



***To make sure you receive our Quarterly Newsletter, please add us to your "Safe Senders" List!**

Spring 2010
Volume 10 Issue 1

Message from the CEO



As part of our new company newsletter, the "QP Today" will be providing you, our valued clients and partners, with a brief update regarding QPharma and any new and exciting news surrounding our organization, including any new products and services. This newsletter will inform you of any events we will be attending so you can join us on the road. We pride ourselves on the knowledge of our employees and enjoy participating in conferences and meetings that further expand our abilities to better assist our clients. The QP Today will cover any new partnerships we have initiated that will benefit you as our clients. Finally, it will focus on any

geographic expansions we have in the marketplace. One opportunity that I am excited about is the growth of business in the Cambridge, Massachusetts vicinity. I am personally committed to this expansion which you can read more about in our Business Unit Update below.

Inside This Issue

- 1 Message from the CEO
- 1-2 Industry Highlights
- 2 Upcoming Events
- 3-4 Business Unit Update
- 4 Employee News

"President Barack Obama signed the health care reform bill..." which includes provisions for the Sunshine Act.

Industry Highlights

Physician Payment Sunshine Provisions in Health Care Reform

President Barack Obama signed the health care reform bill (HR 3590 - Patient Protection and Affordable Care Act) into law at the White House Tuesday, March 23, 2010. Within this law, federal provisions for reporting payments and gifts to physicians are included, as well as sample transparency.

QPharma has generated a fact sheet and guidance interpretation document which will be published to our website shortly.

Continue to check the QPharma website for additional details.

Final FDA Guidance on Drug Supply Chain

The FDA issued its final guidance on Drug Supply Chain, "Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages" on March 29, 2010. For more information, visit:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf>

The One-Drop Rule – A Current QPharma Perspective

It's a common misconception in our industry that the FDA permits one sample drop as sort of a "free pass" when practitioners are not determined sample eligible at the time of the sample drop. Many pharmaceutical manufacturers and distributors have asked our position on this rule. QPharma feels the one-drop rule is not in compliance with the law. As such, we believe the law, regulation, and information we've received from FDA regulators is clear that the requirement is to validate the practitioner **PRIOR** to sampling. Below is a statement received from an FDA representative (bolding our emphasis).

“Prior to sampling practitioners, the distributing firm must verify against information obtained from the appropriate state authority...”

“21 CFR 203.30(a)(2) and 203.31(a)(2) require the manufacturer or authorized distributor of record to verify with the appropriate state authority that the requesting practitioner is licensed or authorized under state law to prescribe the drug product. **Prior to sampling practitioners**, the distributing firm must verify against information obtained from the appropriate state authority that the requesting practitioner is, in fact, currently licensed or authorized to prescribe the drug product(s) being sampled.”

With the technology and information available today, it would be irresponsible for a company to permit sampling to practitioners that have not been validated.

Missouri Will Require Pharmacies to Use Real Time Tracking System for PSE Products

Missouri Governor Jay Nixon announced on March 8, 2010, that Missouri will implement the National Precursor Log Exchange (NPLEx) system to track pseudoephedrine (PSE) product sales in order to combat the manufacture of methamphetamine. NPLEx denies the purchase of PSE products when a consumer has exceeded the daily limit of 3.6 grams, or 120 standard tablets, and thus prevents individuals from circumventing the law by travelling to various pharmacies to purchase the legal limit of PSE. The governor's news release indicates that Missouri's NPLEx should be implemented within three months. According to a CNBC news article, the NPLEx system is now connected to nearly one-third of the nation's pharmacies and thus helps to combat the production of methamphetamine by restricting the sales of its main precursor ingredient at these participating pharmacies.

“Missouri will implement the NPLEx system to track pseudoephedrine product sales in order to combat the manufacturer of methamphetamine.”

Mississippi Law to Require Prescription for PSE Products

Signed into law by Governor Haley Barbour on February 11, 2010, House Bill 512 will require patients in Mississippi to obtain a prescription for medications containing PSE beginning July 1, 2010. By including PSE – the key precursor ingredient in methamphetamine production – as a Schedule III controlled substance, Mississippi's law aims to curb the illegal manufacture of methamphetamine, as explained in the governor's news release. The March 2010 NABP Newsletter article “Regulating Methamphetamine Precursors: Which Laws and Programs Are Most Effective?” reviews federal and state meth-precursor laws and program outcomes.

“House Bill 512 will require patients in Mississippi to obtain a prescription for medications containing PSE beginning July 1, 2010.”

QPharma's First Annual Validation Conference – A Success!

