

## Curriculum Vitae



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Senior Consultant  
Biologics Consulting Group, Inc.  
Germantown, MD  
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### **EXPERIENCE**

#### **Biologics Consulting Group, Inc., Senior Consultant**

Germantown, MD (Jul. 2004 to present)

- Provide consulting expertise in CMC product development strategies from pre-Phase I to commercialization, with emphasis on drug substance and drug product characterization, comparability assessment, release and stability testing.
- Review product regulatory submissions for suitability relative to current FDA and EMA expectations for CMC data from biotechnological/biological products.
- Perform gap analysis of sponsor's internal policies and SOPs to assess suitability of their technical and quality practices for product development activities.
- Provide technical and quality expertise in identity, purity, potency, and stability test method development, validation.
- Provide technical and quality expertise in development and validation of immunogenicity tests (screening, confirmatory and neutralizing assays).
- Perform analytical method troubleshooting and review OOS investigations for biopharmaceuticals.
- Conduct independent quality audits of laboratory compliance activities under GLP and cGMP, and evaluate R&D laboratory quality practices.
- Conduct independent due-diligence audits for pending acquisitions or partnerships to determine gaps in CMC analytical and stability activities.
- Develop and deliver internal and external training sessions on technical, regulatory and quality elements of biological product CMC analytical and stability studies.
- Serve as a subject matter expert on committees for professional societies, technical publications, university undergraduate and graduate programs, and regulatory bodies

#### **American Red Cross Plasma Derivatives, Contractor**

Rockville, MD (2002-2004)

- Served as principle CMC RA/QA associate for Plasma Derivative product development projects.



- Established and implemented R&D quality practice policies (“Good Development Practices” or “GDP”) to support the development of plasma-derived products for FDA and international submissions.
- Established and implement \$250K NuGenesis SDMS electronic documentation system for six product discovery and development laboratories.
- Prepared internal guidance documents and conduct training sessions on technical, regulatory and quality elements of biological product development.
- Prepared and review FDA IND and BLA submissions for nationally and internationally manufactured plasma products.
- Participated in international project teams to plan and execute regulatory and quality strategies for product development from Phase I to BLA.

**NMR Biotech**, *Speaker and Trainer*  
Germantown, MD (2002-2004)

- Provided expertise on biotechnology product development, laboratory quality practices, test method validation, product stability programs, and management of outsourced biopharmaceutical testing and manufacturing.
- Prepared and review CMC sections for IND and BLA submissions for a wide variety of biological and biotechnological products, participate in IND/BLA meetings with regulators, and respond to regulatory reviewer questions.
- Conducted quality audits of US and international facilities for cGMP and GLP compliance assessment. Design and review quality system documentation required for laboratory facilities for R&D, GLP and cGMP.
- Designed and review protocols for product characterization, process and test method validation and product stability programs.
- Presented seminars and training classes on the technical, regulatory and quality elements required in biotechnology product development and commercialization. Serve as subject matter expert in preparation and review of journal articles and book chapters.
- Facilitated professional meetings on biopharmaceutical industry issues, including interactions among industry and regulatory bodies.

**BioReliance Corporation**, Analytical Services Division, *Director of Technical and Regulatory Affairs*

Rockville, MD (2001-2002)

- Served as the principal point of scientific and regulatory CMC interaction with over 150 worldwide pharmaceutical clients for their national and international product submissions for biotechnology products.
- Provided expertise on product development requirements for recombinant proteins, monoclonal antibodies, plasma products, transgenic proteins, viral vectors, vaccines, and synthetic biomolecules (e.g. peptides and oligonucleotides).
- Supported Analytical Division project managers and study directors to ensure successful design and execution of complex or custom projects.
- Served as consultant to clients for technical and regulatory issues related to the CMC sections of INDs, BLAs, NDAs, annual reviews and supplements.
- Consulted internally and externally on quality practices and compliance issues.



- Developed and updated corporate Analytical marketing and training materials.
- Supported the sales force and other members of the Sales and Marketing team as Analytical expert for client inquiries.
- Delivered client presentations, professional seminars and training classes on biomolecular methods, regulatory product development guidelines, laboratory management, and quality/compliance practices.
- Interacted with regulatory bodies as industry expert and served as client advocate to regulatory reviewers for product submissions.

