# Nadine M. Ritter, Ph.D.

***President and Sr. Analytical Advisor***

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## Professional Experience

For 30 years I have been highly involved in CMC technical, regulatory, quality and compliance efforts for global biopharmaceutical products. I have substantial professional expertise in analytical methods and laboratory operations for numerous product modalities. My objectives are to leverage these experiences in client projects to facilitate and expedite CMC successes in development and commercialization of biotechnological, biological and biosimilar products, and to promote suitable technical and quality practices in R&D and GxP analytical laboratories.

## Consulting and Training Positions

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| 2014 – cur. | President and Senior Analytical Advisor, Global Biotech Experts, LLC, Germantown, MD |
| 2002 – cur. | Professional Scientific Trainer, CPD Accredited Courses, PTI-Global (UK) |
| 2004 - 2014 | Senior CMC Analytical Consultant, Biologics Consulting Group, Alexandria, VA |
| 2002 - 2004 | CMC Scientific Contractor, American Red Cross Plasma Derivatives, Rockville, MD |
| 2002 – 2013 | Independent CMC Consultant, NMR Biotech Consulting, Germantown, MD |

## Professional Activities in these Roles

Each of my professional roles and responsibilities encompassed the following sets of activities with increasing expertise. My efforts have significantly contributed to the success of over 80 national and international biotechnology and biosimilar product IND/IMPD filings and BLA/MAAs for drug substance and drug products, including approved break-through therapeutic products, global biosimilar products, and gene therapy and cell therapy products. I have provided substantial CMC analytical and stability guidance to numerous international PAS filings for process and/or analytical method changes made to legacy biopharmaceutical products.

On the compliance side, I have contributed to many successful laboratory PAIs and cGMP surveillance inspections. In addition, my work has been instrumental in remediating gaps and obtaining successful resolution to BLA CRL and RTF actions. I have helped to resolve laboratory quality problems in more than 30 firms with PAI or cGMP observations, including firms under consent decree and firms with observations on data integrity gaps.

For over 25 yrs I have been a global professional scientific trainer for biopharma CMC analytical and lab quality, delivering both public and in-house classes that are CPD certified. I am one of the inaugural faculty of the BioProcess Training Academy on-line courses.

***Analytical Sciences Technical and Regulatory Expertise for Product Submissions***

- Provide consulting expertise in CMC biotechnology and biosimilar product development analytical strategies from pre-Phase I through commercialization for the establishment of release and end-of-shelf life specifications for drug substance and drug product for a wide array of product types (therapeutic proteins, antibodies (including ADCs and BiTEs), peptides, vaccines, plasma proteins, VLPs, gene therapy and cell therapy products; many in different types of presentations (lyophiles, PFS, patches, creams, etc…) and in selected medical devices and combination products.

- Provide detailed technical and regulatory advice on the design and execution of analytical studies for assessing product biomolecular comparability following process changes during clinical development and after post-approval, as well as between biosimilar and originator products, for product-related substances (structural and functional), product-related impurities, process-related impurities, and process contaminants (as defined in ICHQ6B).

- Review and edit, or generate, ICH Common Technical Document (M4Q) regulatory submission analytical and stability sections (Module 3) for biotechnology and biosimilar products for US and international regulatory bodies, in alignment with current expectations for various biotech/biosimilar product types.

- Provide technical and quality expertise in the selection, development, qualification, validation, bridging and tech transfer of analytical methods used for identity, purity, impurities, concentration, and potency testing in accordance with current guidelines for biotechnology and biosimilar products using standard and state-of-the art technologies (e.g. spectrophotometric, electrophoretic, chromatographic, immunological, enzymatic)

- Provide guidance on a wide variety of in vitro cell-based bioassays (bacterial, yeast, mammalian culture; primary cells; receptor binding, protein activation, gene activation or surface marker endpoints)

- Provide guidance in the qualification/validation of stability-indicating methods per ICHQ2(R1), and in the design of phase-appropriate stability studies in alignment with the ICH Q1 series and ICHQ5C.

- Provide technical and quality expertise in the selection, development and validation of immunogenicity assays (screening, confirmatory and neutralizing cell-based assays) and in the design of immunogenicity testing protocols for detection of anti-drug antibodies (ADAs) and neutralizing ADAs.

- Conduct independent due-diligence audits for pending acquisitions or partnerships to determine gaps in CMC analytical and stability R&D to GMP activities as required for product regulatory filings.

- Provide support in the remediation of regulatory review observations for deficiencies in product filings; provide guidance for the remediation of analytical elements of refusal-to-file determinations from regulators.

