# BI SPECTRA 

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## Supplier Management

As an originator of compliance in the excipient biological buffer industry, the BioSpectra team understands the industry's evolving needs in quality and regulatory compliance. BioSpectra's supplier management requires the inspection and approved testing of each incoming raw material. These ensure the identity, strength, quality and purity of each product is met before being introduced into our facility. This Quality System maintains the integrity of the supply chain, guaranteeing the compliance, safety, security, traceability and quality of the manufacturing, storage and shipment of each raw material.

Supplier Risk Management Questionnaire Risk Rating Calculation: Severity (S) x Occurrence (O) x Detection (D)

| Key Questions for Risk Assessment | Compliance |  |  | Risk Rating |  |  |  | Risk Mitigation Plan |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Key Questions for Risk Assessment | N/A | Yes | No | S | O | D | Total |  |
| Is there a procedure to control Standard Operating Procedures and Records? |  |  |  |  |  |  |  |  |
| Is there a record retention procedure? |  |  |  |  |  |  |  |  |
| Is there a procedure for approving and verifying packaging and labeling of material? |  |  |  |  |  |  |  |  |
| Are there adequate controls to prevent cross contamination? |  |  |  |  |  |  |  |  |
| Does the supplier have a procedure for the lotnumbering each product? |  |  |  |  |  |  |  |  |
| Is there an approved sampling plan for Raw materials, in-process and finished goods? |  |  |  |  |  |  |  |  |
| Does the Quality Unit review and approve documentation records, labels, testing and batch records before release? |  |  |  |  |  |  |  |  |
| Is every batch tested and approved before shipment? |  |  |  |  |  |  |  |  |
| Is there a stability program for all finished products? |  |  |  |  |  |  |  |  |
| Is there an expiration date issued for each lot of product? |  |  |  |  |  |  |  |  |
| Are there written procedures for change control? |  |  |  |  |  |  |  |  |
| Is there a system to trace raw material to the original manufacturer? |  |  |  |  |  |  |  |  |
| Does each lot of raw material have a certificate of analysis with the appropriate intended end use statement? |  |  |  |  |  |  |  |  |

