

Vendor Risk Assessment Questionnaire

Case: Critical, Life-Saving Infusion Raw Materials Supplier

1. Regulatory & Compliance

1. Do you hold all required regulatory approvals (e.g., FDA, EMA, GMP) for manufacturing this raw material?
2. When was your last regulatory inspection, and were any major findings reported?
3. Do you follow Good Manufacturing Practices (GMP) and maintain written SOPs for all key processes?
4. Are you compliant with all applicable pharmaceutical safety regulations in your operating country?
5. Do you notify customers of any regulatory actions, warnings, or penalties within a defined timeframe?

2. Quality & Manufacturing

1. Do you have a validated and documented manufacturing process for this raw material?
2. What controls are in place to ensure batch-to-batch consistency and purity?
3. Do you perform final product testing before release? If yes, please describe.
4. How do you handle deviations, non-conformances, and corrective actions (CAPA)?
5. Are your production and testing equipment regularly calibrated and maintained?

3. Documentation & Data Integrity

1. Do you follow ALCOA/ALCOA+ data integrity principles (Attributable, Legible, Contemporaneous, Original, Accurate)?
2. Are batch records, test results, and audit trails fully traceable and securely stored?
3. How do you ensure documentation cannot be altered without proper authorization?
4. Do you maintain product certificates (CoA, CoC) for every batch shipped?
5. What is your retention period for quality and manufacturing records?

4. Cybersecurity & Technology

1. Do you have basic cybersecurity controls in place (firewalls, MFA, access controls, backups)?
2. Are quality systems, lab systems, and manufacturing systems protected against unauthorized access?
3. How do you secure electronic batch records and sensitive production data?
4. Do you have an incident response plan for cyber events or system failures?
5. Do you conduct regular vulnerability assessments or system updates?

5. Supply Chain & Logistics

1. Do you have multiple sources for critical raw inputs used to manufacture this material?
2. How do you ensure continuity of supply during disruptions (e.g., political instability, natural

disasters)?

3. What controls are in place to prevent contamination, mix-ups, or temperature deviations during transport?
4. Do you maintain full traceability of materials from origin to final shipment?
5. What is your typical lead time, and how do you communicate or manage delays?

6. Legal, Ethical & Financial Risk

1. Are you financially stable and able to support long-term supply commitments?
2. Do you comply with ethical sourcing, anti-corruption, and anti-bribery laws?
3. Are there any ongoing legal actions or disputes that could affect your ability to supply products?
4. Do you carry appropriate liability insurance for pharmaceutical raw materials?
5. Do you ensure that all subcontractors or secondary suppliers meet equivalent quality and compliance standards?