

WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

May 2017
VOLUME XVI ISSUE 1B

An ISO/IEC 17025 Accredited Laboratory

FROM THE COO's DESK



In addition to providing services to the pharma, dietary supplement, health & beauty, and OTC industries, Q Laboratories also has a food laboratory division. Having almost 30-years of experience working with manufacturers and stakeholders in these industries, I have learned that many successful ideas and concepts find their way across industries, and what works in one

area is soon implemented in another. For example, the concept of Hazard Analysis Critical Control Point (HACCP) was developed in the 1950s by food scientists from Pillsbury, working with engineers from NASA. It involved three principles: identification and assessment of hazards; determination of the critical control points to control any identified hazard; and establishment of a system to monitor the critical control points. By the turn of the 20th Century, HACCP had become the predominant food safety principle for food manufacturers of all sizes. Subsequently, manufacturers in the pharma, cosmetic and health & beauty industries, who were also concerned about microbiological hazards and potential contamination of their products and materials, were applying HACCP concepts to their environmental monitoring and product safety programs. We were therefore able to utilize our food HACCP experience for a new sector of clients. Our versatility and knowledge base allowed us to provide more dynamic laboratory and consultative services.

David G. Goins

David G. Goins, COO

PRACTICES MAKE PERFECT

The Council for Responsible Nutrition (CRN) (of which Q Laboratories is a proud member) and the International Probiotics Association (IPA) have teamed up to develop a document entitled, "Best Practices Guidelines for Probiotics." According to the text, the purpose was to, "develop scientifically-based voluntary guidelines that address labeling, stability testing, and storage recommendations for probiotic-containing dietary supplements and functional foods. These guidelines are intended to facilitate transparency and consistency." The labelling guidelines require product information to be listed for consumers such as identity and quantity of the probiotic(s). For the label of probiotic products, it is recommended the probiotic amount be expressed in Colony Forming Units (CFUs) and should indicate the quantity of live microorganisms present at the end of the suggested shelf life rather than at the time of manufacture. The genus, species and strain of each microorganism should be identified on the label as well. Stability guidelines contain a framework for establishing accurate shelf-life data for the product. Guidelines on storage provide uniform instructions for the consumer to follow after purchase. Stability testing temperature ranges are provided following established ICH Q1A(R2) and USP Chapter <659> guidelines. The document adds, "Stability testing should be conducted under real-time conditions to support the stated shelf life of the product. Use of accelerated or other testing in a program to support product release should be scientifically justified and documented."

NEW APPOINTMENTS

Fran Nunan has been named Vice President of Human Resources for Q Laboratories. Fran brings a wealth of experience to the company after leading the HR departments at Hydro Systems Company and School Outfitters, as well as operating her own HR Consulting firm. Fran holds the Senior Certified Professional (SCP) designation, as well as the Senior Professional in Human Resources (SPHR) certification. She will be tasked with continuing the talent pipeline by recruiting and hiring scientists and support personnel.

Bobby Loew has been appointed Facility Engineer at Q Laboratories. He will oversee the ongoing expansion and optimization of the company's facilities as well the maintenance and upkeep of all current facilities. Bobby is a Certified Electrician and has over 25 years of experience in industrial construction and renovation.

Kenny Zampelli has been promoted to Media Prep Supervisor. Kenny will provide leadership for the department tasked with preparing all the microbiological media for the laboratories, as well as sterilizing and discarding all infectious waste generated, while adhering to strict quality guidelines. Kenny had previously served as Chemistry Lab Group Leader—Pharma for Q Laboratories.

IMPURITIES THOUGHTS

In 2015 when the United States Pharmacopoeia (USP) delayed the implementation date of General Chapters <232> Elemental Impurities—Limits and <2322> Elemental Contaminants in Dietary Supplements to January 1, 2018, it seemed like a long way off. But as we are entering the 2nd Quarter of 2017, that January 1 date looms and those who haven't done so, need to get their house in order regarding these new USP guidelines. One of the reasons given for the implementation delay was to align the implementation of General Chapter <232> more closely with the ICH Q3D Guideline for Elemental Impurities, which was published in December 2014. The new chapters will replace USP Chapter <231> which involved a simple qualitative method for the presence/absence of heavy metals. The new requirements mandate quantitative analysis for specific metals and require ICP-MS instrumentation (or ICP-OES, when limits of detection are high or the sample causes interference with ICP-MS methodology). The new chapter includes 24 elements, grouped into 4 categories based on their relative toxicity, likelihood of occurrence and route of administration. Four elements are defined as Class 1 (arsenic, cadmium, mercury, and lead). The new requirements will increase cost and potentially turn-around time for many of the materials in the USP/NF, and method development and validation will be required for some materials to prove results are accurate. The validation step will determine the optimum sample preparation technique for the material (direct analysis, dissolution, or digestion) and confirm the method is fit for purpose.

TRADE SHOWS

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

- ▶ **NYSCC Suppliers Night**, May 2-3, New York (Booth# 1142)
- ▶ **CPHI North America**, May 16-18, Philadelphia; (Booth# 3134)