BIOSPECTRA

AUDIT GUIDELINES

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BioSpectra Audit Guidelines

BioSpectra welcomes auditors and visitors. Our customers and business partners are assured access to our facilities based on purchased product grade attributes and/or Supply/Quality Agreements. BioSpectra allows scheduled audits to maintain assurance of current information related to the systems, equipment, utilities and operations at each site. Potential customers and potential business partners may be provided with appropriate access while establishing business relationships. Audits may be restricted in the absence of a current commercial relationship.

Audits of a BioSpectra facility are submitted after successful completion of the Audit Request Form. This Form includes the necessary details to organize and coordinate the appropriate resources to ensure each audit of BioSpectra is meaningful, productive and rewarding to each party involved.

Customers may submit audit requests via email to: RA@biospectra.us

Audits of BioSpectra Facilities and Systems

1. **Federal, State and Local Agencies** with authority over the operation or compliance of our manufacturing facilities are given immediate and unrestricted access to our sites with top priority.
    a. When: On Demand
    b. Typical Duration: As required

2. **Contract Customers of BioSpectra brand materials including Bio Pharma Grade, Bio Excipient Grade, Bio Active Grade and Bio FUISA Grade** are given priority access based on the compliance attributes of the purchased product grade and corresponding BioSpectra facility.
    a. When: As available by request
    b. Typical Duration: ½ day – 2 days (Depending on products and applicable grades)

3. **Contract Manufacturing Customers** of private label products are given priority access to corresponding BioSpectra facility specific to the products purchased. End-customers of our Contract Manufacturing Customers are given audit access based on the terms and conditions of the Contract Manufacturing Customer's current quality and/or supply contract. Audits by end-customers of Contract Manufacturing Customers must be scheduled through the Contract Manufacturing Customer.
    a. When: As available by request
    b. Typical Duration: 1 hour - 1 day

4. **Customers of BioSpectra brand** materials including Bio Pharma Grade, Bio Excipient Grade, Bio Active Grade and Bio FUISA Grade are welcome to schedule audits based on established business relationship and grade of product purchased. Typically audits for these customers include:
    a. Annual / Biannual / Triannual compliance audits: These are coordinated through our Regulatory Department.
    b. When: As available by request (90 Day notice requested)
    c. Typical Duration: ½ Day - 2 days (Depending on products and applicable grades)

5. **Customers of BioBuffer Solutions brand** materials including Bio Ultra Grade are welcome to schedule technical visits based on established business relationship and grade of product purchased. Typically technical visits for these customers include:
    a. Technical Visit: These are coordinated through our Regulatory Department.
    b. When: As available by request (90 Day notice requested)
    c. Typical Duration: Up to ½ Day and can include 1-3 visitors

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Applicable Audit Standards

An audit of BioSpectra's facility and Quality System will be scheduled in accordance with the compliance attributes of the grade of product purchased or requested for purchase.

1. **Federal, State and Local Agencies** will apply current guidelines applicable to the organization performing the audit and the systems being audited.

2. Bio FUISA Grade Audits will reference ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, as applicable for use in sterile applications, and the Federal Food, Drug, and Cosmetic Act, as currently amended.

3. Bio Active Grade Audits will reference ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, as applicable for use in non-sterile applications, and the Federal Food, Drug, and Cosmetic Act, as currently amended.

4. Bio Excipient Grade Audits will reference ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients and/or current Good Manufacturing guidelines provided by the International Pharmaceutical Excipients Counsel.

5. Bio Pharma Grade Audits will reference current Good Manufacturing guidelines provided by the International Pharmaceutical Excipients Counsel.

6. Bio Ultra Grade Technical Visits will be based on the portions of recognized systems and standards necessary to demonstrate traceability and adherence to analytical standards related to a particular batch of material. Supply Chain Management evidence related to the qualification of a supplier may be included if agreed to in advance. This audit will correspond to BioBuffer Solutions Quality System.

7. Bio Contract Grade Visits/Audits will reference the compliance standards or quality system attributes outlined in the current Contract Manufacturing Agreement, Supply Agreement/Contract or Quality Agreement used to define that particular business relationship.

Additional Considerations

Failure of an audit request to appropriately classify an audit may result in postponement of the audit or early termination of the audit. This will allow for documented communication outlining the standards of compliance which were agreed to when scheduling your audit.

Inclusion of "internal" or "proprietary" audit standards that are not accepted industry practices or that are designed to elevate the compliance of an audit above that which was scheduled and agreed to may result in postponement of the audit or early termination of the audit. This will allow for documented communication outlining the standards of compliance which were agreed to when scheduling the audit.

By signing below, you acknowledge that you have received, read and understood the BioSpectra Audit Guidelines.

Audit Requestor Signature: _____Date: _____