Questions you should be asking a USP <901> cGMP Asbestos in Talc Testing Lab

Laboratories should be able to provide not only compliant data, but also the scientific rationale and documentation necessary to support regulatory scrutiny and downstream decision-making.

Reference Standards & Controls

- **Where did you obtain qualified asbestos reference standards** (e.g., chrysotile, tremolite, actinolite)?
- Are your reference standards traceable to certified sources (e.g., NIST or equivalent), and do you maintain CoAs?
- If your reference standards are not NIST traceable, have they been authenticated with at least two orthogonal analytical techniques?
- How do you verify identity and crystallinity of your reference standards before use?
- Do you run positive and negative controls with each batch?

Method Execution (XRPD + PLM specifics)

- Are you performing both **XRPD and PLM**, or only one technique?
- **For XRPD:**
    - What instrument configuration (radiation source, scan range, step size)?
    - **What detection limits have you demonstrated for each asbestos type?**
- **For PLM:**
    - Are analysts trained specifically in asbestos fiber identification?
    - How do you distinguish talc cleavage fragments from amphibole fibers?

Sample Preparation (A source of many false negatives)

- How is the talc sample prepared prior to analysis (grinding, dispersion, mounting)?

- What steps are taken to avoid destroying or masking asbestos fibers?
- Do you evaluate multiple subsamples or just one aliquot?
- How do you ensure representative sampling of a heterogeneous talc lot?

Method Verification

- **Have you formally verified the USP <901> method in your lab?**
- What are your demonstrated **LOD/LOQ** for each regulated asbestos species?
- Have you performed spike recovery studies in talc matrices?
- Can you provide verification reports?
- Can the lab demonstrate the proper implementation and execution of the method via a verification protocol?

“Compendial method” does NOT mean “no validation required.”

“Compendial methods” require verification by the testing laboratory with qualified standards.

Contamination Control

- What controls are in place to prevent cross-contamination between samples?
- Are asbestos-containing standards handled in the same lab space?
- How are blanks handled and trended?

Data Interpretation & Reporting

- Who reviews and signs off on asbestos determinations?
- Do you provide raw data (XRPD patterns, PLM images) or just a pass/fail?
- How do you handle borderline or ambiguous findings?
- What is your policy on reanalysis or confirmatory testing?
- How do you interpret the **“1 fiber in 2 grams”** requirement in USP <901> when analyzing sub-samples?

Regulatory & Inspection Readiness

- Has your asbestos testing approach been reviewed during inspections?
- Have you supported client regulatory submissions with this data?
- Can you defend your method under audit (FDA, EMA, etc.)?

Throughput, Turnaround, and Reality Checks

- How many talc asbestos samples do you run per month?
- What is your typical turnaround time?
- Do you outsource any portion of the testing?

Supplier Qualification Outcome

☐ Approved
☐ Approved with Conditions
☐ Not Approved

Reviewer: _____
Date: _____