**BioReliance Corporation**, Analytical Services, *Director of Analytical Services Operations*  
Rockville, MD (1998-2000)

- Managed a \$4 million department of 20-24 project managers, technical writers, study directors and analytical scientists to provide contract biomolecular analysis for the characterization, stability and release testing of over 200 bulk and formulated biotechnology products.
- Designed and managed CMC analytical studies from pre-Phase I through Phase III and commercialization.
- Supervised divisional quality system programs to ensure top-down GLP and cGMP compliance.
- Served as the responsible divisional authority for quality audits conducted by project sponsors, national and international regulatory officials.
- Implemented management systems to increase efficiency in resource scheduling and facilities utilization.
- Developed budgets, monitored profits and costs, and operated laboratories and support functions at the highest levels of responsiveness to meet timelines and deliverables to clients.
- Successfully recruited and retained highly skilled scientific staff in a competitive technical location.
- Improved and expanded testing services and optimized laboratory growth to support new client projects.

**Abbott Diagnostics Division**, Analytical Development and Validation, Infectious Diseases  
Sector R&D, *Senior Scientist, Bulk Biomolecular Products*  
Chicago, IL (1996-1998)

- Served as a senior technical supervisor of \$2.2 million analytical R&D laboratory with 12 analysts developing and validating analytical methods for well-characterized biologicals used in CBER-regulated immunodiagnostic products.
- Prepared molecular biology, manufacturing, purification, analytical characterization and lot release and stability sections for 12 IND, 6 PLA/BLA submissions, 25 PMA submissions, and 10 IPMF submissions to international regulatory agencies.
- Acted as divisional R&D representative in major technology transfer projects of antibody and viral bulk products from contract manufacturing operations.
- Directed outsourced analytical studies through contract testing organizations.



- Provided expertise on Abbott test method and process validation strategies at the division and corporate levels.
- Established the Abbott "Quality Technical Reviewer" model for approval of divisional analytical method validations and method SOPS to provide greater technical and quality expertise and increase efficiency.
- Served as scientific specialist for two 40-member cGMP QC operations teams that manufactured and tested over 100 biotechnology bulk products from US and international plants.

**Abbott Diagnostics Division**, Infectious Diseases Sector R&D, *Senior Research Biochemist, Biomolecular Products*  
Chicago, IL (1992-1996)

- Performed analytical biochemistry of over 75 natural and rDNA proteins, monoclonal and polyclonal antibodies, and synthetic peptides using characterization techniques such as HPLC, amino acid analysis, protein sequencing, peptide mapping, SDS-PAGE, scanning densitometry, IEF, immunoblots and assays, capillary electrophoresis, light scattering, surface plasmon resonance and protein identification via proteomic databases.
- Prepared method SOPS, with transfer, training and troubleshooting of methods to a 30-member QA laboratory.
- Established ISO-9000 compliance activities in the department, and served on corporate ISO certification task force.
- Certified in the use of biohazardous and potentially biohazardous viral materials, including BL3 biohazard suite access.
- Contributions to over 125 analytical test method characterizations and validations.
- Performed direct supervision and review of 5 R&D laboratory scientists.

**University of Texas Dental Branch**, Department of Biological Chemistry, *Postdoctoral Research Fellow*  
Houston, TX (1988-1992)

- Performed biochemical characterization of the protein-protein interactions between the bone protein osteopontin and other bone extracellular matrix proteins.
- Techniques included tissue culture, protein purification and characterization, various ligand binding assays, in vitro and in vivo radiolabelling of proteins, SDS-PAGE, immunoblots, and glycoprotein analysis.

**Rice University**, Department of Biochemistry and Cell Biology, *Graduate Fellow*  
Houston, TX (1984-1988)

- Conducted molecular and cell biology studies of the subcellular translocation of glutamine synthetase and other urea cycle enzymes in shark and stingray tissues.
- Techniques included DNA and RNA isolation, RIPA, nucleic acid blots, subcellular fraction purification, kinetic enzyme assays, immunohistochemistry, radiolabelled pulse/chase assays, IEF and SDS-PAGE.
- Certified in the use of beta and gamma radiation emitters.

Nadine M. Ritter, Ph.D.





**University of Texas**, Dental Science Institute, *Senior Research Assistant*

Houston, TX (1980-1984)

- Purification and comparative biochemical analysis of proteins from microbial and animal models of biomineralization. Techniques included microbial culture, lipoprotein purification and characterization, in vitro mineralization assays, and Xray diffractometry.
- Contributed to cartilage extracellular matrix studies aboard Space Shuttle missions for NASA.

**University of Texas**, Dental Science Institute, *Research Assistant*

Houston, TX (1978-1980)

- Analytical biochemistry of calcified cells and tissues for the functional characterization of mineralizing proteolipids.
- Techniques included microbial and tissue culture, protein concentration and enzyme assays, and electron microscopy.

