2015 NJ SYMPOSIUM ON BIOMATERIALS SCIENCE
"THE PROMISE AND CHALLENGE OF BIOACTIVE MATERIALS"

Featured Speaker Series

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what they will be presenting, &
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Judith E. O'Grady,
R.N., M.S.N., R.A.C.
Corporate Vice President of Global Regulatory Affairs
Integra LifeSciences Corporation

Integra Dermal Regeneration Template - The Regulatory Strategy for FDA Approval of a Novel Medical Device

On **November 9** at the ***NJ Symposium on Biomaterials Science***, Judith O'Grady will address the complexities and challenges of the regulatory pathway for regenerative products, and the process of developing a collaborative working relationship with the FDA.

INTEGRA® Artificial Skin, Dermal Regeneration Template was the first regenerative product approved by the FDA for the treatment of life-threatening burn and scar revision surgeries. Since gaining the initial FDA approval in 1996, the INTEGRA® Template has been used successfully on over 100,000 patients, and is sold worldwide.

Judith O'Grady will share the pathway from concept to product in her talk **Integra Dermal Regeneration Template - The Regulatory Strategy for FDA Approval of a Novel Medical Device**. She will relate the product's journey through biocompatibility testing, pre-clinical testing, multicenter, controlled, randomized clinical trials, submission to FDA and the post-approval study phase. She will emphasize the strategic milestones on the road to approval, negotiation techniques as well as the implementation of post-approval requirements.

Judith O'Grady has worked in the areas of medical devices and collagen technology for over 30 years, and led the team that obtained this FDA approval. Prior to joining Integra she has held positions with Colla-Tec, Inc. a Marion Merrell Dow Company and Surgikos, a Johnson &Johnson company, and she was also on the faculty of Boston University College of Nursing and Medical School. Aside from her success with Integra®, she has also played a pivotal role in the approval of DuraGen® Dural Graft Matrix, DuraGen Plus® Dural Regeneration Matrices, and NeuraGen® Nerve Guide. She has also been a driven leader for over 500 FDA and international submissions and approvals.

At Integra she has been an essential part of the regulatory due diligence process on many of the company's acquisitions. She is a published author, and a sought after presenter both nationally and internationally for her perspective on the regulatory landscape. She received her B.S. degree from Marquette University and M.S.N. in Nursing from Boston University and has a Regulatory Affairs Certification. Join us at this year's ***NJ Symposium on Biomaterials Science*** and learn more from Ms. O'Grady about the regulatory pathways that facilitate rapid approval of safe and effective regenerative medicine products.

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