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PlantForm Board Chair publishes chapter in international pharmaceutical regulations guide


The book chapter, Nonclinical Safety Assessment: Canada, details the regulatory pathway for pharmaceuticals in Canada, including biologics and subsequent entry biologics (SEBs). It also provides a case study of Omnitrope™, the first SEB approved in Canada. Jamie L. Doran of Intrinsik Health Sciences Inc. is the chapter’s co-author.

“This chapter provides a comprehensive regulatory overview and advice to companies wanting to get their pharmaceutical products approved in Canada,” Dr. Goldberg said. “I’m pleased to be able to share the knowledge I’ve accumulated from 20 years as a regulatory consultant.”

Dr. Goldberg’s extensive experience in drug research and development has helped companies get numerous products approved, including Atorvastatin (Lipitor®), the world’s best selling pharmaceutical. He is a PlantForm founder and has chaired the company’s Board of Directors since its inception. View his full bio.

PlantForm Corporation’s mission is to provide low-cost biologic drugs for cancer and other critical conditions. The company is currently raising Series A capital to advance into the regulatory approval process for its first antibody product, a biosimilar (SEB) version of the breast cancer drug Herceptin® (trastuzumab). Biosimilar versions of two additional antibody drugs for cancer are in development, as are antibodies for the treatment of human immunodeficiency virus. PlantForm is also developing an enzyme to protect against nerve agent exposure under contract with the U.S. Defense Advanced Research Projects Agency. Projected revenue is more than $50 million by 2017.

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