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

Development of Ciprofloxacin Tablets - Using the Concept of Quality by Design

Jointly Presented by

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Thursday, March 31, 2011

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:50 PM – Program (a 10-min break at 7:40 pm)
8:50 – 9:10 PM – Door-prizes drawing; Networking

Open to Public - **Free to ASQ Members** (***Become a ASQ Member & Save***)
$5 for non-ASQ members to cover pizza/drink cost
Free to all Local High/Middle/Elementary School Students, interns, and FDA Commissioner's Fellows

Location: Kelly's Deli Conference Center, **7519 Standish Place, Rockville, MD 20855**
Registration Deadline: Please register by ***Thursday noon, March 31****, 2011.*
Registration Website: http://www.asq509.org/ht/d/DoSurvey/i/35817
Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

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.

Presentation Summary:

"Development of Ciprofloxacin Tablets - Using the Concept of Quality by Design"

The quality-by-design (QbD) paradigm requires process understanding. The main challenge faced with process understanding is that there are several variables involved, from raw materials or the manufacturing process, which could affect the critical quality attribute of the drug product. The problem worsens by the fact that most pharmaceutical operations have no fundamental first-principle models that can be used; thus, most of our knowledge of unit operation behavior is based upon empirical correlation; which is typically assessed by use of statistical methods. The underlying concern from this is that studying too many variables increases development costs, which will delay bringing the product into market. This, of course, has a direct impact on development costs, but more importantly will delay treatment for patients who have potentially life-threatening illnesses and are in need of timely medication. Although studying too many variables has its consequences, studying too few variables has its risks as well. Another big risk is not to understand the process well enough. This could result in product failures, product recalls, and/or safety issues due to poor product performance.

To illustrate these concepts, a case study using Ciprofloxacin as a model drug will be presented. The main goal of that study conducted was to illustrate how risk analysis could be used to rationally set a guideline for experiments and to establish the design space with too many or too few variables during product development, while targeting the development to factors that had the most impact on patient health. To illustrate that process, we used a two- phase risk analysis approach. During phase one, a qualitative risk analysis was used which relied on prior knowledge and qualitative risk assessment. During phase two, a quantitative risk analysis was used, which relied on design of experiment (DOE), statistical modeling, and data simulation.