Joint Department of

BIOMEDICAL ENGINEERING

UNC CHAPEL HILL | NC STATE UNIVERSITY

Coulter Seminar Series Presents

"Commercial Prospects for a Regulated Medical Product: Determinants to Evaluate *A Priori*"

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Art Coury holds a B.S. degree in chemistry from University of Delaware (1962), a Ph.D. in organic chemistry (1965) and an M.B.A. (1980) from the University of Minnesota. His industrial career of 43 years included technical and executive positions at General Mills, Inc., Medtronic Corporation, Focal, Inc. and Genzyme Corporation. His career focus has been polymeric biomaterials for medical products such as implants and drug delivery systems. He holds fifty seven distinct patents and has published and presented widely. After several academic appointments during his industrial career (1965-2008) he became University Distinguished Professor in Chemical Engineering at Northeastern University (2014). His professional service has included: Chair, Minnesota Section, American Chemical Society (1989-1990); President, Society for Biomaterials, USA (1999-2000); President, American Institute for Medical and Biological Engineering (AIMBE) (2003-2004) and membership on a number of university, professional society and corporate advisory boards. Recent recognition has included Member, National Academy of Engineering, Fellow, American Chemical Society and AIMBE, recipient of three major Society for Biomaterials awards, AIMBE Pierre Galletti award, and Outstanding Alumni Awards of the Universities of Delaware and Minnesota.

ABSTRACT

Translating a regulated medical product from concept to profitable, marketed application requires progressing through several stages of development mandated by regulatory, economic and other requirements. Potentially disruptive technologies usually begin with "proof of concept" studies that can proceed to more extensive and expensive stages. If the technology looks promising, at some stage a decision must be made about the feasibility of further development. It is most advisable to consider the positive and negative potential of achieving success at a low expenditure stage (common to technologies emanating from academic labs) in terms of a checklist of dozens of variables that must be satisfied. If even one or a very few of these "imperatives" are not achieved, commercial success will unlikely transpire. This lecture considers the opportunities and threats encountered at each product development stage, provides the "checklist" of variables impacting success and a gives comparison of a successful and unsuccessful regulated medical device in terms of the controlling variables.

Friday, October 30th
12:00 Noon

Seminar will be presented virtually via Zoom:
https://go.unc.edu/f3QHx