WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

May 2015
VOLUME XVI ISSUE 1B

An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

A report by Future Market Insights (FMI) estimates the global Dietary Supplement Market will grow from $ 61.84 billion in 2014 to $ 84.8 billion in 2020, realizing a Compound Annual Growth Rate (CAGR) of 5.3% between 2015 and 2020. Along with this rapid growth has come increased regulatory scrutiny in the form of new Dietary Supplement GMPS and the FDA's increased enforcement of the GMPs as well as the Dietary Supplement Health and Education Act of 1994 (DSHEA). With this increased enforcement comes more demand for the services we provide to dietary supplement manufacturers and the raw material manufacturers who supply products to them. We have made several changes here at Q Laboratories, Inc. to enable us to meet this expanded need. We have added technology such as, FTIR, ICP-MS, etc., have sent our analysts to relevant training and have attended industry events such as Ingredient Marketplace and Supply Side West. We have also continued to expand our facilities to accommodate an increased volume of samples. As a laboratory that serves the food and pharmaceutical industries, we are uniquely positioned to provide services to the dietary supplement industry, which often overlaps the line between foods and pharmaceuticals.

David G. Goins

David G. Goins, President

FAST 55

For the second year in a row, Q Laboratories, Inc. has been named one of the 55 fastest growing privately owned companies in the Greater Cincinnati Region by the Cincinnati Business Courier.

MEET THE Q LABORATORIES STAFF

Matthew Lemp has been hired as Chemistry Laboratory Group Leader at Q Laboratories, Inc. Matthew will be responsible for sample flow-through in the Chemistry Lab and will also have a role in analyst training and scheduling, new client development and expanding lab capabilities. Matthew has a B.S. in Chemistry from Xavier University.

WATER ACTIVITY

According to USP Chapter 1112, *Application of Water Activity Determination to Nonsterile Pharmaceutical Products*, establishing water activity can help manufacturers to, "optimize product formulations to improve antimicrobial effectiveness of preservative systems, reduce the degradation of active pharmaceutical ingredients within product formulations susceptible to chemical hydrolysis, reduce the susceptibility of formulations to microbial contamination, and provide a tool for the rationale for reducing the frequency of microbial limit testing and screening for objectionable microorganisms for product release and stability testing."

ELEMENTAL IMPURITIES

An outstanding article appeared in a recent edition of Pharmaceutical Technology magazine regarding the ICH Q3D Elemental Impurities Guideline (and by extension, USP Chapters 232 & 233). Fourteen pharmaceutical industry scientists from companies such as Pfizer, GlaxoSmithKline and AstraZeneca collaborated to publish the article, examining how to best comply with the new standards. The article identifies five ways elemental impurities may be introduced to a drug product: the drug substance, excipients, manufacturing equipment, utilities-such as water, and the container/closure system. Any corresponding risk assessment performed by a manufacturer should at least include these five components, according to the authors of the article.

Regarding a drug component, the article's authors posit, "control of the elemental impurity content of a drug substance can be assured through a thorough understanding of the manufacturing process including equipment selection, equipment qualification, GMP processes, packaging components, and the selection and application of appropriate control strategies." Adding, "an approach based on assessing and controlling potential sources of elemental impurities, coupled with focused, limited testing, is preferable to exhaustive testing on the finished drug substance." The article lists several potential sources of elemental impurities in the drug substance manufacturing process, including solvents, inorganic materials, organic reagents and processing aids.

Another component of concern regarding elemental impurities for drug products is the excipients. According to the article, manufacturers should try to collect as much information as possible from excipient vendors (C of As, excipient sources, etc.), but ultimately the manufacturer is responsible for validating the composition of the excipient(s). A third component for consideration is drug product manufacture. Whether the product is a liquid or solid and whether the product is mixed/blended, encapsulated, tableted, lyophilized or coated, the process should be examined for potential contamination with elemental impurities.

Water used for production or sanitation can also be a cause of elemental impurities contamination and should be monitored to assure that the source water for the facility as well as the water for production is free of elemental impurities. Finally, the container/closure system for the drug product should be examined as well. Like excipients, vendors of the containers/closures should be required to provide information on their products, but it is ultimately the manufacturer's responsibility to validate the materials.

The article concludes, "the implementation of the ICH Q3D guideline can be adequately achieved through using an appropriate risk-based process combined with existing GMP standards. A risk assessment should be performed to identify any elemental impurities that may potentially be present at significant levels in the drug product. Such an assessment is then used to define an appropriate control strategy."

TRADE SHOWS

Q Laboratories, Inc. will have representatives at the following industry event in the upcoming months:

- **NYSCC Suppliers Night,** May 12-13, Edison, NJ; **(Booth #20)**

Q Laboratories, Inc. • 1400 Harrison Avenue • Cincinnati, Ohio 45214-1606
Phone: (513) 471-1300 • Fax: (513) 471-5600 • E-mail: office@qlaboratories.com • www.qlaboratories.com