***Analytical/Stability Quality and Compliance Expertise for Laboratory Operations***

- Conduct third-party quality audits and evaluations of laboratory compliance activities for
  - GLP (e.g. for immunogenicity and pK assays)
  - cGMP (e.g. for product release and stability testing)

- R&D laboratory quality practices (e.g. for data that support process/product characterization, comparability, or similarity studies, and reference standard programs)
- Data integrity requirements for GLP/cGMP/R&D analytical instruments

➢ Perform analytical method troubleshooting for problematic test method procedures (e.g. separation methods, immunoassays, bioassays, residual DNA and HCP methods) and assist in the resolution of root causes and corrective actions for OOS investigations.

➢ Conduct mock Pre-Approval Inspections (PAIs) for analytical testing laboratories readiness for GLP and cGMP regulatory inspections; provide guidance for labs beginning to implement GCLP (e.g. for immunogenicity and pK studies on human samples)

➢ Provide support in the remediation of inspectional observations for non-compliance with GLP or cGMP regulations; provide support for remediation of analytical elements of consent decrees.

➢ Assist with generation/review of Request for Proposals (RFPs) and due-diligence audits of contract analytical laboratories for use as testing sites during product development and for commercial products.

➢ Provide guidance in the negotiation and establishment of suitable contract laboratory quality agreements for GLP, GMP and R&D studies.

***Scientific and Technical Expertise for Biotech CMC Analytical and Stability Issues***

➢ Develop and deliver customized internal training sessions (in-person and webinars) on technical, regulatory, quality and compliance elements of biological/biosimilar product CMC analytical and stability studies.

➢ Deliver annual certification/re-certification training in GLP and cGMP to establish and maintain laboratory compliance requirements.

➢ Serve as a subject matter expert and editorial reviewer for professional working groups, task forces and committees for professional societies, technical publications, university undergraduate and graduate programs, and international regulatory bodies.

➢ Present invited seminars, workshops and training classes on biomolecular methods, regulatory product development guidelines, laboratory management, and quality/compliance practices in analytical laboratories conducting R&D, GLP and GMP testing.

➢ Serve as subject matter expert in preparation and review of journal articles and book chapters, including:

- R&D lab quality practices (PAI readiness, due diligence assessment)
- GMP lab auditing (PAI readiness, general cGMP, and 483 remediation assessment)
- Biopharmaceutical and biosimilars analytical and stability CMC requirements
- Test method optimization, development, qualification and validation
- Test method bridging and method tech transfer
- Specific biotechnology method technology applications and instrumentation

➢ Organize and facilitate professional meetings on biopharmaceutical industry issues, including interactions among industry and regulatory bodies.

➢ Produce high-quality peer-reviewed publications on current and emerging CMC issues in biotech/biosimilar product development and commercialization, and analytical laboratory operations via collaborations with colleagues or through professional scientific organizations (e.g. CaSSS CMC Strategy Forums).

## Corporate Scientific Positions and CMC Activities

**1998 – 2002 Director, Analytical Services Division, BioReliance Corporation, Rockville, MD**

- Served as the principal point of scientific and regulatory interaction with worldwide biopharmaceutical clients for the CMC analytical studies conducted in my division.

- Provided expertise to clients on product development requirements for recombinant proteins, monoclonal antibodies, plasma products, transgenic proteins, viral vectors, vaccines, and synthetic biomolecules (e.g. peptides and oligonucleotides).

- Managed a $4 million division 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 executed CMC analytical studies from pre-Phase I through Phase III and commercialization for US and international customers.

- Supervised divisional quality system programs to ensure top-down GLP and cGMP compliance, and adherence to internal R&D quality practices, for CMC studies.

- Served as the responsible divisional authority for quality and compliance audits conducted by clients and regulatory bodies.

- Implemented management systems to increase efficiency in resource scheduling and maximize facility 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.

- Directed a major analytical laboratory move from the original location of < 1500 sq. ft. to a new, purpose-built site of > 5000 sq. ft. while maintaining a continuous state of GLP/cGMP compliance with no impact on concurrent client project timelines.

- Developed and updated corporate Analytical marketing and training materials, and delivered presentations at client sites to support Sales and Marketing efforts.

- Educated the Sales and Marketing team and other members of the administration by conducting internal S/M training classes.

- Successfully recruited, managed and retained highly skilled scientific staff in a competitive technical location.

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

- 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 though 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.

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

- Performed analytical biochemistry of over 50 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.
- Made contributions to over 125 individual analytical test method characterizations and validations for dozens of standard and state of the art technologies.
- Performed direct supervision and review of 5 R&D laboratory scientists.

