



Frequently Asked Questions About the USP Verified Dietary Supplement Ingredient Verification Program

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What are the steps involved in obtaining USP verification?

After a company has spoken with our product team and has decided to enroll in the dietary supplement ingredient verification program (DS IVP):

1. Executes License Agreement with USP.
2. Participant submits pre-audit documentation for facility systems and operations review by USP.
3. Participant submits lot histories for submitted dietary supplement ingredients from which USP randomly selects ingredient lots.
4. Participant submits samples and the quality control (QC) and manufacturing documentation for the randomly selected ingredient lots.
5. USP performs the on-site audit, conducts analytical testing, and reviews the QC and manufacturing documentation.
6. USP notifies the participant of any observations or deficiencies that may preclude successful completion of the program requirements.
7. USP prepares summary report of findings and the corrective and preventative action taken by the participant.

8. Upon successful completion of the program requirements, USP grants the participant the right to use the USP Ingredient Verified Mark on the labels and certificate of analysis of the USP verified dietary supplement ingredient.

What is acceptance criteria?

Dietary supplement ingredient manufacturers are audited against the stringent requirements of the International Conference on Harmonisation [ICH Q7](#) Guideline: Good Manufacturing Practices Guide for Active Pharmaceutical Ingredients.

How can we apply for the qualification and verification program?

Contact V. Srinivasa, USP Vice President, Verification Programs, at vs@usp.org or by telephone at +1-301-816-8334.

Is your audit a substitute for a regulatory audit?

The USP audit is **not** a substitute for a regulatory audit, but it will prepare a participant for the strictest of regulatory audits. USP employs world-class professional auditors, all of whom have many years of experience, to help ensure that your organization can meet the challenges of the most rigorous regulatory scrutiny.

If my site is ISO certified, does this automatically lead to USP Verification?

ISO certification does not automatically lead to USP verification. There are many differences between the ISO certification and USP verification. USP verifies ingredient manufacturing practices that are specific to the site where the ingredient is manufactured, whereas ISO certifies the company's overall processes. Also, ISO does not deal with individual products/ingredients, or with manufacturing practices that are specific to the ingredients and the site.

My company is frequently audited already. Why should we invite USP to audit us?

USP's audit is a mandatory component of a comprehensive verification program. The program goes far beyond just an audit to include also 1) document review, 2) laboratory testing and 3) post-verification monitoring and surveillance. USP's comprehensive approach assures participants that USP is thoroughly and objectively verifying the quality of their ingredients and processes, not just one or the other.

What guidance is used to determine cGMP compliance?

Dietary supplement ingredient manufacturers are audited against the stringent requirements of the International Conference on Harmonisation [ICH Q7](#) Guideline: Good Manufacturing Practices Guide for Active Pharmaceutical Ingredients.

What is the time cycle for these audits? Is the audit a surprise?

USP will visit a site for approximately 3-5 days for the initial audit with 3 days being the target. The participant will have already prepared for the audit by completing pre-audit steps with USP. USP and the participant will collaborate on an audit date window, during which the participant will be manufacturing the ingredient. USP will inform the participant of the schedule and agenda for the audit. However, if USP has reason to be concerned about a situation or an event at the participant's manufacturing facility, USP reserves the right to conduct an unannounced audit at its sole discretion.

Will USP Verification replace the DMF?

No, the DMF-type of information is a critical portion of the document review associated with the verification program.

Will USP Auditors help train and improve the skills of my staff to advance the quality of our internal audits?

Our auditors will offer observations that the audited company should be able to use in order to improve manufacturing quality. Training the participants' staff is beyond the scope of this program.

How can I tell my customers what USP Verification means to them?

The USP verification assures that the consistency of quality in process (good manufacturing practice) and ingredient has been verified by an independent, ethical, and credible third party, as evidenced by the use of the USP Verified Ingredient Mark on product/ingredient labels and certificate of analyses.

How does USP protect participants' data?

USP protects participants' data with the utmost confidentiality. We are bound by United States law in the Document Non-Disclosure Agreement that we sign with each participant to do so. Furthermore, USP has nearly 200 years of independent experience in handling and protecting the confidentiality of companies' data through their submissions of information that are used for standards development.

Would USP report an adverse situation to a regulatory body?

If an imminently threatening deficiency were exposed regarding an ingredient that is used in an ingredient in the marketplace, USP would work with the participant's management to report these deficiencies to the appropriate regulatory authority in the interest of the public health. If the participant's management chose not to comply, as stated in the programs' Manual for Participants and License Agreement, USP would be compelled to report these deficiencies on behalf of the public health.

How does USP determine the fee structure for Verification?

