



**Anne P. McElderry Zurbay, RN,
MSN, ND**
amzurbay@bcg-usa.com
Consultant
Biologics Consulting Group, Inc.
P 303-449-3344

AREAS OF EXPERTISE

Experienced in the preparation of:

- Summaries of Clinical Safety for New Drug Applications (NDAs)/Biologics License Applications (BLAs),
 - Clinical study reports,
 - Clinical study protocols,
 - Investigational New Drug (IND) Annual Reports,
 - Investigator brochures and
 - Informed consent documents
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- Proficient in the use of the International Conference on Harmonisation (ICH) Common Technical Document (CTD) format;
 - Trained Good Clinical Practice (GCP) auditor;
 - Provides safety data management services such as receiving, assessing, coding and preparing regulatory reports on emerging clinical trial safety data;
 - Trained user of the European Agency for the Evaluation of Medicinal Products (EMA) EudraVigilance safety database and ArisGlobal

EXPERIENCE

Biologics Consulting Group, Inc., Consultant

Boulder, CO (Jan. 2005 to present)

- Clinical consultant working with drugs and biologics in Phases I through III of development;
- Medical writer with responsibility for analyzing and summarizing large, complex safety and efficacy data sets from clinical trials;
- Evaluate and provide input on Statistical Analysis Plans (SAPs) for individual clinical studies and pooled clinical data sets;
- Specialize in the preparation of Integrated Summary of Safety (ISS) and Summary of Clinical Safety (SCS) documents for Biologics License Applications (BLAs) and New Drug Applications (NDAs);
- Experienced in the preparation of clinical study protocols, clinical study reports, informed consent documents, IND Annual Reports, Investigator Brochures, IND Safety Reports



- Provide pharmacovigilance consulting services including serious adverse event processing plans, design and implementation of pharmacovigilance systems, and processing/reporting of SAEs
- Provide auditing services including GCP and Pharmacovigilance systems audits

OSI Pharmaceuticals, Clinical Safety Associate II

Boulder, CO (July 2002 to Dec. 2004)

- Worked with products in Phases I through III of development
- Received, assessed, processed SAE reports and prepared and expedited regulatory reports, analyses of similar events and investigator letters
- Assisted in data quality planning, CRF design, protocol review
- Worked closely with Regulatory and Clinical Departments, development partners, CROs and regional medical monitors to ensure timely and accurate reporting of clinical trial safety data
- Prepared periodic safety summaries, analyses, safety sections of IND Annual Reports and Investigator Brochures, and development core safety information (DCSI)
- Performed database reconciliation, coding review and query generation
- Authored departmental SOPs and guidelines

Sirna Therapeutics/Ribozyme Pharmaceuticals, Clinical Safety Specialist/Consultant,

Boulder, CO (Jan. 2002 – Jan. 2004)

- Performed all clinical safety data management activities for company
- Worked closely with Clinical, Biostatistics and Regulatory staff on protocol development, adverse event data collection planning, preparation of regulatory submissions, querying and data cleaning
- Responsible for preparation of SAE form and instructions, safety section of IND Annual Reports, Investigator Brochures, ad hoc safety summaries and materials for Investigator meetings
- Assisted in the identification of a safety signal and in notification of regulators and investigators

University of Colorado School of Medicine. Professional Research Associate

Denver, CO (May 2001 – Jan. 2002)

- Acted as a study coordinator for three ongoing clinical trials
- Assessed, treated and managed pulmonary hypertension patients, including performing study-related assessments
- Assisted in development of an investigator-sponsored protocol, designing the case report form, and creation of the study database
- Submitted protocols and informed consent documents to the local Institutional Review Board



The People's Clinic, Homeless Outreach Program

Boulder, CO (Jan 2000 – May 2001)

- Co-created and managed a new homeless outreach nursing program
- Nurse case-managed medically fragile, homeless patients
- Created and maintained a program utilization database

University of Colorado School of Nursing, Clinical Instructor (Jan 1999 – Dec. 1999),
Doctoral Resident and Research Fellow, (Sept. 1997 – Jan. 1999) Denver, CO.

- Completed an IRB-approved correlational study of 208 homeless women, regarding the relationship between their physical and mental health, substance abuse, family status and history of exposure to violence
- Trained doctoral residents and nursing students
- Assisted in creating a clinic and medical case management program

University of Colorado Health Sciences Center, Family Nurse Practitioner Program,
(1999 to 2001), *Nursing Doctorate Program* (1995 to 1999)

Denver, CO.

- Full-time graduate nursing student, completing over 3,000 hours of direct patient care and 1,000 hours of research during the period
- National Health Service Corps Fellow, 1996

EDUCATION

N.D. *Doctor of Nursing*, University of Colorado, Denver, CO (1999)

M.S.N. *Master of Science in Nursing*, Family Nurse Practitioner Program, University of Colorado, Denver, CO, (2001)

B.A. *Summa cum Laude*, University of Maine, Portland, ME, (1990)

CONTINUING EDUCATION

Interpreting and Reporting Biostatistics, **Graham School, University of Chicago, 2007**

Risk Management and Pharmacovigilance, **Drug Information Association, 2006**

Good Clinical Practice Auditing, **Drug Information Association, 2005**

Good Clinical Practice Training, **Colorado Bioregulatory International, 2004**

EudraVigilance User Training, **Drug Information Association, 2004**

Principles of Molecular Oncology, **American Society of Clinical Oncology, 2004**

Mount Sinai School of Medicine Chemotherapy Symposium, **2003**

Clinical Trial Drug Safety Assessment, **Pharmaceutical Education and Research Institute, 2002**

Clinical Drug Development 101, **Drug Development Consulting, 2002**

MedDRA: An Introduction, **Integrated Safety Systems, 2002**

PROFESSIONAL SOCIETIES

Member, American Medical Writers Association, **2004 to Present**

Member, Drug Information Association, **2002 to Present**