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ROUND TABLE DISCUSSION SERIES  
**GxP and Beyond: Why Quality Practices Matter**  
Wednesday, May 13, 2009 – 12:00 – 1:30 PM  
Rochester BioVenture Center Break Room

Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and related quality systems are essential for compliance with FDA regulations and for research credibility.

GxP compliance requires that analytical studies and manufacturing of pharmaceuticals or medical devices are carried out by trained staff, using calibrated instruments and validated methods, paying highest attention to detail, and following documented procedures that meet regulatory requirements.

Researchers and medical device product developers that implement GxP processes at the earliest stage are in better positions for rapid regulatory approvals and will gain credibility from third-party reviewers for having documented quality systems in place to support consistency and repeatability.

Presenters for the event include:

- **Scott Rosebrough, Ph.D.: EVP Lighthouse Biosciences.** As an introduction to GLP and GMP, Scott will share his real life experiences on quality and regulatory processes that he acquired after transitioning from academic research into commercial medical device product development and manufacturing.
- **Carol Wright and James Benz: Principal Consultants and Co-Owners, Enterprise Solutions, Inc.** Carol and Jim are quality systems auditors and will provide a high-level description of GxP related to manufacturing, why it is important, how it relates to FDA compliance, and what pitfalls are frequently observed.
- **Tom Pawlaczyk: Medical Device Software Quality Consultant.** Tom will discuss the essentials of GxP related to software validation.
- **James Hewlett: New York Hub Director, Northeast Biomanufacturing Center and Collaborative.** Jim will present information about GxP training programs offered by the Biomanufacturing Center in Canandaigua as well as the availability of trained students.

Early-stage companies, medical device inventors, and medical researchers that are considering developing new medical devices, pharmaceuticals, or biologics are encouraged to participate.

NO CHARGE FOR ADMITTANCE—REGISTRATION REQUIRED  
SPACE IS LIMITED--PLEASE REGISTER EARLY!  
A light lunch will be available

Please register by contacting Kathy Goforth at [Kathy.goforth@htr.org](mailto:Kathy.goforth@htr.org) or call 585 413-9060 by May 11, 2009

***Pease pass this on should you know of anyone else who might be interested in this subject.***

The Rochester BioVenture Center (RBC) is a technology incubator with wet-lab facilities that serves as a link in the chain of resources to promote and foster the growth of early stage life science companies. The facility is located at 77 Ridgeland Road off of Jefferson Road east of the intersection of Interstate 390.