GMP Quality Audit Interactive Checklist

Company (Auditee) Name:

Company (Auditee) Address:

Quality Audit Date(s): **to**

mm/dd/yyyy mm/dd/yyyy

Company (Auditor) Name:

Company (Auditor) Address:

Quality Auditor Name(s):

Company (Auditee) Name(s) and Function:

GMP Quality Audit Interactive Checklist

Company Name: _____ **Quality Audit Date(s):** _____ **to** _____

mm/dd/yyyy mm/dd/yyyy

Section 1: Organization and Personnel

1(a) Does a Quality Assurance unit (department) exist as a separate organizational entity?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.22(a)

See Regulation

Notes:

1(b) Does the Quality Assurance unit alone have both the authority and responsibility to approve or reject all components, drug product containers and closures, in-process materials, packaging materials, labeling and drug products?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.22(a)

See Regulation

Notes:

1(c) Does the QA unit review and approve or reject all production records (including contracted manufacturing by another company)?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.22(a)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: _____ **Quality Audit Date(s):** _____ **to** _____

mm/dd/yyyy mm/dd/yyyy

Section 1: Organization and Personnel

1(d) **Are Manufacturing and QA personnel adequately trained in both their function and in cGMP on a continuing basis? Does each employee receive retraining in an SOP (procedures) if critical changes have been made in the procedure? Is this training documented?**

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.25(a)

See Regulation

Notes:

1(e) **Are employees trained on proper gowning and aseptic technique?**

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.28(a)

See Regulation

Notes:

1(f) **Are manufacturing personnel shown to have an apparent illness or open lesions excluded from contact with drug product until corrected? Are employees instructed to report to supervisory personnel any applicable health conditions?**

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.28(d)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: _____ **Quality Audit Date(s):** _____ **to** _____

mm/dd/yyyy mm/dd/yyyy

Section 2: Facilities

2(a) Does the manufacturing facility have adequate space to maintain the orderly placement and flow of equipment and materials to prevent mixups and cross-contamination?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(b)

See Regulation

Notes:

2(b) Is the manufacturing facility of suitable size and construction to facilitate cleaning, maintenance, and proper operations?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(a)

See Regulation

Notes:

2(c) Does the facility have an adequate pest control system for both insects and rodents? Is there a SOP for pest control? Is trash held and disposed of in a timely and sanitary manner?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.56(a)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 2: Facilities

2(d) Is the cleaning / housekeeping of the facility documented? Are work surfaces, floors, overhead piping, ceiling fixtures, equipment, etc. free of accumulated dirt and debris?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.56(a)

See Regulation

Notes:

2(e) Are floors, walls and ceilings in the aseptic area made of smooth, hard surfaces that are easily cleanable and sanitizable? Is there a sanitization schedule with documentation for the clean and aseptic areas?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(c)

See Regulation

Notes:

2(f) What sanitizers / cleaning agents are used in the facility? Are there written procedures describing the sanitation /cleaning schedules, procedures, equipment and materials used?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.56(b)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 3: Environmental Control

3(a) Are the controlled areas temperature and humidity controlled and monitored?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(c) See Regulation

Notes:

Inspection Tip:
Review the temperature record for a selected cleanroom from a random date.

3(b) Are the air quality classifications for each of the aseptic and clean processing rooms acceptable?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(c) See Regulation

Notes:

3(c) How often are the air flow velocities checked for each HEPA filter? How often are the HEPA filters integrity tested? Is the air flow in critical class 100 areas laminar when delivered to the point of use?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(c) See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 3: Environmental Control

3(d) Is there a system for continuously monitoring air pressure differentials for the controlled areas? Are there suitable limits and alarms for dP programmed into this system?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.42(c) See Regulation

Notes:

3(e) What type of equipment is used for non-viable particulate sampling? What type of equipment is used for viable (microbial) air and surface sampling?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.46(b) See Regulation

Notes:

3(f) What action is taken when a non-conforming result for viable and non-viable monitoring is obtained? Are there written procedures describing these actions?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.113 See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 3: Environmental Control

3(g) Is there an SOP describing the gowning requirements for each clean and aseptic processing area?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.28(a)

See Regulation

Notes:

3(h) Are the gowning and degowning rooms and procedures acceptable from an aseptic standpoint?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR211.113(b)

See Regulation

Notes:

3(i) How often is microbiological monitoring performed on filling room personnel? What are the alert and action limits for personnel monitoring?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.28(a)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 4: Utilities

4(a) Is compressed air monitored for the presence of oil, moisture, particulate and microorganisms?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.65(a)

See Regulation

Notes:

4(b) What type of air compressor is used? What other compressed air filters are utilized in the system?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.65(b)

See Regulation

Notes:

Inspection Tip:
Compressor should be oil-free type. Other filters include coalescing, particulate, activated carbon, dessicant or sterilizing depending on classification of usepoints.

4(c) What process is used to produce Water for Injection / Purified Water? What process is used to produce Clean Steam? What is the testing / sampling program?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.84(d)

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: _____ **Quality Audit Date(s):** _____ **to** _____

mm/dd/yyyy mm/dd/yyyy

Section 5: Equipment

5(a) Is processing equipment designed to be easily cleaned, sanitized, sterilized (if necessary) and maintained?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.63

See Regulation

Notes:

5(b) Is processing equipment properly designed and located so as not to disturb proper airflow in critical areas?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.63

See Regulation

Notes:

5(c) Are there SOP's describing the proper cleaning and sanitization of equipment and utensils? Are there cleaning schedules and cleaning logbooks for equipment?

☐ Compliant ☐ Not Compliant ☐ Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.67

See Regulation

Notes:

GMP Quality Audit Interactive Checklist

Company Name: Quality Audit Date(s): to

mm/dd/yyyy mm/dd/yyyy

Section 5: Equipment

5(d) Are all automatic, mechanical, or electronic equipment used in manufacture routinely calibrated, inspected, or checked according to an appropriate SOP? Are there records of all calibration and maintenance checks?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.68(a)

See Regulation

Notes:

5(e) What type of product sterilizing filters are used? How are these filters sterilized? Is the sterilization process validated?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.113(b)

See Regulation

Notes:

Inspection Tip:
Check documention for evidence that post-integrity testing was performed on a sterilizing filter after it has been used in manufacture.

5(f) During manufacture, are all compounding equipment and processing lines properly identified as to product content and stage of processing? Is major equipment identified by a distinctive ID No. or Name in the batch record?

Compliant Not Compliant Not Applicable

Observation Category: NONE

Regulatory Reference: CFR 211.105

See Regulation

Notes: