



## **Kinexum Announces Collaboration with Regulatory Harmonization Institute (RHI) and Korea Health Industry Development Institute (KHIDI)**

*Kinexum Will Provide Strategic Services to Facilitate Overseas Expansion and Advancement of Regulatory and Commercial Goals for Korea Health Industry Development*

*Dr. Ronda Balham Joins Kinexum As Senior Partner, Medical Device Practice*

([PRWEB](#)) August 22, 2011 -- Kinexum has been invited by [RHI](#), a non-profit organization comprised of Group/Institutional members and industry and academic professionals having a deep and broad range of experience in international regulatory requirements to assist in the development of the Korean Pharma/Device health product industry. Under the support of the Ministry of Health & Welfare Korea (MoHW), the Korea Food & Drug Administration (KFDA) and [Korea Health Industry Development Institute](#)(KHIDI), the Columbus Project's goal is to support Korean companies and products for entry into the North American market with the aim of boosting globalization of the country's health product industry.

The Columbus project kicked off with a two day meeting and presentations in Seoul, South Korea on June 13-14. Kinexum CEO Dr. Alexander Fleming's regulatory, technical, and development expertise has been requested in numerous international settings including the World Health Organization, where he was assigned during 1991-92. Dr. Fleming was a member of the expert working groups on Good Clinical Practices and General Considerations for Clinical Trials of the International Conference on Harmonization (ICH) and participated on other ICH committees. Chris Yun, Kinexum VP of Clinical Operations presented at the two day workshop interacting with the Korean Pharma industry executives strategizing to outline goals for global development programs to advance regulatory submissions and clinical trials.

Ronda A. Balham, O.D. was also a presenter in Seoul and has recently joined Kinexum as Senior Partner, Medical Device Practice, to lead regulatory and development strategic services for medical devices. Dr. Balham has 19 years of Food & Drug Administration (FDA) experience including 13 years at the FDA in many capacities including several years at the [Center for Devices and Radiological Health](#) (CDRH) where she began her career as a clinical reviewer. Additionally, she has experience as a medical device consultant/strategist in both the European Union and in the U.S. Dr. Balham brings to Kinexum her expertise in the premarket approval and clearance processes for medical devices; the Humanitarian Device Exemption process; and regulatory due diligence for medical device products.

Kinexum's highly experienced regulatory and clinical development team will play an important role to guide health product development and regulatory strategy to achieve development and commercialization goals for the US market and the rest of the world.

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