



## MEDIA RELEASE

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De Young & Hayden, LLC to form strategic alliance with former FDA Division Director, Cynthia Rask, M.D.

De Young & Hayden, LLC (DYH), a biopharmaceutical consulting partnership, and Cynthia Rask, M.D., have agreed to form a strategic alliance designed to facilitate successful interactions between biopharmaceutical development teams and regulatory authorities such as FDA.

According to DYH Senior Partner, Larry De Young, Ph. D., "This alliance strengthens our mutual commitment to help companies develop commercially important new drugs and biologics that meet scientific, clinical, and regulatory hurdles. Cynthia will be invaluable in providing our clients with clinical and regulatory guidance and feedback on their strategic plans."

Dr. Rask, a neurologist, has extensive experience in both drug development and regulatory oversight of drug development, including more than 3 years working at FDA as a Division Director, where she supervised clinical and preclinical reviews of all cell, tissue, and gene therapies under IND for all clinical indications, including neurologic, oncologic, metabolic and cardiovascular diseases.

"This alliance between Dr. Rask and DYH enhances our ability to provide unique expertise in support of our clients in their critical interactions with regulatory agencies such as FDA," says Brad Hayden, Ph. D., senior partner. "This expertise is especially useful in regulatory planning and the preparation of IND and NDA documentation and FDA Advisory Committee interactions."

Prior to having been named Division Director, Dr. Rask worked at FDA as a primary reviewer where she performed the clinical reviews of Phase 1, 2, and 3 protocols for a wide variety of product classes, including cytokines, therapeutic proteins, monoclonal antibodies, cellular, and gene therapy, with a primary focus on biologics for treatment of neurologic diseases. She also reviewed several Biologic Licensing Applications for neurologic indications.

"I worked with the other neurologists in my Division to ensure consistency between the standards applied in CBER and CDER," notes Dr. Rask.

Dr. Rask also has a broad range of experience within the biopharmaceutical industry, having spent 5 years working at Genentech, where she led an international clinical development program and was the neuroscience interface between clinical development, research and business development for the company.

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De Young & Hayden, LLC  
Cynthia Rask, MD  
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“Before that, I spent 2 years working at Abbott, where I learned the operational aspects of clinical drug development from a sponsor’s perspective, doing everything from monitoring in the field alongside the CRAs on my team to designing and implementing a clinical development program that culminated in a successful NDA for the epilepsy medicine Gabrilitril,” Dr. Rask states.

She received her A.B. from Cornell University and her M.D. from the University of Minnesota. She was a faculty member and clinical investigator at the University of Minnesota and Dartmouth Medical Schools.

De Young & Hayden, LLC is a consulting partnership that helps biopharmaceutical companies bring new products to market. Located in the San Francisco Bay Area, DYH has global experience with clients around the world. DYH helps companies to determine and clearly articulate the potential value of internal development candidates and prospective in-licensed products. It also provides the knowledge, tools, and services to help clients develop and successfully file NDAs/BLAs and to interact effectively with regulators.

DYH recently announced a liaison in Asia Pacific, where the former head of the Department of Clinical Pharmacology at Nippon Roche, Norio Himori, Ph. D. now represents DYH interests and activities in Japan. A highly respected scientist and pharmacologist with a wide range of experience in pharmaceutical development, Dr. Himori-san will work along side of DYH to strengthen pharmaceutical developments in Japan by improving interactions with Japanese regulatory authorities (the Ministry of Health, Labour and Welfare) and by applying processes to shorten development times while strengthening label claims.

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