

NEWS RELEASE

For Immediate Release

Contact: Daniel Blasi
Product Genesis
617.234.0070 x200
info@productgenesis.com

Product Genesis to Lead MassMEDIC Design for Six Sigma - Designing Quality into Medical Devices Seminar

Dr. Kevin N. Otto, Lead Consultant at Product Genesis and Master Black Belt, Design for Six Sigma, presents on “Designing Quality into Medical Devices” at the MassMEDIC Palmer & Dodge Medical Technology Breakfast, March 24, 2005 in Waltham, Massachusetts.

Cambridge, MA, February 25, 2005 – Product Genesis, the premier Strategic Innovation consulting firm, today announced that Dr. Kevin Otto, Lead Consultant at Product Genesis, has been selected to speak at MassMEDIC’s **Design for Six Sigma – Designing Quality into Medical Devices Palmer & Dodge Medical Technology Breakfast**, March 24, 2005 in Waltham, Massachusetts. Dr. Otto’s presentation is titled “Design for Six Sigma—Current Applications and Opportunities for Medical Devices.” Dr Otto joins a select, invitation only group for this presentation.

According to MassMEDIC, “significant numbers of defects are often found during the Verification and Validation Test phases of Medical Device Development, which increase the cost of development and time required to complete development projects. Some flaws even make it into manufacturing, resulting in dangerous and costly product recalls.”

“This seminar will address how medical device companies can employ the Design for Six Sigma (DFSS) methodology to detect and eliminate these defects earlier in the Development Life Cycle. It will also explore how DFSS complements and supports existing Quality System Regulations. Case studies will be discussed of leading medical device companies that have begun deploying a customer-driven, world-class product development platform, based on DFSS principles.”

Dr. Otto’s paper reviews methods to understand and manage uncertainty before reaching the Verification and Validation Test phases. Tools are reviewed that confirm the integration of new technologies for maturity and safety for transfer into medical device projects. His paper also explores product reliability, evaluation and life testing, and the benefits of statistical design-of-experiments methods.

For more information on the 2005 MassMEDIC Design for Six Sigma - Designing Quality into Medical Devices Breakfast visit <http://www.massmedic.com/meetings.htm>

About Dr. Kevin N. Otto

Dr. Otto has worked closely with Product Genesis for over ten years as a Lead Consultant. He has been a Professor of Mechanical Engineering at MIT, where he helped found the *Center for Innovation in Product Development* at the MIT Sloan School. He led the product architecture research area within the center, and has developed several methods for sizing the variety of platforms and modularizing products.

Dr. Otto has primarily been involved in the fuzzy front end of product and technology development, to effectively apply technology and create architectural breakdowns of products and systems into modular subsystems. His past experience includes projects with automotive companies on vehicle definition, the U.S. Navy with submarines, and many other companies including everything from document handling systems, air handling equipment, and print film.

Dr. Otto is a Master Black Belt in Design for Six Sigma, and is the co-author of **Product Design: Techniques in Reverse Engineering and New Product Development**, Prentice Hall, 2000.

About Product Genesis

Product Genesis, headquartered in Cambridge, Massachusetts, specializes in Strategic Innovation consulting services that help our clients create new opportunities, a sustainable competitive advantage, and increased shareholder value. Spun out of the MIT Innovation Center in 1986, Product Genesis has worked with diverse organizations from Global 1000 corporations, to venture capital and private equity-backed firms, accelerating their success in the medical, industrial, commercial, consumer and technology markets.

For more information about Product Genesis, visit www.productgenesis.com.

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