Richard J. Stec, Jr., Ph.D.

Business:
Hospira, Inc.
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Education:

1987	Ph.D. in Analytical Chemistry, University of Missouri
1983	M.S. in Chemistry, University of Iowa
1981	B.S. in Chemistry, Illinois Benedictine College

Experience:

06/07 to present — Vice President, Regulatory Affairs, Americas, Hospira, Inc., IL
Responsible for US, Canada and Latin America regulatory operations for Hospira's drug and device product portfolio. Responsible for the integration of regulatory operations resulting from the acquisition of Mayne Pharma. Maintain responsibility for drug and device labeling operations and US manufacturing quality system documentation. Manage a staff of ——

07/04 to 06/07 — Vice President, Global Regulatory Affairs, Hospira, Inc., IL
Responsible for global regulatory operations for Hospira's drug and device product portfolio. Develop and execute regulatory strategies to bring quality products and innovative technologies to customers in a rapid, cost effective manner. Implement operational strategies that increase efficiency and compliance of core regulatory functions. Manage a staff of ——

08/03 to 07/04 — Director, Regulatory Transition Team, Hospira, Inc., IL
Responsible for separating regulatory operations from Abbott Laboratories and establishing the international regulatory structure to support the hospital product drug and device business of Hospira. Execute regulatory strategies to support the formation of the new company and grow the international business. Establish program priorities with Regional Directors. Manage a staff of —

05/01 to 08/03 — Director, Regulatory Affairs, Abbott Laboratories Hospital Products, IL
Responsible for IND and NDA/ANDA CMC support for new product launches and the post approval CMC support of all commercial drug products ———. Execute bundled submission regulatory strategies to support manufacturing plant and commodity conversions. Establish regulatory systems that improve submission quality, regulatory compliance and operational efficiency. Negotiate program priorities with director level management and manage resources within plan. Manage a staff of —

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06/00 to 05/01	Director, Regulatory Affairs, Abbott Laboratories Hospital Products, IL Responsible for directing capitalized program to establish a Part 11 compliant division specification repository and provide universal access to all divisional manufacturing sites. Responsible for establishing an e-submission publishing facility to support NDA submissions to FDA. Program capitalized over – years at $——— Manage a staff of —
05/99 to 06/00	Associate Director, Regulatory Affairs, Abbott Laboratories Hospital Products, IL Responsible for developing regulatory strategies to facilitate timeline compression and the marketability of new drug delivery systems. Submit dossiers to global regulatory agencies in support of parenteral product contract manufacturing business. Participate with the commercial managers in the assessment of new business opportunities. Track key regulations and influence legislation that impacts the business. Manage a staff of —
11/95 to 05/99	Associate Director, Regulatory Affairs, Abbott Laboratories Specialty Products, IL Responsible for providing regulatory strategy and support for drug substance, generic and animal health drug submissions. Interface with Abbott International Affiliates for the manufacture of product for global markets. Responsible for divisional labeling operations supporting the Pharma, Agricultural and Animal Health businesses. Manage a staff of —
06/95 to 11/95	Section Manager Labeling, Abbott Laboratories Specialty Products, IL Responsible for development, retention and change control and of all new and existing agricultural product and bulk drug labeling. Manage label activities with product managers, marketing, packaging, production, planning, regulatory affairs, quality assurance, graphics studio and print vendors. Manage a staff of —
08/87 to 06/95	Group Leader, Analytical R&D, Abbott Laboratories Specialty Products, IL Responsible for analytical method development and validation supporting new bulk drug product (chemical and fermentation) development and scale-up. Manage daily activities of — staff chemists and technicians.
02/84 to 01/85	Chemist Grade 05, USGS, Columbia, MO Develop and evaluate methods to concentrate heavy metals in acid rain samples. Supervise on technician.