QPharma held its first New Jersey-based validation conference at the Hyatt Headquarters Plaza on Thursday March 18, 2010. The theme centered on success solutions for automating critical utilities. The conference was a half day seminar featuring three key lectures on successful cost effective implementation of automated critical utilities.

Bruce Fieggen, PMP, Vice President of Project Management for QPharma, spoke on “*How to Plan Any Project*.” Bruce provided insight into how upfront smart project planning can save you on time and budget at the end of the project.

Joseph J. Manfredi, President, and CEO of GMP Systems, Inc. spoke on “*Water System Design and Implementation*”. Joe provided details of a 6 years multi-phase utilities implementation of a new Purified Water System designed to fit in a tight space.

Kerry Godfrey, Director of Business Development for ThermoSystems spoke on “*Best Practices for Implementing Building Management Systems (BMS) in the Pharmaceutical Environment*”. Kerry's talk centered on smart implementation of Building/Data Management System using SCADA or PLC system.

“The conference was a half day seminar featuring three key lectures on successful cost effective implementation of automated critical utilities.”

Continue to check the QPharma website for interesting industry updates and to register for our upcoming events.

Upcoming Events

Medical Design and Manufacturing East	June 9
DIA 46th Annual Meeting	June 12
NJ ISPE Chapter Day	June 16

Have you checked out the new look of QPharma's web site?
www.qpharmacorp.com

QPharma Presented at IVT's Computer and Software Validation Conference

Robert Finamore, Director of Professional Services, and Alexis Stroud, Manager of Regulatory Compliance, spoke at IVT's 11th Annual Computer and Software Validation Conference April 21-23 in San Diego, California! QPharma presented on the following topics:

- Conducting a GAP Analysis of your CSV Program
- Understanding Audit Trail Requirements

Business Unit Update

Engineering Services

QPharma has implemented an Engineering Services Group. This group will provide the life-science and associated industries with the resources necessary to manage, design, construct, commission, and validate the successful execution of projects. The Engineering Services group further enhances the suite of services already provided by QPharma, including Regulatory Compliance and Validation Services. Engineering Services completes our objective of being a single-source provider. We now have the ability to implement and maintain systems, processes, and facilities from start to finish. QPharma's Engineering Services will operate out of our Cambridge, MA facility.

To see QPharma's latest events, visit our website at www.qpharmacorp.com/events

Newest Call Center Service Program

QPharma is engaged in a new program providing a client with a non-personal outreach program that strives to achieve three main goals. First, is to reach the practitioner or office "decision maker" confirming receipt of recent mailings sent out by the client. Second, is to assist the office with any questions and actively suggest sending another mailer to the office in the event they did not receive the original mailer. Third, is to engage the decision maker in completing the sample request and mailing it back in for verification and fulfillment.

In addition to helping Pharmaceutical companies reduce costs while maintaining product recognition, these services provide for cleaner more accurate practitioner information. Address verification services, phone number verification services and current state of the physician i.e. moved, retired, actively practicing etc. are recorded during each call. In summary, the pharmaceutical manufacturers are staying in front of their practitioner base, receiving quality data points all while reducing their overall costs – phone call vs. sales call.

Engineering Services completes our objective of being a single-source provider. We now have the ability to implement and maintain systems, processes, and facilities from start to finish.

Newest Validation Assignment- Cambridge, MA

We currently have two validation assignments in Cambridge, MA. First, we are performing a number of tasks from reviewing and updating existing quality documentation to executing validation on newly installed equipment. Second, we are building a Master Validation Plan using our Project Management Services. Our biotech client has a heavy workload of new products, new equipment, and revalidation of existing systems and has assigned QPharma to organize a Master Validation Planning Schedule. The Validation Planning tool will be used to assess the current scope of work versus resource allocation, tracking, reporting, and overall planning.



Alexis Stroud, HBA's Rising Star

Employee News and Announcements

Congratulations Alexis Stroud for being a "Rising Star"!

Alexis Stroud was nominated for the Healthcare Businesswomen's Association (HBA) "Rising Star" award for 2010. Alexis was nominated for her significant contributions to QPharma, exemplifying true leadership, being a role model to others, exhibiting dedication to the healthcare industry and being a true example of "top talent".

Rising Stars are honored at the annual HBA Women of the Year event in May, which attracts over 2,000 industry women and men. Alexis will be honored and receive significant recognition at this event.

NO MATTER WHAT THEY THROW AT YOU, WE'VE GOT YOU COVERED!



Questions or Feedback? Please contact Jessica Labita, Marketing Communications Manager, at jessica.labita@qpharmacorp.com or 888.742.7620.