

Inmedix welcomes Lee S. Simon, MD, to its Regulatory Advisory Team

Engaging with Dr. Simon to prioritize all aspects of regulatory compliance.

NORMANDY PARK, WA, USA,
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EINPresswire.com/ -- Seattle-based
medtech/biotech [Inmedix](#), Inc.,
developers of immuno-autonomics
and cloud-based clinical diagnostics to
quantify stress biology with precision,
announced today the consultant engagement of SDG, LLC Principal Lee S. Simon MD, FACP,
MACR to lead its regulatory oversight efforts.



Dr. Simon is a rheumatologist and has been the Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products (DAAODP) (2001-2003), within the Center for Drug Evaluation and Research (CDER), FDA. He has served on and has been the Acting Chair of the Arthritis Advisory Committee of the DAAODP (1993-2001). He has also served on the advisory committees for the Division of Over the Counter Drugs (1996), Center for Devices (1995), and for the Division of Hematologic and Gastroenterologic Drug Products (1996).

He has been a clinical Rheumatologist for 25 years. He is a fellow of the American College of Physicians (1991) and a Master of American College of Rheumatology (2019). He was at Harvard Medical School and the BIDMC as an Associate Professor of Medicine (1996-2001) and as an Associate Clinical Professor of Medicine (2001-2008). Dr. Simon has had extensive experience in drug development in the US and has served on consulting advisory boards for many different companies. He was a National Institutes of Health (NIH) funded investigator for 12 years working at the "wet bench" at the MGH.

He has served for two terms on the Board of Directors of the American College of Rheumatology (ACR) (1991-1993, 1994-1997), served as the Chair of Education for the ACR and on the committee of the National Arthritis Foundation. He has served as the Scientific Abstract Selection Chair of the Annual Meeting of the ACR (2002). He has been awarded the 2003 Distinguished Service Award of the ACR and has been awarded the 2003 Scientific Leadership Award of the Lupus Research Institute. He served on the Steering Committee of IMPAACT, a

group developing recommendations for the design and implementation of clinical trials investigating pain and now on the steering Committee of ACTION, a public private partnership with FDA studying improved clinical trials designs and outcomes for both acute and chronic pain. He is on the Steering Committee and was Co-chair of the 2012, 2020, 2023 OMERACT (Outcome Measures in Rheumatology) Biannual Meeting. He served on the Steering Committee of the NIH Osteoarthritis Initiative (2001-2003). Dr. Simon has served as Chair of the biannual "Innovative Therapies in "Autoimmune Disease" conference sponsored by the ACR, FDA, NIH, and the Arthritis Foundation (2001-2005).

"This is a great opportunity to collaborate with Inmedix on furthering an improved understanding of this fascinating and evolving important area of medicine," said Dr. Simon.

Inmedix is defining the emerging medical field of immuno-autonomics: the interface between immune function and stress biology, controlled within the brain by the autonomic nervous system (ANS). The natural stress response can beneficially impact immune function in the near term (1). However, chronic activation of the immune system by stress, mediated by the ANS, has been implicated in adversely affecting the onset and severity of autoimmune disease (2). With its CloudHRV™ diagnostic in development, Inmedix intends to provide the leading, precision tool to quantify ANS stress state to support research and clinical care.

"Dr. Simon continues to be a leading beacon of clinical acumen and regulatory guidance," said Inmedix CEO & Co-founder Andrew J Holman, MD. "Since meeting him in 2000 as a young rheumatologist, then witnessing his featured lectures at the American College of Rheumatology (ACR) over many years, and eventually interacting with him while he was at FDA, he continues to be a trusted and most respected professional. I could not be more pleased to have his ongoing advice and oversight to ensure Inmedix maintains all aspects of regulatory compliance."

References

1. Elenkov IJ, Wilder RL, Chrousos GP, Vizi ES. The sympathetic nerve – an integrative interface between two supersystems: the brain and the immune system. *Pharmacol Rev* 2000;52:595-638.
2. Taylor PC, Holman AJ. Rheumatoid arthritis and the emergence of immuno-autonomics. *Rheumatology (Oxford)*. 2019 Dec 1;58(12):2079-2080. doi: 10.1093/rheumatology/kez216. PMID: 31177267.

About Inmedix, Inc. and its subsidiary, Inmedix UK, Ltd.

Seattle-based biotech/medtech Inmedix, Inc. and its subsidiary Inmedix UK, Ltd., are committed to engaging in world class research to discover innovative solutions for pressing healthcare needs related to the impact of stress, modulated within the brain by the autonomic nervous system (ANS). The Inmedix® CloudHRV™ system is leading the development of heart rate variability (HRV).

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