BUYER DUE DILIGENCE

Sterile Injectable CMO Audit Checklist

A public, non-confidential framework for screening and structuring due diligence for aseptically processed or terminally sterilized injectable projects. It is not an audit outcome or a conclusion about any facility.

Three answers before shortlisting

01 Legal entity, site and current scope
Identify the exact legal entity and manufacturing site; verify the current licensed and regulatory scope relevant to the proposed product and market.

02 Product-to-train fit
Match formulation, route, presentation, container-closure system, batch-size range, sterilization strategy and required analytical package to the specific train.

03 Integrated sterility-assurance system
Evaluate contamination control, personnel practices, utilities, environment, process simulation, sterilization or aseptic processing, laboratory controls and quality governance as one system.

Ten-point checklist

Checkpoint	What the buyer should establish	Checkpoint	What the buyer should establish
1. Legal identity and current regulatory scope	Confirm the named site, relevant dosage-form scope and target-market route.	**6. Laboratory and data trail**	Assess microbiology, analytical capability, data governance, method status and traceability.
2. Product-to-train fit	Connect the defined product and presentation to the actual manufacturing train.	**7. Quality-system performance**	Use recent deviations, investigations, CAPA, complaints and changes to test how the system operates.
3. Contamination control strategy	Assess how facilities, utilities, people, materials, monitoring and interventions form one control strategy.	**8. Inspection history in context**	Verify source, date, scope, classification and closure; do not treat inspection history as certification.
4. Sterile-process evidence	Review the evidence applicable to terminal sterilization or aseptic processing, not a generic sterile label.	**9. Technology-transfer readiness**	Define transfer package, gaps, training, methods, process evidence, stage gates and acceptance criteria.
5. Personnel and aseptic behavior	Look for qualification, observation, intervention control, accountability and sustained practice.	**10. Supply and lifecycle governance**	Align release, change control, forecast, materials, continuity, responsibilities and escalation.

> Decision principle: a certificate, inspection record, filling line or public capacity statement cannot by itself establish suitability. The conclusion must connect the defined product, site, route, evidence package and target market.

EVIDENCE-BASED REVIEW

Questions to take into due diligence

01 Contamination control

Ask: How are facilities, utilities, people, materials, monitoring and interventions connected in the contamination control strategy?

Evidence examples: current strategy, risk assessments, trend review, investigation examples and governance records

02 Process-specific controls

Ask: What evidence supports the proposed terminal-sterilization or aseptic-processing route for the defined product and presentation?

Evidence examples: cycle rationale, process simulation, intervention catalogue, validation plan and acceptance criteria

03 People and behavior

Ask: How are operators qualified, observed and requalified, and how are poor aseptic practices detected and corrected?

Evidence examples: qualification records, observation programme, gowning and intervention controls, recent corrective actions

04 Laboratory and data

Ask: Can the laboratory support microbiological and analytical decisions with complete, traceable and governed data?

Evidence examples: method status, transfer plan, electronic and paper data controls, OOS/OOT examples, trend reports

05 Quality-system maturity

Ask: How do deviations, investigations, CAPA, change control and management review behave under real project pressure?

Evidence examples: recent representative cases, escalation routes, effectiveness review and sponsor-communication model

06 Transfer and supply

Ask: Can knowledge, methods, process and supply responsibilities be transferred through measurable stage gates?

Evidence examples: gap assessment, RACI, transfer protocol, readiness reviews, continuity and lifecycle plan

> Inspection-history boundary: record the regulator, inspection date, inspected scope, classification, observations, responses and closure status. An inspection history is context; it is not a certificate, approval or proof of readiness for a different product, route or market.

Red flags that require deeper evidence

- The legal entity, site or proposed manufacturing train is unclear.
- Public statements are used as a substitute for current product-specific evidence.
- Change-control, deviation or escalation responsibilities are not defined between parties.
- The proposed schedule assumes that development, method or validation gaps do not exist.
- Inspection language is presented as certification or universal approval.
- Sensitive information is requested before confidentiality, purpose and access controls are agreed.

CONTROLLED PROJECT PATH

From public screening to a governed decision

01	Public fit screen Use legal identity, public dosage-form scope, target market and a non-confidential project objective.
02	Confidentiality and scope Agree purpose, permitted use, access and review scope before exchanging sensitive information.
03	Structured document review Assess product, process, analytical, quality, regulatory, capacity and supply evidence.
04	On-site and technical due diligence Test the documented system against facilities, people, practices, data and recent examples.
05	Risk decision and agreements Record gaps, mitigations, decision rights, quality responsibilities, commercial scope and acceptance criteria.
06	Transfer, validation and lifecycle Execute stage gates, verify readiness, govern changes and sustain supply through the product lifecycle.

Non-confidential information for the first discussion

- Dosage form, presentation, route and high-level product characteristics
- Development/commercial stage, proposed cooperation model and intended timing
- Target market, dossier status and current regulatory objective
- Indicative batch-size range, supply objective and container-closure system
- The specific technical, quality, regulatory, transfer or supply decision to be resolved

> Information boundary: do not send patient information, prescriptions, complete formulas, detailed process instructions, unpublished dossiers or trade secrets before an appropriate confidentiality arrangement. An initial discussion does not confirm project acceptance, capacity, price, regulatory outcome or service commitment.

Discuss a non-confidential sterile-injectable project fit

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Authoritative references

1. WHO TRS 1044, Annex 2 - GMP for sterile pharmaceutical products
2. European Commission - EudraLex Volume 4, Annex 1
3. U.S. FDA - Sterile Drug Products Produced by Aseptic Processing - CGMP
4. PIC/S PE 009-17 Annexes, Annex 1
5. NMPA - Contract-manufacturing supervision requirements