

Regulatory Compliance Associates® Inc. partners with Unique Pharmaceuticals as leaders in compounding pharmacy to demonstrate compliance with the new federal requirements for 503B

April 16, 2015 (Pleasant Prairie, WI) – Regulatory Compliance Associates® Inc. (RCA), a life sciences consultancy focused on quality, regulatory and technical consulting, announces its cooperative effort with Unique Pharmaceuticals as they demonstrate compliance with new federal compounding industry regulations.

“We’re proud to partner with Unique Pharmaceuticals as they lead the compounding pharmacy industry in demonstrating their commitment to quality,” said Andrew Harrison, Chief Regulatory Affairs Officer at RCA. Recent federal legislation, the Drug Quality and Security Act (DQSA), established a new oversight section of the Federal Food & Drug Administration (FDA) for sterile compounding pharmacies like Unique Pharmaceuticals which are now held to more stringent quality standards and requirements much like drug manufacturers.

“We wanted to be early adopters of this emerging regulatory framework, and we were fortunate to choose RCA as our independent third party cGMP regulatory experts. Unique Pharmaceuticals leveraged RCA’s extensive experience surrounding the more mature regulatory landscape of aseptic processing for pharmaceuticals, and RCA accelerated our compliance path,” according to Unique Pharmaceuticals’ CEO Travis Leeah.

Over the course of nine months, RCA performed a comprehensive cGMP baseline review of Unique Pharmaceuticals, led by Andrew Harrison and Ty Duginske, RCA’s Pharmaceuticals & Biologics Director. RCA guided Unique Pharmaceuticals through intensive remediation and re-engineering of its facility, processes, procedures and testing to meet the new 503B Current Good Manufacturing Practices (cGMP) guidance requirements. Leeah says, “The new requirements are strengthening the outsourcing compounding industry, and that’s good for our business, our customers and, ultimately, their patients who benefit from high-quality, safe, life-saving and life-sustaining medications.” He adds, “The team at RCA has been a true blessing for Unique and we would not have succeeded without their coaching, expertise and knowledge. We always felt that Unique was their top priority.”

About Regulatory Compliance Associates Inc.

Regulatory Compliance Associates Inc. brings full-spectrum solutions to compliance, regulatory, quality assurance, R&D, and operational challenges for life science clients. As leaders in both aseptic drug manufacturing and the compounding pharmacy industries, RCA is a frequent contributor in publications and industry events such as The FDA’s Center for Drug Evaluation & Research and the Compounders on Capitol Hill (CCH) event. Visit www.rcainc.com or call 262-842-1250 for top-tier strategic planning, mid-level project management, and hands-on support to provide a customized action plan to meet your needs, on time, and on budget.

About Unique Pharmaceuticals, Ltd.

Unique Pharmaceuticals, Ltd., (UNIQUE PHARMACEUTICALS) is a FDA-registered 503B outsourcing facility dedicated to improving quality of life and providing trusted compounded preparations for hospitals and health systems. The company is headquartered in Temple, Texas, with more than 18 years of industry experience and is committed to delivering quality, assurance and peace of mind with every solution. For more information, please visit www.upisolutions.com or call 888-339-0874.

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