

US FDA cGMP for Dietary Supplements

The major action for Dietary Supplement Manufacturers and Marketers will be raw materials testing for identification, potency, heavy metal, microbial, and the manufacturing in-process control for Quality Control (QC) and Quality Assurance (QA).

The burden of all QC and QA are put on manufacturers according to the new FDA cGMP for Dietary Supplements. Vendors of raw materials may be included in the compliance operation but may need FDA review and approval. This is the so-called Validation of Vendors.

Currently, the pharmaceutical industry is working with the FDA on Quality by Design (QbD). QbD is a program to have important control parameters and ranges to establish specifications for drug production to meet desired quality. Dietary Supplements can reach the same level but may cost much more than drugs due to complex ingredients.

Most Dietary Supplements need to work together to maintain our health structures and/or functions. Therefore, single ingredient Dietary Supplements may not work well compared to the many ingredient version. Most pharmaceuticals are formulated in single and pure (98% and up) active ingredient dosage forms that make clinical and CMC (chemistry, manufacture and control) drug studies possible. Dietary Supplements, especially herbs, contain many active ingredients that work synergistically. Herbal formulations typically feature multiple active ingredients and clinical and CMC studies and other regulatory documents are much more difficult to produce.

However, DSHEA (enacted by the US Congress) granted the Dietary Supplements industry the right to produce and market such products to promote public health. The FDA cGMP can further assure the quality of products, but the cost increases are likely to deter consumers, manufacturers and marketers. There will be a 2 to 3 year learning experience for the FDA, Dietary Supplement industry and public (users). The export of these products may be impacted as well. The economic impact remains to be seen and adjusted in the next 3 years.

Based on the FDA cGMP, we are searching for the best way to comply with the regulation.

Vendor HPLC, TLC, IR, UV, microscopic testing data will be included in the program to work together with in-house Fourier Transform Near-Infrared (FTNIR) spectroscopy to collect and compare data for more than 3 lots for vendor validation on raw materials. FTNIR can also be used to find out if there is any changes in the raw materials received in the future by comparing the new materials with the established data library. FTNIR can use the built library to identify a material quality change in various sources, i.e.

source of origin, contamination, different species etc. Our in-house FTNIR affords fast and reliable QC work on received raw materials.

Microbial and heavy metals are also done to compile data for our products to compare to Vendor materials. Heavy metal contents in our products use the California Proposition 65 standard to make sure they comply with that regulation, which is the most stringent and clear regulation on the heavy metal contents available. A good article for more information, written by Ginny Bank, can be found in the Whole Foods Magazine, September 2007 issue.

SUSS Technology Corp.'s mission is to bring to the public quality products for health maintenance and optimal quality of life. There are more innovative products to be introduced in 2008. Please continue to visit susstech.com for new products and services. Thank you for visiting us. We wish you good health and continued success.

Prices are subject to change without notice. These statements are property of SUSS Technology and may not be reproduced or retransmitted in any way without the written permission of SUSS Technology.