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# What is Reasonable to Expect from a Third-Party Contract Lab

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# Identifying Your Testing Needs

- **What is the goal of the analysis?**
  - **ID Testing**
    - Do you have the correct species or plant part (mandated by cGMPs)
  - **Qualification of a new supplier**
    - Conformation of **all** test results listed on C of A
    - Conformation that all test results meet product specifications you have set
    - QA Check to ensure product is not adulterated or contaminated
  - **Litigation**



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## Development and Validation of Analytical Methods for Dietary Supplements

# What Initial Questions to Ask of a 3<sup>rd</sup> Party Laboratory

- 1) Do you have previous experience with this analyte(s) and particular or related matrix?
- 2) Are you accredited with any organization?
- 3) Do you have an independent QA unit? Do you have a quality manual and SOPs?
- 4) Do you have all the necessary equipment to do the work or will you be outsourcing any of the work to another lab?
- 5) Do you have training records demonstrating the person handling the sample is properly qualified?



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## What Documents to Check When Auditing a Third Party Laboratory - General Controls

- 1) Is there an Organizational Chart and are there job descriptions for each laboratory position
- 2) Are all test procedures in writing and are they being followed?
- 3) Is there a training programs in place and is the training documented in writing?
- 4) Do they have a formal Quality Unit in place and an SOP for Internal Audits?



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# What Documents to Check When Auditing a Third Party Laboratory - Equipment Control

- 1) Does the laboratory have the adequate equipment to perform the required testing?
- 2) Do SOP's exist for each piece of equipment for maintenance along with operation and calibration?
- 3) Are there visible labels on each piece of equipment used for measurement indicating when the last calibration was performed?
- 4) Are records of calibration easily accessible?
- 5) Do they have SOP's for scheduled performance verification of instruments used for testing?



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# What Documents to Check When Auditing a Third Party Laboratory – Safety (**No Influence on Results**)

- 1) Do they have a Safety Manual and documentation demonstrating each employee has been trained?
- 2) Are there first aid kits, operational eye washes etc. conveniently located?
- 3) Is there adequate procedures for disposal of waste?
- 4) Is there adequate ventilation?
- 5) Are chemicals stored appropriately - flammables, acids etc.
- 6) Do laboratory personal wear safety glasses and lab coats?



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# What Documents to Check When Auditing a Third Party Laboratory - Reference Standards, Reagents, Media and Solutions

- 1) Is there a SOP for the receipt, log-in, handling, storage and expiration of standards, reagents, media and solutions?
- 2) Are the standards, reagents, media and solutions labeled with the proper name, date opened and expiry date?
- 3) How do they qualify their standards and supplier?
- 4) How do they determine the expiration date of the standard if it has not been supplied and once it has been made up in to a solution?



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# What Documents to Check When Auditing a Third Party Laboratory - Sample Receipt etc.

- 1) Do they have SOP's for receipt, handling and storage of test samples?
- 2) Are there written procedures for disposal of samples
- 3) Is each sample assigned an unambiguous sample number when logged in?
- 4) Are samples logged in to a notebook or computer system and how is this information backed up?



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# What Documents to Check When Auditing a Third Party Laboratory- Records Management

- 1) Are records and reports adequately secured and retained for the required length of time
- 2) Do they have a SOP for Proper Documentation Procedures?
- 3) Are the chemist trained in this procedure and do they follow good documentation practices?
- 4) Do they identify the standard used, manufacturer, lot number and expiration date in their lab notebook?
- 5) Do they identify the sample and site the specific method being used as well as any modifications made to accommodate the sample?



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# What Documents to Check When Auditing a Third Party Laboratory: Handling of OOS

- 1) Is there a SOP and form for reporting out-of-specification test results?
- 2) Does the SOP require an investigation of all out of specification result be documented prior to any retesting?
- 3) Who makes the decision on retesting the sample if no mistakes can be found in the procedure used and reporting?
- 4) Are all activities pertaining to the OOS result(s) documented adequately?



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## Examples of FDA Findings

- 1) “No documentation to explain the rationale behind the testing method performed and the specifications for various raw materials using USP methods intended for use in testing drug products but no evidence that these testing methods are suitable for use in testing DS ingredients and finished products.”
- 2) “Failure to conduct appropriate tests or examinations or rely on a C of A to determine whether components met established specifications.”



"OF COURSE YOU CAN'T REPLICATE MY EXPERIMENTS. THAT'S THE BEAUTY OF THEM."



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## Main Causes for Conflicting Laboratory Results

- 1) Analytical Method
- 2) Reference Material-Sigma Caffeine
- 3) Instrumentation
- 4) Human Error
- 5) Fraudulent activity-Dry labbing



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# Existing Protocols and Guidelines For Method Verification and Validation

- 1) ORA Manual (Check FDA Website)
- 2) International Conference on Harmonization (ICH)
- 3) AOAC SLV Guidelines
- 4) USP/NF 29/24 – 30/25
- 5) ISO/IEC Guide 25
- 6) FDA Guidance for the Validation of Chromatographic Methods



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### Conclusion

- 1) If a Laboratory's pricing and turn around time are too good to be true they usually are just that
- 2) Determining validity of a method is more than copying a method from a journal-verification is required to demonstrate that the method is still "fit for purpose"
- 3) Certain modifications to an existing method may require revalidation or verification of the method
- 4) If you are a manufacturer and are using a contract laboratory as an extension of your company, you need to pay them to do the required required method verification for your specific product



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***Thank You !***

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