503B Outsourcing Facility Checklist

Conducting a 503B Facility Audit to Assess State-of-Control

Sterility Assurance

Evaluate the sterility assurance program within the facility

- ☐ Is there an EM/PM program in place that evaluates microbial activity for personnel, within all clean rooms, and ISO 5 areas?
- ☐ Are there positive EM/PM microbial samples identified?
- ☐ Is there an EM/PM program in place that evaluates microbial activity for personnel, within all clean rooms, and ISO 5 areas that represent every batch and every shift?
- ☐ Is EM sampling daily of by batch?
  - Does the EM program include surface testing?
  - Does the EM program include viable air testing?
  - Does the EM program include non-viable air testing?
- ☐ Are personnel media fills (to supplement PM qualifications) done for all compounders and clean room personnel, and at what frequency? Are three media fills completed for qualification?
- ☐ Is there a complete investigation and evaluation of batch impact for filled media tests of personnel or process?
- ☐ Is there a CAPA program associated with out-of-specifications (OOS) for environmental monitoring that performs comprehensive investigations and evaluates batch impact?
- ☐ Are batch release criteria dependent on the passing results of EM/PM sampling?
- ☐ Does the facility require validation of new or changed facilities, equipment, and processes?
- ☐ Do all testing media undergo growth promotion and/or qualification?
- ☐ When OOS samples are discovered, does the facility identify the organisms and the source?
- ☐ Is method suitability performed for sterility and testing?
- ☐ Are all test methods validated to GMP and USP?

Review the cleaning processes and cleaning agents. Are they monitored through the EM Program?

- ☐ Are SOPs and protocols in place for cleaning and disinfectants?
  - Do they include sterile disinfectants for clean room and ISO 5?
  - Do they include contact time for spores and microbes?
  - Do they include batch, daily, weekly, and monthly cleaning protocols?
- ☐ What is the frequency of cleaning?

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Regulatory

Review licenses and registrations

- ☐ Federal regulations (FDA, DEA).
- ☐ Is state licensing in place to ship products across state lines?
- ☐ Are appropriate state-controlled licenses in place for shipping controlled substances across state lines?
- ☐ Are individual pharmacists' state-mandated licenses in place and up to date?
- ☐ Does the facility dispense patient-specific prescriptions?
    - For prescriptions, are the states appropriately licensed?
    - Are the pharmacists state-licensed for 503B outsourcing and for dispensing prescriptions?

Labeling/Packaging

- ☐ Is there a robust labeling process to approve accurate labels and for changing labeling information?
- ☐ Does the facility evaluate all labels to make sure they meet the 503B labeling requirements, including:
    - All contents and amounts?
    - Needed statements such as "this is a compounded drug" and "for office use"?
    - Total drug amount and concentration?
    - Facility address and phone number?
    - Cautionary statements, high alerts, and contraindicated routes of administration?
    - FDA adverse reaction statement and telephone number?
    - Statement of preservatives?
- ☐ Does the facility have safety measures within the labeling to help practitioners avoid medication or dosing errors?
    - ISMP-required TALL man lettering
    - ASTM color coding standards
    - USP chapter 7 labeling requirements

Quality Control

Review variance log and investigations

- ☐ Review the variance process. Is there a state-of-control over variances/out-of-specifications?
- ☐ Do the variances/OOS account for all batches that could be impacted from a retrospective perspective?

Quality Control (Continued)

Is the quality oversight group independent of production?

- ☐ Is the quality oversight group well-staffed to effectively monitor all production and processing activities?
- ☐ Does the quality oversight group have full independence to accept or reject production batches?

What are the facility's batch release criteria? Do they release at risk?

- ☐ Is every batch quarantined for passing release testing (potency, sterility, and endotoxin)?
  - Sterility testing (USP <71> or other USP validated method)?
  - Endotoxin (are endotoxin levels calculated from maximum dose and dosage route)?
  - Potency (are methods GMP and USP validated)?
  - Is every batch being tested for sterility using the representative number of units (IV, syringes, etc.) defined in USP <71>?
  - Is USP <71> testing completed?
  - Is ScanRDI© or other sterility testing processes done?
  - Does ScanRDI© evaluate and assure validation to USP <71> and USP <1223>?
  - Is every product validated on ScanRDI©?
- ☐ Are EM/PM results reviewed with batch release?
- ☐ Does the facility have a robust recall system?

Evaluate all processes to ensure there is control from beginning to end of the production process.

- ☐ Assess what is double-checked and other verifications within the batch process.
- ☐ Are there good documentation practices (GDP) requirements within the policy/procedures of the company?
- ☐ Are there validated shipping methods which protect the integrity of the drug product from excessive temperatures and theft?

Evaluate all facility OOS and the investigations that result.

- ☐ Evidence of a robust CAPA system.
- ☐ Are all batches that can possibly be impacted investigated?
- ☐ What is the quarantine process?
- ☐ Are investigations robust and comprehensive with post-investigation evaluations to analyze effectiveness?

Evaluate customer complaints and investigations.

- ☐ Does the facility have a 24/7 Adverse Drug Reaction (ADR) and drug safety hotline to a pharmacist?
- ☐ Review all reported ADR response and FDA reporting.
- ☐ Review all recalls and recall history.
- ☐ Review all customer complaint logs and investigations.

Laboratory

Evaluate how BUD is determined; if applicable, review their testing results for BUD.

- ☐ Does the facility have a stability testing protocol/policy?
- ☐ Does the facility rely on BUDs established by the FDA or do they perform their own BUD testing?
- ☐ Review BUD testing and evaluate stability-indicating methods?
- ☐ Does the stability testing done use validated methods?
- ☐ Is there stability testing for all products?
- ☐ Does the stability testing encompass pH, precipitation, endotoxin, sterility and container/closure?

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