



NERCSQA CANDIDATE'S BIOGRAPHY

Candidate for Vice President

NAME: Cheryl McCarthy, CQA, CBA
YEARS IN QA: 11+
TITLE: Manager, Quality Assurance
COMPANY: Eliassen Group, eClinical Solutions Division

EDUCATION (degree/institution): Bachelors of Science in Biomedical Engineering, Marquette University

QUALITY / REGULATORY EXPERIENCE: Experience in GCP and 21 CFR Part 11 compliance. Industry experience includes current position as Manager, Quality Assurance in a eClinical Solutions company that focuses on End-to-End eData Management activities and previous experience in a CRO where I have been responsible for developing the quality system documentation, developing and overseeing a corporate training compliance program, providing corporate training on regulatory issues (GCP, HIPAA, 21 CFR Part 11), developing and performing validation of computerized systems used to support clinical trial activities, and performing internal and vendor audits. Other experience includes a development position for a hospital information system vendor where I was responsible for quality control of software used in clinical settings and ensuring that they were compliant with the electronic records and electronic signatures requirements defined by 21 CFR Part 11, implementing design control and change control procedures and understanding the regulatory requirements for a 510k submission for a blood-bank software product.

PREVIOUS/CURRENT SERVICE TO NERCSQA: Member of NERCSQA (2007) – Program Committee Member (2008).

PREVIOUS/CURRENT SERVICE TO SQA: Affiliate member of SQA (2005), Active member (2007) I have developed and presented GCP sessions at the 2006 Fall Training (Boston, MA) and the 2007 Annual Meeting Pre-Conference Training (Austin, TX). I presented Pre-Conference Training, a Poster and a Conference Session at the 2008 SQA Annual Conference (Memphis, TN). I am a member of the Clinical Specialty Section.

OTHER PROFESSIONAL SOCIETIES:

Drug Information Association (DIA)

- Member of GCP and Validation Special Interest Area Communities (SIACs)

American Society of Quality (ASQ)

- Achieved certification as a Quality Auditor and a Biomedical Auditor
- Member of Audit, Biomedical and Quality Management forums

FURTHER QUALIFICATIONS FOR THE POSITION SLATED AND TESTIMONY AS TO WHAT I HOPE TO GIVE THE SOCIETY: I was looking for a volunteer opportunity in a local industry group that supports quality initiatives and became aware of the NERCSQA open position for the Vice President. I am interested in promoting the mission of this group and working with the Board of Directors to expand membership and benefits to the quality community here in New England. In addition to my professional experience in quality, I have some personal experience that may assist in this role. My children are involved with both town and club soccer and I have served on the Board of Directors for both of these organizations. My role for both of these organizations is to attract interest in these programs, manage volunteers and to support the initiatives of the Boards. I am committed to dedicating the time to help NERCSQA by using my professional

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and personal skills in increasing awareness of the program and its ability to provide educational and professional support to its members. Please consider my application as a candidate for the Vice President.