

# WHAT'S NEW AT Q

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## An ISO/IEC 17025 Accredited Laboratory

### FROM THE PRESIDENT'S DESK



*As you can see from the text above my head here, Q Laboratories, Inc. has recently attained ISO/IEC 17025 Accreditation in multiple microbiological and analytical chemistry methods. I would like to recognize the entire staff here at Q Laboratories, because this achievement, like everything else we do here, is a team effort. The process of gaining ISO*

*accreditation was led by our Quality Assurance Unit, under the leadership of our Director of Quality, James Agin. However, credit also belongs to all of our lab managers, all of the analysts working in the labs and our excellent support staff. As a privately-owned, independent laboratory, we are proud to be able to say that our quality system and laboratory proficiency measures up to any lab in the world. ISO 17025 is the gold standard by which laboratories are judged and while we are not surprised we reached this level of excellence, we are certainly proud to have done so.*

*David G. Goins*

David G. Goins, President

### DIETARY SUPPLEMENT BILL

It has been quite a ride for US Senate bill S.3002, the *Dietary Supplement Safety Act of 2010*, which was introduced in February by Senators John McCain (R-AZ) and Byron Dorgan (D-ND). Dietary Supplement trade organizations vociferously objected to the legislation, complaining that the bill would inflict much higher costs on dietary supplement manufacturers, subsequently passing the costs on to the consumer, effectively limiting consumer access to many dietary supplement products. Senator McCain responded that the bill simply, "would require dietary supplements to list all ingredients on packaging, mandate that manufacturers register with FDA, and provide FDA with mandatory recall authority for dietary supplements it determines are hazardous to human health." Opponents contended the bill would give the FDA arbitrary power over what ingredients and supplements could be marketed and some ingredients currently accepted would be banned. In early March, Senator McCain withdrew his support for the bill, essentially leaving it dead in the water, and agreed to work with a group of legislators to incorporate certain, more widely accepted aspects of the bill into the Food Safety Modernization Act (H.R. 875), currently being considered in Congress. The parts of the Dietary Supplement bill that would be included in H.R. 875 would include: requiring all dietary supplement manufacturing, processing and holding facilities to register with the Secretary of Health and Human Services; giving the FDA authority to issue a mandatory recall order if a dietary supplement is adulterated or misbranded or "the use of such supplement could cause serious adverse health consequences such as death"; requiring the FDA commissioner to publish guidelines on new dietary ingredients "as soon as possible"; and mandating that the FDA notify the DEA when a new product contains a synthetic anabolic steroid.

### MINDING YOUR Q'S

The FDA has released the document, *Guidance for Industry: Q8, Q9, and Q10 Questions and Answers*. The introduction of the document provides the reason for the guidance, "Since the Q8, Q9, and Q10 guidances were made final, experiences implementing the guidances in the ICH regions have given rise to requests for clarification. This question and answer (Q&A) document is intended to clarify key issues. The guidance reflects the current working procedure of the ICH Quality Implementation Working Group (Q-IWG) for implementing the Q8, Q9, and Q10 guidances. The benefits of harmonizing technical requirements across the ICH regions can be realized only if the various quality ICH guidances are implemented and interpreted in a consistent way across the three regions. The Q-IWG is tasked to develop Q&As to facilitate implementation of existing quality guidance." One of the questions in the document is, "What are the benefits of implementing a pharmaceutical quality system (PQS) (in accordance with ICH Q10)?" The answer reads, "Further reducing risk of product failure and incidence of complaints and recalls, thereby providing greater assurance of pharmaceutical product consistency and availability (supply) to the patient; Better process performance; Opportunity to increase understanding between industry and regulators and more optimal use of industry and regulatory resources; enhance manufacturer's and regulators' confidence in product quality; and, Increased compliance with GMPs, which builds confidence in the regulators and may result in shorter inspections."

### LABORATORY CONTROLS

Current FDA Good Manufacturing Practices (cGMPs) for Cosmetics recommend: Raw materials, in-process samples and finished products are tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants; Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration, and are retested for continued compliance with established acceptance specifications; The water supply, particularly the water used as a cosmetic ingredient, is tested regularly for conformance with chemical-analytical and microbiological specifications; and, Fresh as well as retained samples of finished products are tested for adequacy of preservation against microbial contamination which may occur under reasonably foreseeable condition of storage and consumer use.

### CAUGHT IN THE WEB

Some new features of the Q Laboratories, Inc. website include multiple pages devoted to the ongoing construction of our 9000 sq. ft addition to our facility. The site includes pictures of various and continuing stages of this project. Construction is currently on schedule and slated to be completed in late summer, early fall of 2010.

Also being added to the website is a link to current job openings at Q Laboratories, Inc. **Please visit [www.qlaboratories.com](http://www qlaboratories.com).**