

Welcome to our Spring 2006 Newsletter. Spring is in the air. The snow has melted. And new buds are on the trees. Growth is everywhere and CSI is growing with the community. Read below to learn about our collaborative efforts with Rochester Institute of Technology (RIT) and the Drug Information Association (DIA).



CSI Joins Forces with RIT

Rochester Institute of Technology (Rochester, NY), has a strong record of partnering with industry and government on applied research and preparing students for technical and professional careers. In biotechnology, the university's expertise is illustrated under the Center for Biotechnology Education and Training (CBET). With its applied research focus, and emphasis on workforce development for emerging industries, RIT is uniquely positioned to be a tremendous resource and asset to companies as a university partner. With a grant from the State of New York, RIT is building a 38,000 square foot, state-of-the-art facility to house its new Center. CBET is targeted to open in 2nd quarter of 2006. CBET will continue RIT's leadership role in biotech workforce development by creating innovative academic programs, specialized workshops and seminars for industry partners, certificate training programs for displaced workers seeking new career opportunities in biotechnology, and unique industry/academic research collaborations to drive innovation and discovery for the future. CSI, with its over 60 years of quality, compliance and regulatory experience in the sciences, is joining forces with CBET to develop courses and train attendees on today's hottest compliance issues.

More information on RIT's new Center for Biotechnology Education and Training (CBET) will be available soon. Additionally, course listings will be published when finalized. If you would like to recommend course topics, contact CSI at info@csirochester.com

How 'bout dem apples?

The Drug Information Association (DIA) held the Red Apple II conference in late March at their headquarters in Horsham, PA and CSI played an integral role in updating the guidance. It's been 18 years since the initial guidance document for **Computerized Systems for Nonclinical Safety Assessment** was created. After nearly two decades of technological advances and regulatory updates, it was time for a review of these industry best practices. Topics discussed in the new guidance include:



- System Life Cycle
- Risk Based System Validation
- Electronic Records Retention
- Networks Qualification
- Security
- Computerized Instruments

Look for the DIA to publish the updated guidance document by the end of 2006 (www.diahome.org).