ROD L. HARTWIG
EDUCATION: B.S Chemistry, Austin Peay State University 1995

Mr. Hartwig is the Director of Product Development for Starton Therapeutics, Inc. in Paramus, NJ. He is a pharmaceutical professional with a well-established history of performance in the pharmaceutical industry for over 27 years. He received his B.S. in chemistry from Austin Peay State University. He is an experienced formulation scientist with inventorship on several applications and issued patents in US and EU within the pharmaceutical industry with a primary focus on the development of innovative transdermal delivery systems. He has been involved with the development of drug products from initial concept through proof of concept and supporting commercial product launches for both OTC and Rx drug products. Mr. Hartwig has developed his skills over the years for preparing unique, proprietary, and novel ideas to implement ease of use, ease of process, and ease of manufacturing to alleviate pitfalls often found in the drug development process. He applies a Quality-by-Design (QbD) approach to each project through the development pathway. In his current role, he is responsible for oversite of the facility which performs formulation development, analytical testing, product development, CMC, Clinical Trial Material Manufacturing, Outsource management, and regulatory support for the Starton's programs. He has served in both hands-on responsibility and management of Research and Development, Formulation, Analytical, Quality, Product Development, Metrology, Process Development, Verification and Validation, and Business Development.

Starton Therapeutics, Inc.
www.startontx.com
Rod L. Hartwig
Director of Product Development
215 College Road, Suite 300
Paramus, NJ 07652 USA

Company Email: rhartwig@startontx.com
Personal Email: rlhartwig@yahoo.com
Company Phone: 1-800-449-5405
Mobile Phone: 954-529-1644

Abstract: *"Challenging the Norm: Innovative Approaches for Transdermal Delivery of Lenalidomide"*

Transdermal Drug Delivery (TDD) is not NEW. Many still believe transdermal patches are a new dosage form. It is a rare and relatively under-utilized dose form, with the potential to transform the use of a drug product. TDD is a delivery platform having been around for over 50 years beginning in the middle ages, and commercially viable since 1979 with FDA approval of Transderm-Scop®, a scopolamine (hyoscine) patch for the treatment of motion sickness as the first approved patch. Since the 1970's, a lot has been accomplished by the pharmaceutical industry in the field of transdermal drug delivery. The type of drugs, the amounts of drug delivered, and the platforms of delivery for topical/transdermal have overcome various aspects of product development. Each of these products developed over the last 50 years implemented unique (at that time) and most of the time patentable technology and formulation techniques to gain FDA approval of NDA for commercial marketing of a US drug product. Transdermal delivery has been attempted for many well-known drugs with limited success using historical formulation development approaches. With more complex molecules, challenging the norm is now more essential to achieve transdermal delivery of medicines that will provide a

meaningful clinical benefit and commercially viable product. as Starton Therapeutics, Inc is focused on the development of existing drugs through the NDA 505 b 2 route to continuously deliver known drugs which would bring significant benefit of a continuous and low-dose administration. Potential advantages include increased patient compliance based on reduced toxicity, reduced exposure, lowest effective dose, maintenance of therapeutic blood levels, mitigation of peaks and valleys of typical oral and parenteral dosage forms as well as tolerability and reduced side effects. There are many drugs, such as Lenalidomide, an immunomodulatory drug (IMiD), which present an unmet medical need in their current delivery form. The Reference Listed Drug (RLD), Revlimid™, is a capsule of lenalidomide for oral delivery. Patients may discontinue use of oral delivery due to toxicity and tolerability issues related to peaks and valleys of this route of administration. Lenalidomide poses significant product development challenges, such as solubility and stability - Starton obtained US Patent 11,197,852 for "Continuous Delivery of Lenalidomide and other immunomodulatory agents". Lenalidomide continuous delivery may be obtained from several types of dosage forms and routes of administration. Starton developed innovative approaches to continuously deliver lenalidomide to eliminate peaks and valleys of oral administration through subcutaneous administration utilizing several animal models and a recently completed human study provided proof of concept. Starton has recently evaluated the development of transdermal patch formulations utilizing several in vitro models and an in vivo animal model to further the potential of continuous low-dose delivery of lenalidomide.