WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

August 2017
VOLUME XVI ISSUE 2B

An ISO/IEC 17025 Accredited Laboratory

FROM THE COO's DESK

As a manufacturer, you are ultimately responsible for the product that ends up in the consumers hands. The purity, quality and authenticity of that product is a reflection of your company and provides end users with their perception of your business. Therefore, notwithstanding the regulatory onus you endure to assure that quality, you must take an holistic approach to quality control and quality assurance to position your company as a successful industry leader in production of your product type(s). This approach is a "soup to nuts" proposition that starts with assuring the raw materials, ingredients, and excipients you use are of the utmost quality and purity. If the raw materials do not meet your exacting standards, it is unlikely the finished product(s) will meet the level of quality that consumers demand. Testing raw materials and verifying provided Certificates of Analysis (COA) helps assure the components that comprise your product(s) meet industry standards. Your suppliers are responsible in many cases with providing the CofA for the material, but you are responsible for confirming that each lot meets the standards indicated. The United States Pharmacopoeia (USP/NF), Food Chemicals Codex (FCC), and European Pharmacopoeia (to name a few) provide basic standards and methods for confirming raw materials are sufficient for use. Having a qualified lab perform these tests on the raw materials begins your product journey on a solid foundation and enables you to produce safe, high-quality products.

David G. Goins

David G. Goins, COO

NEW APPOINTMENTS

Mark Hobart has been named Vice-President of Supply Chain for Q Laboratories. Mark holds a Marketing degree from Miami University and an MBA From Xavier University. Mark will be responsible for all company-wide procurement activities including negotiating pricing with suppliers and qualifying vendors.

Adam Morris has been appointed Chief Financial Officer (CFO) at Q Laboratories. He will oversee all accounts receivable and accounts payable activities for the company. He will also lead all discovery and research activities to determine pricing for the services provided by Q Laboratories. Adam graduated from Indiana University with a degree in Finance and holds an MBA from Xavier University.

Cathleen Owen has joined Q Laboratories as Director of Quality. Cathleen has vast industry experience in pharmaceuticals and personal care products, having previously been employed at Merck, Elizabeth Arden, and Knowlton Development Corporation (KDC), formerly known as Tri-Tech Labs, where she most recently served as Sr. Director of Quality and Regulatory Affairs. Cathleen will oversee the company's accreditation and certification activities as well as internal and external audits. She holds a B.S. in Chemistry from North Carolina State University and is currently Chair of the Quality Assurance Committee for the Personal Care Products Council.

Check out our BLOG at www.qlaboratories.com/blog

DID YOU KNOW?

Q Laboratories can perform a number of Preservative/Antimicrobial Efficacy methods/protocols, including: USP 51 – Antimicrobial Effectiveness Testing, ISO 11930:2012 - Evaluation of The Antimicrobial Protection of a Cosmetic Product, Personal Care Products Council (PCPC) M-3 - Method for Preservation Efficacy Testing of Water Miscible Personal Care Products, PCPC M-6 - Method for Preservation Testing of Atypical Personal Care Products, and PCPC M-7 - Screening Method for Preservation Testing of Water-Miscible Personal Care Products. We can also perform client specific methods and specially designed challenge tests utilizing our extensive organism library.

BIOSCIENCE

Q Laboratories was proud to be mentioned as one of the fast-growing Bioscience companies in the State of Ohio in the 2017 Ohio Bioscience Growth Report published in June by BioOhio, a member-guided service that connects and supports Ohio's bioscience community through networking, advocacy, events, talent information, and cost savings.

METHOD VALIDATION

ICH Q2, *Validation of Analytical Procedures* lists the characteristics which should be considered as part of a validation study: **Accuracy** (the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found); **Precision** - the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: repeatability, intermediate precision and reproducibility; **Specificity -** the ability to assess unequivocally the analyte in the presence of components which may be expected to be present; **Detection Limit -** the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value**; Quantitation Limit** - the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy; **Linearity** the ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample; and **Range -** the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity.

TRADE SHOWS

Q Laboratories will be exhibiting at the following industry events in the upcoming months:

- **ContractPharma Contracting and Outsourcing Tabletop Exhibit;** September 14th, New Brunswick, NJ**;** (**Booth# 22).**
- **Supply Side West 2017,** September 27-28**,** Las Vegas; **(Booth# I102)**
- **Personal Care Products Council (PCPC) Science Symposium and Expo,** October 24-25, Alexandria, VA.

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