



Protocol Link

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Protocol Link Enhances Website Publication Series with New White Paper on Reprocessing SUDs

VERNON HILLS, IL – (February 26, 2009) Protocol Link, Inc., a leading project management and consulting firm to the FDA-regulated life sciences industry, today announced the addition of a white paper titled “Quality System Requirements for Reprocessing Single Use Devices” to its website publication series. This white paper provides knowledge-sharing relative to the practical process for applying key elements of the FDA regulations governing quality systems for purposes of enhancing and ongoing compliance.

The author addresses specific steps that manufacturers of Single-Use Devices (SUDs) must take to assure product safety, efficacy and customer satisfaction, by highlighting in detail, the minimum required elements of Quality System Regulation (21 CFR Part 820) and providing insight into the corollary responsibilities of SUD reprocessors.

“From my experience, hospitals and companies that reprocess Single-Use Devices typically do not realize their product is classified as a medical device that falls under the purview of QSR regulations,” said Raymond Cerny, Project Manager at Protocol Link. “An important aspect of our services at Protocol Link is working closely with our clients to ensure their compliance requirements are met and providing tools to assure ongoing compliance,” he added.

Mr. Cerny has more than 15 years of experience in the pharmaceutical, biotechnology and process filtration industries and has assisted Protocol Link clients with fulfilling their regulatory requirements. He holds an MBA in International Business from Roosevelt University Chicago and a Bachelor of Science in Chemical Engineering from Iowa State University.

About Protocol Link

With an established client base worldwide, Chicago-based Protocol Link, Inc., is a leading project management and consulting firm dedicated to providing comprehensive regulatory compliance, quality assurance, cGMP documentation, validation, and technology services to FDA-regulated life sciences companies worldwide. Founded in 1996, Protocol Link’s mission is to provide customer-focused services with ethical conduct, mutual trust, and personnel empowerment. Additional information can be obtained by visiting Protocol Link’s Web site at: www.protocollink.com.

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