**EDUCATION**

Ph.D. - Rice Graduate Fellow Award, Molecular and cell biology, Department of Biochemistry and Cell Biology, Rice University (1984-1988)

B.S. - Biology/Chemistry, Department of Natural and Applied Sciences, University of Houston at Clear Lake (1979-1984)

A.S. - Biology/Chemistry, Department of Biology, San Jacinto College, Houston (1976-1978)

**HONORS AND AWARDS**

Who's Who of American Professional Women – 2005, 2006, 2007, 2008

Pharmaceutical Training Institute Trainer of the Year - 2002

Pharmaceutical Training Institute Trainer of the Month - 2001

BioPharm Featured Ten Outstanding Women of Biotech - 2000

Abbott Diagnostics Division R&D Technology Team Award for Scientific Excellence – 1998

Abbott Diagnostics Annual Outstanding Women Scientists - 1997

Abbott Corporate Chairman's Award for Individual Performance Excellence - 1997

Abbott Diagnostics Division Business Team Quality Award - 1997

Abbott Diagnostics Division Infectious Diseases R&D Director's Award - 1994

American Men and Women of Science - 1992

Outstanding Young Investigator Award, Texas Society for Mineralized Tissue - 1990

Outstanding Graduate Student Award, Association for Women in Science - 1989

Rice University Graduate Fellowship -1984

Outstanding Young Women of America –1979

**COMMITTEE AND BOARD APPOINTMENTS**

**University of Maryland Baltimore County (UMBC)**

- Biotechnology Career Forum Panelist (2008)



- “From Bench to Business: Biotechnology Career Opportunities”
- Scientific Advisory Board Member (2007)
  - Establishment of master’s program curriculum for Applied Biotechnology

**Parenteral Drug Association (PDA)**

- Co-chair, Analytical Method Development Task Force

**California Separations Sciences Society (CaSSS):**

- Industry-FDA CMC Strategy Forum Industry Co-Leader, Jan 2007,
  - “Current Expectations for Comparability and Stability of Gene Therapy Products”
- Industry-FDA CMC Strategy Forum Industry Co-Leader, Jan 2006,
  - “Biotechnology Product Reference Standards”
- Industry-FDA CMC Strategy Forum Industry Co-Leader, July 2005,
  - “Biotechnology Product Stability”
- Well-Characterized Biotechnology Product (WCBP) 10<sup>th</sup> Annual Industry-FDA Meeting; Industry Chair (2006; first female industry chairperson)
- WCBP Workshop Committee Co-Chair (2004); Chair (2005)
- Industry-FDA CMC Strategy Forum Industry Co-Leader, July 2004,
  - “Test Method Qualification and Validation”
- Industry-FDA CMC Strategy Forum Permanent Advisory Board Member (2002 – present)
- Industry-FDA CMC Strategy Forum Co-Founder (2002)
- WCBP Program and Workshop Committee Member (2001 – Present)

**BioProcess International:**

Charter Editorial Board Member (2002 – present)

**Pharmaceutical Training Institute:**

Scientific Advisory Board (2001 – 2003)

**BioProcessing Journal (Williamsburg Bioprocessing Foundation):**

Editorial Board            Member (2000-2002)

**Association for Biomolecular Resource Facilities (ABRF):**

- Co-Founder and Chairman, Quality and Compliance Committee (1996-1998)
- ABRF-NIST Peptide Standards Committee (2001 – Present)
- ABRF Annual Professional Society Meeting, Co-Chair (1999)

**Association for Women in Science:**

President and Board Member, Houston (1984-1992) and Chicago (1994-1998)

## **BIBLIOGRAPHY**

### Books and Chapters

**Ritter, N.M., et al.** *Analytical Test Method Development and Method Qualification*, PDA Technical Report (in progress)

**Ritter, N.M.** (editor) *Biotechnological/Biological Product Stability – Principles and Practices* (in progress).

**Ritter, N.M.** (chapter) “Selection, Qualification, and Validation of Analytical Test Methods for Product Characterization, Comparability, Release and Stability Testing” in **Bioseparation and Bioprocessing, 2nd edition**, (G. Subramanian, editor), (in progress).

**Ritter, N.M.** (chapter) “Analytical Test Methods for Product and Process Impurities” in *Advances in Large Scale Biopharmaceutical Manufacturing and Scale Up Production, 2<sup>nd</sup> Edition*, ASM Press and BioPlan Associates, Inc., in progress.