The fee structure is based on the anticipated and actual costs associated with review of manufacturing and quality control documents, laboratory testing, and performance of the GMP audit.

How is the fee paid to USP?

The fee is payable at the time the License Agreement is signed and work commences. The fee will be placed in account designated only for the participant and charges will be debited against it. The participant will receive a monthly statement of account.


What is the re-verification process and what does it cost?

The life cycle of the license agreement is for three-years. Re-verification follows the exact process as the initial verification, and a well-prepared company following best practices could expect to move through re-verification with ease.

Will the GMP audit be ingredient specific or manufacturing site specific or ingredient cluster specific? Does this affect my pricing?

GMP audits are normally ingredient specific, however, if a parent ingredient is verified, derivative ingredients (e.g. d-alpha-Tocopherol Acetate from d-alpha Tocopherol) may be covered without an additional GMP audit, as long as the derivative ingredient was manufactured using similar equipment and on the same site. These derivative ingredients are subject to the same performance standards and testing as the parent ingredient. If other ingredients are manufactured at the same site, it may be possible to perform an extended audit and cover all of these ingredients at the same time, which might reduce the cost of the audit.

What is the remedy structure of the USP Audit when a deficiency is identified?

Deficiencies noted during the audit will be described in writing in the form of a report and grouped by their severity. Manufacturers are required to address each deficiency with the goal of full compliance to the ICH Q7 Good Manufacturing Practices Guide. All deficiencies must be fully addressed before the verification process may move to the next program step. Details on types of deficiencies can be viewed in the program's [participants manual](#)  (2MB).

Who are USP auditors?

USP auditors are highly competent professionals with years of second- and third-party auditing experience, as well as rigorous training with USP. USP uses our own staff as auditors and, when necessary, complements that staff with carefully selected contract auditors who serve as highly experienced independent consultants to USP. Our contracted auditors serve USP under the same rules of confidentiality as our employed staff.

If your auditor travels to my company and finds it is not prepared for an audit, what happens?

USP will make every effort to ensure the participant is prepared for the cost and activities related to an audit before it is scheduled. This is supported by the requirement for pre-audit documentation which provides USP staff the opportunity to assess the level of preparedness and enables the participant to understand whether they are ready for the audit. If the USP staff believes that the participant is prepared for an audit, the USP staff will schedule the audit at a time convenient to both parties. If the participant is unprepared, USP will provide feedback to the participant regarding the deficiencies that need to be addressed.

If my company has manufacturing sites in a third country, how will that be addressed?

USP is prepared to have their auditors travel to the locations where participant's manufacturing sites are located, recognizing that actual travel expenses are billed separately from the verification fee.

If my company purchases small quantities of ingredients from another company that purchases the bulk amount, how will that be handled?

If a participant is purchasing small amounts of ingredients from another company the additional company might have to be audited as part of the process. Factors that play into this decision include review of the participant's vendor qualification program and the nature and intended use of the ingredient purchased.

If my company makes different grades (food, cosmetic, drug) of the same ingredient, how will this affect the audit process?

The USP Verification Programs cover a broad range of ingredients used in human health care, such as drug substances, dietary ingredients, and excipients. These programs differ from each other with respect to the Good Manufacturing Practices (GMP) requirements. The most stringent GMP requirement will be used in the case of multiple uses of the same ingredient.

Who will collect the samples for surveillance studies?

USP may request the participant's representative to collect and ship the samples of selected lots of the ingredient(s) to USP's laboratory. Alternatively, the USP auditor may collect the samples during the audit and/or the post-verification surveillance period.

What is the time between signing the License Agreement and completion of the verification process?

A highly prepared participant can expect to complete the verification process within 6-8 months after the License Agreement is signed.

What is the procedure for getting another ingredient verified after a time lapse of, for example, 6 months since the initial ingredient's verification?

If the new ingredient is manufactured using similar procedures as the first one with similar equipment at the same site, a second audit might not be necessary. At the time of the next regularly scheduled audit, both ingredients will be evaluated. In either case, document review and analytical testing will be required for the new ingredient.

Will regulators from my country recognize the USP verification?

USP is meeting with selected regulatory agencies worldwide to help them understand the value that USP verification brings to improving health care quality. Each regulatory agency will determine what recognition to give USP verification.

If specifications are different from the USP-NF monograph, what is the course of action by USP?

Where there is no USP-NF monograph, then USP will use the specification submitted by the participant for the laboratory testing. Part of this testing will include a determination of the adequacy of the specification. Upon successful completion of the Dietary Supplement Ingredient Verification Program, the participant may be asked for permission to use the submitted information in developing a draft monograph that will be published in Pharmaceutical Forum for public comment and eventual inclusion into the official compendia.