WHAT'S NEW AT Q

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FROM THE PRESIDENT'S DESK

During a speech at the 2013 CBI Pharmaceutical Compliance Congress, U.S. Department of Justice (DOJ), Deputy Assistant Attorney General Maame Ewusi-Mensah Frimpong indicated that one of the main areas of focus for the DOJ going into 2013 was drug safety and assuring that pharmaceutical companies were complying with Current Good Manufacturing Practices (cGMPs). As head of the Consumer Protection Branch of the Civil Division of the DOJ, Mr. Frimpong said that his department works closely with the FDA and considers its primary mission protecting consumers. This is a clear indicator that scrutiny of the pharmaceutical industry by regulators is getting more acute. Pharmaceutical product safety has always fallen under the purview of the FDA, but now it appears the DOJ is involved as well. This serves as another reminder that the best path to compliance is hypervigilance and preventive action to assure that we are meeting our regulatory burden.

David G. Goins, President

Q11

On November 20, 2012, the Food and Drug Administration (FDA) released a notice in the Federal Register, announcing, "(T)he availability of a guidance entitled 'Q11 Development and Manufacture of Drug Substances.' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes approaches to developing and understanding the manufacturing process of a drug substance and provides guidance on what information should be provided in certain sections of the Common Technical Document (CTD). The guidance is intended to harmonize the scientific and technical principles relating to the description and justification of the development and manufacturing process of drug substances (both chemical entities and biotechnological/biological entities) to enable a consistent approach for providing and evaluating this information across the three regions (Japan, the US and the European Union). The discussion of principles in the guidance is intended to apply only to the manufacture of drug substances, not the manufacture of finished drug products." The ICH Expert Working Group recommended for adoption the final draft of the Q11 Document in May 2012 to the regulatory bodies in the three regions. ICH Q11 addresses such issues as, Manufacturing Process Development, Description of Manufacturing Process and Process Controls, Selection of Starting Materials and Source Materials, Control Strategy, Process Validation/Evaluation, Submission of Manufacturing Process Development and Related Information In Common Technical Documents (CTD) Format and Lifecycle Management.

Please visit www.Qlaboratories.com for more information on the services offered by Q Laboratories, Inc.

METALS

According to the US Pharmacopeial (USP) Convention website, the implementation of the two new elemental impurities chapters, <232> Elemental Impurities-Limits and <233> Elemental Impurities-Procedures, was postponed pending a review of appeals made regarding the proposed chapters. According to the USP Council of Experts, the Executive Committee of the Council of Experts (CoE EC), "(t)he purpose for the postponement was to allow adequate time for the CoE EC to adjudicate and render a decision on three appeals related to the two general chapters. Due to the similarity of issues raised, these appeals were consolidated and considered simultaneously as a single appeal." The CoE EC met on January 7, 2013 and determined to keep February 1, 2013 as the official date for publishing of the two chapters. The CoE EC also kept May 2014 as the official enforcement/implementation date, adding, "USP intends to implement these general chapters through a proposed provision in the General Notices that would make <232> and <233> applicable to all articles in the compendia (except where noted otherwise) on May 1, 2014 (USP 37–NF 32). Conformance with <232> and <233> in applicable monographs will thus be required as of this date. It is important to note that although general chapters <232> and <233> will become official on February 1, 2013, there will be no requirement for an article covered by an applicable USP–NF monograph to comply with their provisions on this date. USP's position is that until a general chapter is referenced in a monograph or in General Notices, it is not applicable to any article named in USP–NF. Typically, a standard becomes official six months after publication in a book or supplement, and implementation is required as of that official date. In this case, however, the official date is separate from the implementation date, as implementation cannot occur until the general chapters are referenced in a monograph or in General Notices." This provision currently is proposed in Pharmacopoeial Forum 39(1) [Jan–Feb 2013] for public comment. Stakeholders may submit comments on the General Notices proposal until March 31, 2013 for consideration by the Executive Committee.

MEET THE Q LABORATORIES' STAFF

Michelle Kelly has been named Microbiology Laboratory Supervisor-Pharma at Q Laboratories, Inc. Michelle has been a member of the Q Laboratories' staff since 2004, serving as Microbiology Lab Supervisor for the last 5+ years. She will be responsible for all clients and samples for the pharma, dietary supplement, cosmetic and health and beauty care industries. She will oversee training of analysts in pharma related methods and manage the day-to-day operations of the Pharma Microbiology Lab.

TRADE SHOWS

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

- **Interphex,** April 23-25**,** New York, NY; **Booth #1010**

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