



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

Biomed/Biotech Special Interest Group Meeting

“Changing Regulatory Environment in India for Global Clinical Trials, Etc.”

Presented by

Mukesh Kumar, PhD, RAC

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Amarex Clinical Research, Germantown, MD

August 27, 2009 (Thursday) Evening

6:00 PM – Networking and Pizza/ soft drink and networking

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

8:40 – 9:00 PM – Door-prize drawing and networking

Open and free to the public

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, August 27, 2009.

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 Summary:

The Changing Regulatory Environment in India for Global Clinical Trials

India is an attractive destination for conducting clinical trials. However, the regulatory environment in India is changing rapidly to harmonize with the rest of the world making it hard to stay on top of the regulations and business environment. It is tough for a new entrant to distinguish hype from reality to take advantage of the opportunity while avoiding pitfalls. This seminar will discuss key issues related to clinical trial conduct in India and possible solutions. The major regulatory requirements, logistical issues and practical concerns for conducting clinical trials

in India will be addressed. Information about medical device regulation, manufacturing, drug importing, safety reporting and changing regulatory landscape will also be touched upon.

Speakers' Bios:

Mukesh Kumar, PhD, RAC, Senior Director, Regulatory Affairs and Quality Assurance, Amarex Clinical Research

Kumar leads the Regulatory Affairs and Quality Assurance departments at Amarex Clinical Research. His key expertise is in global regulatory and business processes for medicinal and diagnostic products. Kumar has made several hundred submissions to the US FDA and also has submission experience in the EU and India. Additionally, Kumar has reviewed/compiled more than 100 clinical trial protocols and has supervised more than 60 multinational clinical trials in the US, Canada, Latin America, Africa and Asia. He has authored numerous peer-reviewed journal articles, a few patents for gene therapy and has been an invited speaker at organizations including NIH, RAPS, BIO and BCIL (India). Kumar is an Adjunct Professor and Program Advisor for the Professional Science Masters program at the American University. He serves on the Board of Editors for RAPS and is the President of the Global Alliance of Indian Biomedical Professionals. Kumar holds a PhD in Biochemistry with specialization in virology, gene therapy and molecular biology.