Hunt Valley PharmaLAB

Quality Assurance FAQ

Hunt Valley PHARMACY

Licensure	**Under what license do you operate?** We hold pharmacy license # P06672 with the **State of Maryland Board of Pharmacy**. We are certified by the **Accreditation Commission for Health Care** (ACHC). ACHC is the recognized leader in accrediting firms that prepare custom pharmaceutical (sterile and non-sterile) preparations. ACHC accreditation assesses the preparation process based on a specific set of standards focused on the quality and consistency of medications produced. ACHC accredits organizations dispensing medications pursuant to a prescription order for an individually-identified patient. **Do your technicians have licenses? How do you measure their proficiency?** All sterile compounding technicians hold a specific pharmacy license with the Maryland Board of Pharmacy. In addition, among other tests, we require each technician to pass several challenging hands-on proficiency tests prior to preparing custom medications and every six months thereafter. **In what states do you offer CSPs?** We are focused on serving the needs of patients in the State of Maryland. As such, we provide a very high level of consultative and logistical service to physicians, their staff, and patients. As our customer portfolio grows, we will register and expand into additional states.
Environmental Monitoring	**Do you have an environmental monitoring program in place to assure a state of control?** Yes. To ensure a state of continuous control, we perform weekly environmental surface monitoring of all critical areas under dynamic conditions including but not limited to our ISO 5 and ISO 7 clean rooms. In addition, we perform viable air particle environmental monitoring monthly and non-viable air particle testing every six months. We also routinely perform glove tip testing on our technicians. **How do you monitor the cleanliness of your facilities?** We have standard operating procedures ("SOPs") that define the frequency and standards of daily, weekly, and monthly facility maintenance and cleaning. All maintenance and cleaning activities are recorded on logs of use, maintenance, and cleaning ("LUMACs"). In addition, we monitor the temperature, humidity, and pressure of each clean room. **How would you know if you are having a problem?** Several indicators of quality problems are in place, including air pressure, temperature, and humidity monitoring, air and surface environmental sampling, and product sterility testing. **Does your pharmacy have separate areas dedicated to prepare sterile and non-sterile medications, product inspections, labeling, raw material storage, and dispensing?** Yes. We have dedicated areas for product inspections, labeling, raw material storage, and dispensing. **In a particular workspace, how many different formulations are being compounded at once?** Only one custom medication is prepared at a time.

Personnel	**What steps of the preparation process are reviewed and verified by a licensed pharmacist?** All steps are reviewed and verified by a compounding pharmacist with particular attention on: • Pre-preparation formulation review; • Pre-preparation ingredient review; • Technician qualification; • Final preparation quality assurance. **Is your technical staff dedicated exclusively for custom preparations**? Yes. **How often are staff trained and re-qualified (validated) in aseptic techniques?** Per USP regulations and our Quality Management System, all sterile preparation technicians must pass a rigorous series of hands on tests every 6 months.
Product Integrity	**Do you use independent experts to inspect and calibrate your equipment?** Yes, our Quality Management System defines the scope and scale of our equipment and facilities cleaning, maintenance, and calibration protocols. All critical equipment is independently re-certified every six months. **Do you purchase pharmaceutical-grade chemicals (USP, NF equivalent) from FDA-registered suppliers?** Yes. We only purchase from FDA registered raw material suppliers. **Do you have a Certificate of Analyses for each lot of all formula ingredients?** Yes. **Does a pharmacist verify the potency of every finished preparation through weight, volume, and yield checks?** Yes. **Do you perform finished product testing?** Per USP 797 we perform robust testing on finished preparations including tests of potency, sterility, and endotoxin content among other tests. We contract the testing to an independent third party laboratory that specializes in testing of custom sterile and non-sterile preparations. **How do you ensure sterile preparations are not degraded by light or temperature?** All finished preparation storage areas, including refrigerators and freezers, are monitored for temperature and humidity. Preparations that are subject to light degradation are packaged in amber containers and/or amber over packaging. **Do you perform filtration sterilization? If yes, how do you ensure filter integrity?** Yes, we do routinely perfume sterilization via filters with pore sizes 22 micron and less. We perform bubble point filter testing on every filter to ensure the integrity of each filter. **Does your pharmacy perform sterility testing according to USP <71> - Sterility Tests and USP <85> - Bacterial Endotoxin Tests?** Yes, per applicable USP 797 guidelines. **Do you perform pH testing on injections, ophthalmic and other preparations?** Yes.

Quality Management System Documentation	**How do you ensure traceability of each custom preparation?** We utilize a specific software program to track and trace our raw materials, formulations, technicians, expiration dates, labeling, and patient specific information, among other things. This software system has robust security and the data is backed up at a secure server off site. **How long do you maintain lot records for specific CSPs?** We retain these electronic records indefinitely. **Can you produce lot batch records upon request?** Yes. **Does your Quality Management System spell out the process for a new formulation?** Yes. Our Quality Management System has SOPs defining the process of developing a formulation, selecting raw materials, quality control, sterility, stability, strength, and beyond use dating. **Do you have a dedicated and experienced Quality Assurance professional?** Yes. He has over 10 years of experience in regulated manufacturing environments. He also co owns the company with our Pharmacist-in-Charge. **How often are your Quality Management System documents reviewed and modified?** The Quality Management System is reviewed in entirety at least annually. Individual SOPs are reviewed and modified on an as-needed basis routinely.
Quality Assurance	**Do you have a complaint handling procedure?** Yes. All customer complaints are investigated until a root cause is determined, if possible. The root cause is reviewed internally and often we initiate a corrective and preventative actions (CAPA). The CAPA might result from analyzing processes, customer complaints, and audit reports among other things. The CAPA program involves: • Identifying problems that may require corrective action; • Deciding if corrective action is required; • Correcting the problem; • Investigating and determining the root cause(s) of the problem and proposing appropriate corrective action if necessary; • Implementing the corrective action to eliminate the root cause(s); • Verifying that the corrective action is implemented and that it is effective. **Have you ever issued a recall notice for any reason whatsoever?** No. **If you had to issue a recall, do you have an SOP that governs how you would conduct a recall?** Yes. **Who can audit you?** We are routinely audited by regulatory agencies and customers. **Do you allow customers to audit your facility?** Yes. In fact, we have a self-audit checklist you can use to guide you through the audit. Call us to schedule your audit.