



American Society for Quality ([www.asq.org](http://www.asq.org)) – Washington DC and Maryland Metro, Section 509 ([www.asq509.org](http://www.asq509.org))

Biomed/Biotech Special Interest Group (SIG) Meeting  
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

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## “Introduction to Regulatory Hematology and Oncology”

To be presented by

**Paul G. Kluetz, MD**

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Deputy Director

Office of Hematology and Oncology Products (OHOP)

Office of New Drugs (OND)

Center for Drug and Evaluation and Research (CDER), US FDA

**Thursday, January 7, 2016**

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:45 PM – Program

8:45 – 9:00 PM – Door-prizes drawing; Networking

**Online Registration site:** <http://www.asq509.org/ht/d/DoSurvey/i/35817>

**Open to Public –**

**\$5: non-ASQ members to cover pizza/drink cost;**

**Free: ASQ members, veterans, senior citizens, past speakers, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, CKUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, and current job-seekers**

**Location:** Kelly’s Deli Conference Center, 7529 Standish Place, Rockville ([Derwood, for GPS users](#)), MD 20855

**Registration Deadline:** Please register by **Thursday noon, January 7, 2016.**

**Question:** Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; [gchang2008@yahoo.com](mailto:gchang2008@yahoo.com) or 240-793-8425 (cell).

**Driving directions: By Cars:** 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 venue is on the first floor of 7529 Building with its external entrance opposite to the left side of 7519 building main entrance.](#) **By Metro trains:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

## Summary

FDA/CDER clinicians and scientists from the Office of Hematology and Oncology Products (OHOP) play an important role in the highly publicized therapeutic area of cancer drug development. Policy decisions surrounding cancer and cancer drug development are often vigorously debated by a very involved group of stakeholders including a vocal advocacy community, requiring a sound scientific and regulatory rationale that is articulated as clearly and openly as possible. The regulation of cancer drugs requires a continual balancing act, and OHOP endeavors to employ the right combination of efficient yet thorough, interactive yet independent, and flexible yet consistent regulatory advice and decision making.

Because of the severe and life-threatening nature of the diseases we treat, malignant hematology and oncology products frequently take advantage of several expedited programs intended to speed the development of therapies that appear to provide an advantage over existing treatments and/or can fulfill an unmet medical need. Over the past 5-10 years, advances in our understanding of cancer biology, genetics and immunology have brought unprecedented innovation to cancer therapeutics. The U.S. FDA/CDER has worked hard to stay ahead of this remarkable opportunity, proactively reaching out to drug development stakeholders to assist in identifying ways to maximize efficiency while maintaining the core mission to assure the safety and efficacy of cancer drug and biologic products for the American people.

In this talk, I will provide a brief overview of malignant hematology and oncology diseases and therapeutic categories as well as introduce the structure of the Office and how its leadership has built an innovative and academic environment that fosters collaboration and scholarship. The lecture will also review the basics of Oncology clinical trial design and efficacy endpoints and the relationship between efficacy endpoint categories and approval pathways. I will conclude with a brief discussion of some of the more interesting regulatory and scientific challenges we will be facing in the upcoming decade.

There has never been a more exciting time in cancer drug development, and the next decade will be defined by increased numbers of patients responding to rationally developed cancer drugs used alone and in combination, further improvements in immunotherapy, predictive in vitro diagnostic testing and other scientific advances. All of this innovation must not remove us from what must be the focus of drug development—the patients. Continued efforts to improve our ability to measure clinical benefit to patients including better measurement of symptoms and function will strengthen our ability to describe the safety and efficacy of these therapies to allow for the most informed treatment decisions possible for clinicians and the patients whom they treat.

## Speaker's Bio: Paul Kluetz, MD

Dr. Paul Kluetz is a **board-certified medical oncologist** and **internist** and currently serves as the **Deputy Director** of the Office of Hematology and Oncology Products at Center for Drug Evaluation and Research of the US Food and Drug Administration (FDA). In the past years, Dr. Kluetz has been actively engaged with the drug development community, developing a particular interest in several regulatory topics including defining clinical benefit in oncology trials, the use of expedited programs such as accelerated approval and breakthrough therapy, and the opportunities and challenges associated with patient reported outcomes data. More recently, Dr. Kluetz has taken a lead role in the FDA oncology effort to obtain more rigorous and informative patient-focused data in cancer clinical trials. Dr. Kluetz remains clinically active, practicing inpatient medicine as a **teaching attending** at the Georgetown University Hospital.

**This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington ([www.MonteJadeDC.org](http://www.MonteJadeDC.org)) and NTU Alumni Association at DC ([www.ntuaadc.org](http://www.ntuaadc.org)).**