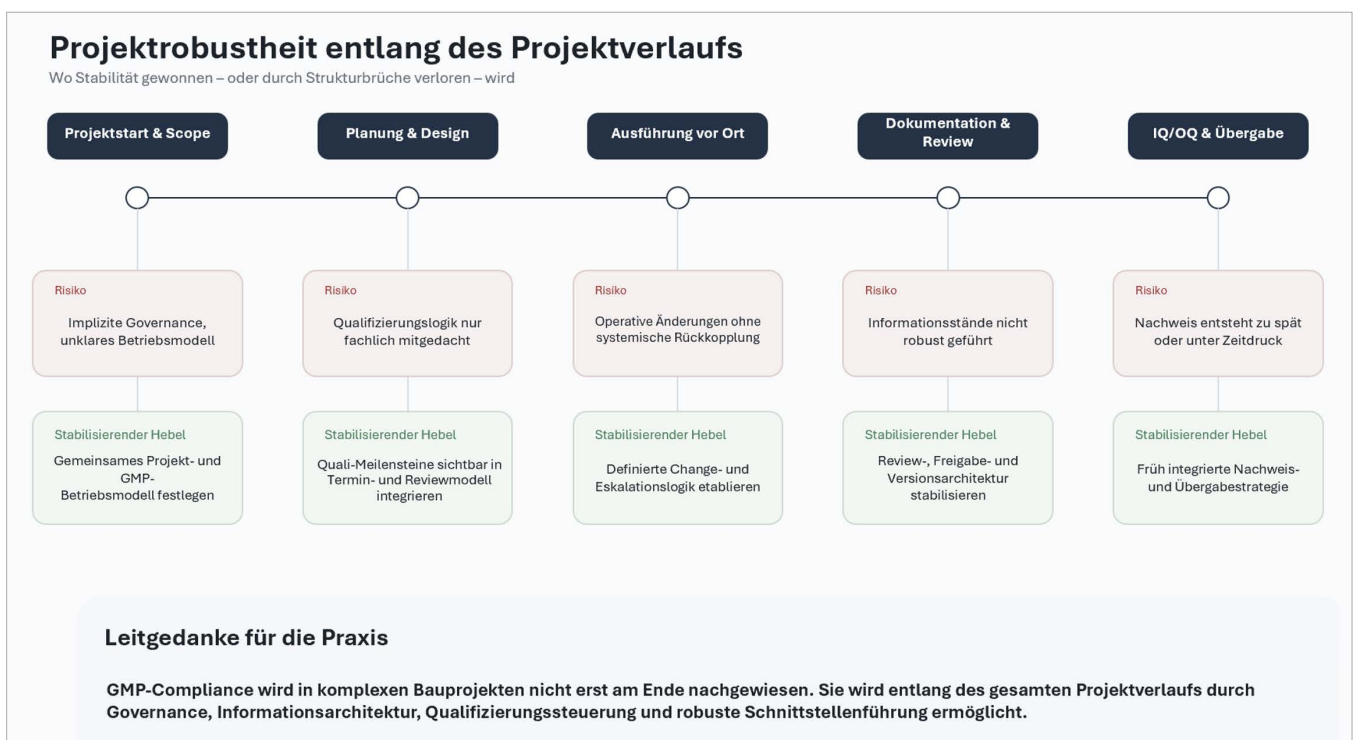


4. Integrate Qualification Phases Visibly Into the Scheduling and Decision Model

URS, design and review milestones, GMP-relevant approvals, and IQ/OQ-related milestones should not be treated as implicit technical background. They must be explicitly represented in the project plan, protected against operational overlap, and actively managed.

5. Actively Manage Interfaces – Especially Where Site Operations and Documentation Intersect

The more complex the project, the more essential structured interface management becomes between project management, site operations, the client, external partners, and qualification. This includes clear handovers, early escalation, and the consistent alignment of operational decisions with the project's regulatory logic.



Conclusion:

Complex GMP construction projects rarely lose stability due to technical issues alone. They become critical where governance, documentation, qualification logic, and operational interfaces are not sufficiently integrated.

The most effective countermeasures are rarely spectacular but are structurally highly relevant: a robust project model, clearly defined areas of responsibility, a structured information architecture, and a qualification logic that is not only applied at the end, but is embedded in project management from the outset.

Those who establish these structures early on not only reduce rework and schedule risks, but also increase the likelihood that GMP compliance is not merely defended throughout the project – but is consistently enabled.



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Maximizing potential in industrial construction and logistics is one of IE Group's core principles. To achieve this, our experts in logistics planning, operations planning, and construction planning collaborate closely with equipment suppliers and authorities. By optimally integrating all requirements, we create highly efficient end-to-end solutions for our clients.

As a specialist in industrial construction and smart logistics concepts, we are pleased to support you as a consulting partner.

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