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**LYNETTE C. CHIAPPERINO, CRA**

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## **EDUCATION**

- B.S. Management of Human Resources, Roberts Wesleyan College
- A.A.S. Medical Laboratory Technology, S.U.N.Y. at Alfred

## **CONSULTANT/RESEARCH EXPERIENCE**

### **Independent Clinical Research Associate**

**September 1998 – present**

*Rochester, NY*

- Independent Clinical Research Associate with experience in Phase II, III, IV pharmaceutical and device studies for therapeutic areas of autoimmune diseases, cardiac stents, dermatology, diabetes, genitourinary tract, hepatic, incontinence, mammography, neurological, ophthalmology, orthopedics, respiratory, wound treatment and wound care.
- Responsible for pre-site visits, site initiation visits, clinical trial monitoring via paper and electronic case report forms (CRFs), and site closures.
- Clinical management and monitoring of projects including protocol design, CRF design, site recruitment, budget and agreement negotiations, IRB submission, Investigator Meeting planning and presentation.
- Provide project management for ensuring study sites performed according to the study protocol, maintained regulatory compliance for deviations/violations, as well as accountability documentation for the Investigational Product
- Conduct all clinical trial activities according to FDA/GCP/ICH guidelines, as well as sponsor SOPs and requirements
- Provide the sponsor with study monitoring reports and site follow-up letters for each monitoring visit
- Participate in sponsor initiated conference calls for project updates

### **Regional Clinical Research Associate**

**July 1997 – September 1998**

*Clinimetrics Research, San Jose, CA*

- Conducted clinical monitoring of Phase I – III pharmaceutical trials in the Northeast United States
- Clinical skills included investigator selection, qualification of sites, orientation visits, monitoring and study close out visits according to GCP, FDA guidelines and regulations

**Clinical Research Associate**

**April 1994 – July 1997**

*Bausch & Lomb, Rochester, NY*

- Responsible for all aspects of clinical study monitoring for domestic and international studies of soft and rigid gas permeable contact lenses and lens care products
- Responsible for IRB liaison for studies, investigator selection, monitoring sites, investigator meeting preparation and presentation
- Responsible for Investigational product accountability, data collection and verification, processing of investigator payments
- Generated and audited all study data for use in statistical analyses
- Responsible for writing final clinical study reports for FDA and other governmental submissions
- Maintained all study records according to GCP and FDA guidelines and regulations

**ADDITIONAL EDUCATION / TRAINING**

- Registry Studies for Medical Devices, March 2010
- Optimizing Clinical Trial Publications, December 2009
- ISO Standards, November 2008
- Adverse Events, February 2008
- Good Clinical Practices, November 2007
- Applied Regulations, September 2007
- Regulations E-Conference, April 2007
- HIPAA Overview and its Impact on Clinical Research, March 2003
- Monitoring a Clinical Research Study for GCP Compliance, June 2002
- Good Monitoring Practices – Safety, Efficacy and Performance for Medical Devices, August 2001
- International Trials – Clinical Device Group Clinical Research seminar series for Medical Devices, October 1995
- Monitoring Medical Device: Basic, July 1994
- GLP Refresher course, February 1994
- Team Oriented Problem solving, January 1994
- Document control Systems, November 1993
- Antimicrobial Technologies Symposium, November 1992
- Skin Care Product Development, September 1992
- MS Office Excel 3.0, June 1992

**COMPUTER SKILLS**

- Proficient with MSOffice XP, Word, PowerPoint, Excel