American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

"From Bench to Bedside - The New NCI Experimental Therapeutics (NExT) Program"

Presented by

Joseph E. Tomaszewski, PhD

Deputy Director, Division of Cancer Treatment and Diagnosis (DCTD)

National Cancer Institute, NIH, HHS

April 29 (Thursday) Evening

6:00 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program (a 10-min break at 7:40 pm)

8:30 – 9:00 PM – Door-prizes drawing; Networking

Open to Public;

Free to ASQ Members (Become a ASQ Member & Save)

$5 for non-ASQ members to cove pizza/drink cost

Location:

Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Driving directions:

From **I-270** (N or S bound): Take Exit 9A and exit from the first right exit.
Turn left (east) onto Shady Grove Dr.
Turn right (south) onto Rockville Pike (**Route 355**).
Turn left (east) onto East Gude Dr.
Turn left (north) immediately onto Crabb's Branch Dr.
Turn left (west) immediately onto Standish Place.
(The first building on your right side is 7519 Standish Place; open parking)

The conference room is on the first floor with its entrance opposite to the left side of building main entrance.

For headcount purpose, please register by *Thursday noon, April 29, 2010.*

Registration Website: http://www.asq509.org/ht/d/DoSurvey/i/35817

For registration problems or further information contact **Dr. George Chang**, Co-Chair of Biomed/Biotech SIG, at gchang2008@yahoo.com or call **240-793-8425.**

Presentation Summaries:

Title: From Bench to Beside; The New NCI Experimental Therapeutics (NExT) Program

Summary: The NCI's Experimental Therapeutics (NExT) Program, a partnership between NCI's Division of Cancer Treatment and Diagnosis (DCTD) and the Center for Cancer Research (CCR), consolidates NCI's anticancer drug discovery and development resources in support of a robust, balanced, goal-driven therapeutics pipeline. Combined, these resources are capable of supporting a discovery and development continuum from initial discovery through Phase II clinical trial evaluation. *The NCI is focused on moving high-priority discovery and development projects through to proof-of-concept clinical trials and, when warranted, will continue non-commercial research and development activities (up through and including clinical trials) on any discovery project in the NExT Program.* The discovery engine of this program is the newly created Chemical Biology Consortium (CBC). The NCI has established this collaborative network comprising 12 of the top Specialized and Comprehensive Screening and Chemistry Centers with world-class capabilities covering high-throughput methods, bioinformatics, medicinal chemistry, and structural biology. Additionally, the highly successful Developmental Therapeutic Program (DTP) provides the resources needed to facilitate preclinical development through the final steps of development to first-in-human clinical studies. Concurrent molecular imaging and/or pharmacodynamic assay development provided by the Cancer Imaging Program (CIP), the Pharmacodynamics Assay Development & Implementation Section (PADIS), the National Clinical Target Validation Laboratory (NCTVL), and CCR allow early assessment of potential clinical biomarkers. These coordinated and focused R&D processes enable continued incorporation of new data and disease insights into every step of the discovery and development process, thereby increasing the potential for successful clinical evaluation of agents.

Speakers' Bios:

Joseph E. Tomaszewski, Ph.D., National Cancer Institute, Bethesda, MD.

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Dr. Tomaszewski was appointed Deputy Director of the Division of Cancer Treatment and Diagnosis (DCTD), NCI in June 2005 and up until August 2008 was also the Chief of the Toxicology and Pharmacology Branch (TPB), DTP, DCTD, NCI for the past 20 years. He received his B.S. in Chemistry from the University of Scranton in 1965 and a Ph.D. in Organic Chemistry from the University of New Hampshire in 1970. His area of specialty is the development of new therapeutics to treat cancer. In 2005, while he was the Acting Associate Director for DTP, he created the Laboratory of Human Toxicology and Pharmacology, which is responsible for developing **human *in vitro* toxicology assays** and the development of **pharmacodynamic biomarker assays**. As a result, he was given the responsibility for developing a **new pharmacodynamic initiative** within NCI to support **early (Phase 0) clinical trials** under the FDA's Exploratory-IND Guidance as well as PK/PD-driven Phase I clinical trials. Thus, the NCI performed the first Phase 0 in oncology in 2006 using Abbott's PARP inhibitor, ABT-888. More recently, he has been designated as the lead in the division and the NCI for developing the new **Chemical Biology Consortium (CBC) initiative** to revitalize drug discovery at the NCI. While Chief of TPB, he had responsibility for the preclinical toxicological and pharmacological evaluation of all new cancer drugs that are developed by the NCI and for non-oncology therapeutics under the **NIDDK Type 1 Diabetes RAID** and **NIH RAID Pilot Programs**. During this period, he has been involved in the preclinical evaluation of more than 180 diverse clinical candidates that has led to the filing of more than 120 INDs/DMFs and the approval of 5 NDAs by the FDA. He is the author/coauthor of over 300 publications / abstracts / presentations at national and international meetings.