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:**

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**Company Name:**

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Section 1: Organization and Personnel

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

Compliant

Not Compliant

Not Applicable

Notes:

Observation Category:

Regulatory Reference: CFR 211.22(a)

**See Regulation**

**NONE**

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?

Notes:

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.22(a)

Not Applicable



**See Regulation**

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

**NONE**

Compliant

Not Compliant Not Applicable

Notes:

Observation Category:

Regulatory Reference: CFR 211.22(a)

**See Regulation**

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Section 1: Organization and Personnel

1(d)

1(e)

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?

Notes:

Are employees trained on proper gowning and aseptic technique?

Notes:

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.25(a)

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.28(a)

Not Applicable



**See Regulation**

Not Applicable



**See Regulation**

1(f) Are manufacturing personnel shown to have an apparent illness or open lesions excluded

Compliant

Not Compliant Not Applicable

from contact with drug product until corrected? Are employees instructed to report to supervisory personnel any applicable health conditions?

Notes:

Observation Category:

Regulatory Reference: CFR 211.28(d)

**See Regulation**

**NONE**



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Section 2: Facilities

2(a) Does the manufacturing facility have adequate space to maintain the orderly placement and

Compliant

Not Compliant

Not Applicable

flow of equipment and materials to prevent mixups and cross-contamination?

Notes:

**Regulatory Reference: CFR 211.42(b)**

**See Regulation**

Observation Category:

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

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.42(a)

Not Applicable



Notes:

**See Regulation**

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

**NONE**

Compliant

Not Compliant Not Applicable

disposed of in a timely and sanitary manner?

Notes:

Observation Category:

Regulatory Reference: CFR 211.56(a)

**See Regulation**



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Section 2: Facilities

2(d) Is the cleaning / housekeeping of the facility documented? Are work surfaces, floors,

Compliant

Not Compliant

Not Applicable

overhead piping, ceiling fixtures, equipment, etc. free of accumulated dirt and debris?

Notes:

**Regulatory Reference: CFR 211.56(a)**

**See Regulation**

Observation Category:

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

Observation Category:

**NONE**

Regulatory Reference: CFR 211.42(c)

Not Applicable



Notes:

**See Regulation**

2(f)

What sanitizers / cleaning agents are used in the facility? Are there written procedures describing the sanitation /cleaning schedules,

Compliant

Not Compliant Not Applicable

procedures, equipment and materials used?

Notes:

Observation Category:

Regulatory Reference: CFR 211.56(b)

**See Regulation**

**NONE**



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Section 3: Environmental Control

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

Compliant

Not Compliant

Not Applicable

Observation Category:

**NONE**

Notes:

**Regulatory Reference: CFR 211.42(c)**

***Inspection Tip:***

***Review the temperature record for a selected cleanroom from a random date.***

**See Regulation**

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

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.42(c)

Not Applicable



Notes:

**See Regulation**

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

Compliant

Not Compliant Not Applicable

in critical class 100 areas laminar when delivered to the point of use?

Notes:

Observation Category:

Regulatory Reference: CFR 211.42(c)

**See Regulation**

**NONE**

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Section 3: Environmental Control

3(d) Is there a system for continuously monitoring air pressure differentials for

Compliant

Not Compliant

Not Applicable

the controlled areas? Are there suitable limits and alarms for dP programmed into this system?

**See Regulation**

Notes:

Observation Category:

Regulatory Reference: CFR 211.42(c)

**NONE**

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?

**See Regulation**

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.46(b)

Not Applicable



Notes:

3(f)

What action is taken when a non-conforming result for viable and non-viable monitoring is obtained? Are there written procedures

Compliant

Not Compliant Not Applicable

describing these actions?

Notes:

Observation Category:

Regulatory Reference: CFR 211.113

**See Regulation**

**NONE**

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Section 3: Environmental Control

3(g)

Is there an SOP describing the gowning requirements for each clean and aseptic

Compliant

Not Compliant

Not Applicable

processing area?

Notes:

**See Regulation**

Observation Category:

Regulatory Reference: CFR 211.28(a)

**NONE**

3(h)

Are the gowning and degowning rooms and procedures acceptable from an aseptic standpoint?

Notes:

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR211.113(b)

Not Applicable



**See Regulation**

3(i)

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

Compliant

Not Compliant Not Applicable

monitoring?

Notes:

Observation Category:

Regulatory Reference: CFR 211.28(a)

**See Regulation**

**NONE**

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Section 4: Utilities

4(a)

Is compressed air monitored for the presence of oil, moisture, particulate

Compliant

Not Compliant

Not Applicable

and microorganisms?

Notes:

**See Regulation**

Observation Category:

Regulatory Reference: CFR 211.65(a)

**NONE**

4(b)

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

 Compliant  Not Compliant

Observation Category:

**NONE**

Not Applicable

Notes:

Regulatory Reference: CFR 211.65(b)

***Inspection Tip:***

**See Regulation**

***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

Compliant

Not Compliant Not Applicable

the testing / sampling program?

Notes:

Observation Category:

Regulatory Reference: CFR 211.84(d)

**See Regulation**

**NONE**

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Section 5: Equipment

5(a)

Is processing equipment designed to be easily cleaned, sanitized, sterilized (if

Compliant

Not Compliant

Not Applicable

necessary) and maintained?

Notes:

**See Regulation**

Observation Category:

Regulatory Reference: CFR 211.63

**NONE**

5(b)

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

Notes:

 Compliant  Not Compliant

Observation Category:

**NONE**

Regulatory Reference: CFR 211.63

Not Applicable



**See Regulation**

5(c)

Are there SOP's describing the proper cleaning and sanitization of equipment and utensils? Are there cleaning

Compliant

Not Compliant Not Applicable

schedules and cleaning logbooks for equipment?

Notes:

Observation Category:

Regulatory Reference: CFR 211.67

**See Regulation**

**NONE**

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Section 5: Equipment

5(d)

Are all automatic, mechanical, or electronic equipment used in manufacture routinely

Compliant

Not Compliant

Not Applicable

calibrated, inspected, or checked according to an appropriate SOP? Are there records of all calibration and maintenance checks?

**See Regulation**

Notes:

Observation Category:

Regulatory Reference: CFR 211.68(a)

**NONE**

5(e)

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

 Compliant  Not Compliant

Observation Category:

**NONE**

Not Applicable

Notes:

Regulatory Reference: CFR 211.113(b)

***Inspection Tip:***

**See Regulation**

***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

Compliant

Not Compliant Not Applicable

of processing? Is major equipment identified by a distinctive ID No. or Name in the batch record?

Notes:

Observation Category:

Regulatory Reference: CFR 211.105

**See Regulation**

**NONE**

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