COMPANION RESOURCE — M&A; / COMPLIANCE DILIGENCE

12-Gap Pre-Diligence Compliance Checklist

A working document for sellers, buyers, and their advisors. Run this before the LOI, not after. Every gap below repriced or killed a real life sciences deal in the last 24 months.

How to use: Score each gap Green (defensible today), Yellow (fixable in <60 days), or Red (needs quarter-scale remediation). Red items are what buyers repricing on.

#	Gap	What you should be able to show	Why it matters at diligence	G/Y/R
1	**Design History Files that stop mid-product-life**	DHF traces from concept through post-market, including post-launch changes.	Buyer's QA lead pulls DHFs first for continuity.	■■■
2	**CAPA backlog with no aging analysis**	Aging report showing open CAPAs by days, closure velocity, RCA discipline.	Open CAPAs > 180 days without active work = red flag.	■■■
3	**Supplier files with no requalification cadence**	Every critical supplier requalified within stated cadence; complete quality agreements.	$500K–$2M price reduction typical for stale supplier files.	■■■
4	**Training records without competency evidence**	Assessment results, not just attendance rosters.	21 CFR 820.25 exposure now shows up in valuation.	■■■
5	**Complaint handling without trend analysis**	MDR/vigilance decision documentation, trending, and CAPA link.	Every buyer's QA lead pulls the complaint log first.	■■■
6	**UDI records that don't match GUDID**	Internal UDI records reconciled to GUDID within last 90 days.	Data drift is instantly visible in diligence.	■■■
7	**Missing risk management updates post-launch**	ISO 14971 risk file updated with post-market data within last 12 months.	Stale risk file signals stale QMS overall.	■■■
8	**Software validation gaps in production tools**	Part 11 validation on every tool used in quality or manufacturing workflows.	Disclose early — late disclosure kills trust.	■■■
9	**Missing or outdated PMS/PMCF plans**	Current post-market surveillance and clinical follow-up plans per MDR.	Hard stop for European buyers if missing.	■■■
10	**Change control records that skip approval steps**	Every change order has complete signatures, no backdating, departed employees replaced.	Missing signatures are diligence gold for buyers.	■■■
11	**Sterilization / process validation gaps**	IQ/OQ/PQ files complete with raw data and signed protocols; current standard revision.	Won't survive a serious buyer's technical review.	■■■
12	**Regulatory correspondence that isn't indexed**	Chronological, searchable, indexed FDA/notified body correspondence.	2+ week response times = deal cools.	■■■

PRE-DILIGENCE ACTIONS (SELLER SIDE)

What to do 90–120 days before the process starts

- **Self-diligence pass.** Run this checklist internally. Fix Red items quietly, before a buyer asks.
- **Index all FDA/notified body correspondence.** Build a chronological, searchable file.

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- **Refresh training competency evidence.** Rosters alone won't hold; add assessments.
- **Reconcile UDI vs. GUDID.** Fix all data drift.
- **Bring QA/RA leadership into deal prep.** Counsel spots risk; QA/RA spot documentation gaps.

PRE-DILIGENCE ACTIONS (BUYER SIDE)

What to do before you sign the LOI

- **Request the target's AI-assisted document index.** If they don't have one, price it in.
- **Run structured diligence extraction on the data room.** 72-hour turnaround is now standard for sophisticated buyers.
- **Score every gap Green/Yellow/Red.** Yellows are negotiation levers; Reds are price adjustments.

Considering a transaction?

Book a free 30-minute working session at alterra-ai.com/contact. No pitch — a working conversation with someone who has run compliance diligence on both sides of the table.

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