Contacts:
Allison Kraut
Director of Marketing
Drug Development Analytics LLC
908/273-8490

Will Maroni
RF|Binder
212/994-7562

Della Burns
RF|Binder
212/994-7553

FOR IMMEDIATE RELEASE

RAPS BOOTH #303

Announcing the Launch of RegCheck™ – Revolutionary Software that Facilitates Pipeline Management

Based on Methodology That Has Successfully Brought 60+ Drugs to Market

SUMMIT, New Jersey, September 29, 2014 – Hurley Consulting Associates, a leading international consultancy within the health sciences industry, today announced the launch of RegCheck™, a unique software platform for efficiently managing one or more drug development programs, now available through Drug Development Analytics LLC (DDA).

RegCheck utilizes Hurley Consulting's proprietary methodology developed by its expert team of regulatory professionals that have successfully guided more than 60 drugs to market over the past 25 years. Now their proven process has been captured in RegCheck – an easy-to-use program that simplifies development management and the regulatory submission process. From pre-IND to NDA, this new software identifies potential pipeline issues before they can become regulatory deficiencies and potential financial losses.

"In the pharmaceutical industry, your pipeline is your lifeline; and from the day a patent is issued, the clock is ticking. Every day spent addressing development oversights equates to one less day of marketplace exclusivity," explained Margaret E. Hurley, M.D., FRAPS, President and CEO of Hurley Consulting. "RegCheck categorizes deficiencies identified in documentation during the development process, but more importantly, it provides a recommended corrective action and points to the most current regulatory requirement pertaining to the issue. As a result, drug developers can resolve issues earlier, providing a smoother path to FDA approval, market launch and profitability."

RegCheck's cloud-based system has a user-friendly interface with easy-to-use checklists annotated to FDA requirements. The software analyzes the responses and generates a comprehensive report that categorizes issues and prioritizes them using an innovative color-code system – critical deficiencies are noted in red; major issues appear in blue; and minor inadequacies are color-coded green. For every deficiency noted, RegCheck provides information on the potential actions to appropriately address the issue or suggests a corrective action. RegCheck focuses on the content of the application, rather than compilation and publishing issues that are handled by widely available document management systems.

RegCheck's powerful analytics and reporting functions facilitate the management of the overall program status from various business perspectives. By addressing the entire drug development process, RegCheck notes the need for additional research studies; deficiencies in marketing applications; and recommended corrective actions. RegCheck can play a key role in facilitating informed business decisions surrounding financial investments, human resource allocations, timing of market commercialization and more.

For more information about RegCheck please visit www.myregcheck.com.

###

About Hurley Consulting Associates

Hurley Consulting Associates Ltd. is an international consultancy that has served the health sciences industry since 1987. For more than 25 years, Hurley Consulting has guided clients through the entirety of the IND and NDA processes, and has been recognized within the health sciences industry for its expertise and quality of work. With unparalleled expertise in preparing datasets, reports, global regulatory submission documents and dossiers, Hurley Consulting offers a broad range of services, including regulatory strategy and submissions, nonclinical assessments, clinical trial design, data analysis and marketing assessments.