**N. Ritter** and J. McEntire, “*Analytical Test Methods for Biological and Biotechnological Products*”, in *Process Validation in Manufacturing of Biopharmaceuticals: Guidelines, Current Practices, and Industrial Case Studies* (A.S. Rathore and G. Sofer, eds), CRC Press, Taylor and Francis Group, Boca Raton, FL, 2005, pp. 227-326.

Remmer, H.A., Ambulos, N.P., Bonewald, L.F., Dougherty, J.D., Eisenstein, E., Fowler, E., Johnson, J., Khatri, A., Lively, M.O., **Ritter, N.M.**, and Weintraub, S. ‘*Synthetic Peptides as Certified Analytical Standards*’, in *Peptide Revolution: Genomics, Proteomics and Therapeutics* (Michael Chorev and Tomi K. Sawyer, eds), American Peptide Society (2003).

Calamai, E.G., Krishnamurthy, R., McEntire, J., Pritchett, T., **Ritter, N.M.**, Seely, R. J., Seaver, S., Venkat, K (coordinators/reviewers), *Guide to BioAnalytical Methods*, BioPharm 14:12 (December, 2001).

**Ritter, N.**, Smith, A., Fowler, B., Canova-Davis, E. Dougherty, J., and Ghrist, B. ‘*Laboratory Quality and Compliance*’, in *The Encyclopedia of Bioprocess Technology: Fermentation, Biocatalysis, and Bioseparation, Vol. 4* (Editors-In-Chief, Michael C. Flickinger and Stephen W. Drew), John Wiley & Sons, Inc., pp. 2113-2115 (1999).

### Peer-Reviewed Articles

**Ritter, N.M.** and Hayes, T. “*Good Development Practice (GDP): Quality Policies to Support Product Development Activities*”, BioProcessing International, (manuscript in progress).

**Ritter, N.M.**, Advant, S., Simmerman, H., Advant, S., Hennessey, J., McEntire, J., Joneckis, C, and Mire-Sluis, A. “*WCBP CMC Strategy Forum: Industry and Regulatory Perspectives on*

*Analytical Test Method Qualification versus Validation During Biotechnology Product Development*", BioProcess Int 2:8, pp. 32-47 (September, 2004).

**Ritter, N. M.** and McEntire, J. "Determining Protein Concentration: Methodology", BioPharm 15:4, 12-22 (April 2002).

**Ritter, N.M.** and Wiebe, M. "Validating Critical Reagents Used in cGMP Analytical Testing: Ensuring Method Integrity and Reliable Assay Performance", BioPharm 14:5, 12-21 (May 2001).

**Ritter, N. M.** and Fowler, B. "Analytical Laboratory Quality, Part I – General Quality Practices", J. Biomolecular Techniques, 12:4-10 (2001).

**Ritter, N.M.**, Hayes, T., and Dougherty, J. "Analytical Laboratory Quality, Part II – Analytical Method Validation", J. Biomolecular Techniques 12:11-15 (2001).

Smith, A. and **Ritter, N.** "Considerations in the Validation of Bioanalytical Methods for Protein Characterization", Applied Biosystems Reporter 22:1994, Applied Biosystems, Inc. (1994).

**Ritter, N.M.**, Farach-Carson, M.C. and Butler, WT. "Evidence for complex formation between osteopontin and osteocalcin", J. Bone and Mineral Res. 7:877-885 (1992).

D'Souza, RN., Happonen, R.P., **Ritter, N.M.**, and Butler, W.T. "Temporal and spatial patterns of TGF-beta expression in developing rat molars", Arch. Oral Biol. 35:957-965 (1990).

**Ritter, N.M.**, Smith, D.D., Jr., and Campbell, J.W. "Glutamine synthetase in liver and brain of the Holocephalan *Hydrolagus collie*", J. Exp. Zool. 243:181-188 (1987).

Smith, D.D., Jr., **Ritter, N.M.** and Campbell, J.W. "Glutamine synthetase isozymes in elasmobranch brain and liver tissues", J. Biol. Chem. 262:198-202 (1987).

Goldschmidt, M.C., **Ritter, N.M.** and Ennever, J.J. "Age-dependency of apatite formation in *Bacterionema matruchotti*", Microbios Lett. 29:15-17 (1987).

Boyan, B.D. and **Ritter, N.M.** "Proteolipid-lipid relationships in normal and vitamin-D deficient chick cartilage", Calcified Tiss. International 36:332-337 (1984).