## Academic Education

**1988-1992** **Postdoctoral Research Fellow – NIH Young Investigator Award**
University of Texas Health Science Center at Houston; Extracellular Matrix Biochemistry and Bone Cell Biology

**1984-1988** **M.A./Ph.D. – Rice Graduate Fellow Award**
Department of Biochemistry and Cell Biology, Rice University; Molecular and Cellular biology

**1979-1984** **B.S., Cell Biology and Biochemistry**
Department of Natural and Applied Sciences, University of Houston at Clear Lake; Biology/Chemistry

**1976-1978** **A.S., Biology and Chemistry**
Department of Biology, San Jacinto College, Houston; Biology/Chemistry

## Academic Positions and Research Activities

**1988-1992 Postdoctoral Research Fellow**
University of Texas Dental Branch, Department of Biological Chemistry, Houston, TX
*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, ligand binding assays, in vitro and in vivo radiolabelling of proteins, SDS-PAGE, immunoblots, and glycoprotein analysis.*

**1984-1988 Graduate Fellow**
Department of Biochemistry and Cell Biology, Rice University, Houston TX
*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, radiolabeled pulse/chase assays, IEF and SDS-PAGE. Certified in the use of beta and gamma emitters.*

**1980-1984 Senior Research Assistant**
University of Texas Dental Science Institute, Houston TX
*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.*

**1978-1984 Research Assistant**
University of Texas Dental Science Institute, Houston, TX
*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.*

## Professional Extracurricular Activities

My professional extracurricular efforts have contributed to the establishment and enrichment of educational and communication activities for key elements of biotechnology product development as well as the career development of emerging biotechnological scientists. All of these activities have been done as a *pro bono* volunteer for the biotechnology community, and to socially promote careers and career development in the sciences, particularly among women, college students and high school boys and girls.

### Professional Science Organizations

**California Separations Sciences Society (CaSSS):**
- President, Board of Directors (2020)
- Vice President, Board of Directors (2018-2020)
- Board of Directors (2012 – 2018)
- Associate Directors (2009 – 2012)
- Member (1996 – 2009)

**CaSSS CMC Strategy Forum**
- CMC Strategy Forum Co-Founder (2002)

- CMC Strategy Forum Global Advisory Board Member (2002 – present)
- North America CMC Strategy Forum Global Liaison (2012– present)
- North American CMC Forum Co-Leader
  - *"Test Method Qualification and Validation" (July 2004)*
  - *"Biotechnology Product Stability" (July 2005)*
  - *"Biotechnology Product Reference Standards" (Jan 2006)*
  - *"Current Expectations for Comparability and Stability of Gene Therapy Products" (Jan 2007)*
  - *"Biosimilar Products: Scientific Principles, Challenges, Opportunities" (Jan 2012)*
  - *"Biotechnology Product Reference Standards" (Jan 2013)*
  - *"Bridging of Analytical Methods" (Jan 2014)*
  - *"Host Cell Proteins" (Jan 2015)*
  - *"Test Method Transfer" (Jan 2017)*
  - *"Phase-Appropriate Method Validation" (Jan 2018)*

**CASSS WCBP Industry-FDA Annual Meeting**
- WCBP 10th Meeting; Industry Chair (2006)
- WCBP Workshop Committee Co-Chair (2004); Chair (2005)
- WCBP Program and Workshop Committee Member (2001 – 2014)

**Parenteral Drug Association (PDA)**
- Member, Biotechnology Advisory Board (BioAB) (2014-present)
- Reviewer, Analytical Method Development Task Force (2011-present)
- Co-Chair, Analytical Method Development Task Force (2009-2011)
- Member, Analytical Method Validation Task Force (2009 – 2010)

**Pharmaceutical Training Institute (Continuing Professional Development Certified Classes)**
- Scientific Advisory Board (2001 – present)
- Senior Trainer (2001 – present)
  - *"Regulatory, Technical and Quality Expectations for Biotechnology Product Stability Programs"*
  - *"Requirements in CMC Analytical Studies for Biotechnology/Biological/Biosimilar Products"*
  - *"Advanced Analytical Study Designs for Biotechnology/Biological/Biosimilar Products"*

**BioProcess International Journal**
- Charter Editorial Board Member (2002 – present)

**<u>Academic Science Organizations</u>**

**University of Maryland Baltimore County (UMBC)**
- **Chair, Scientific Advisory Board (2010 – present)**
  Applied Biotechnology graduate program curriculum, College of Natural and Mathematical Sciences
- **Charter SAB member (2007-2010)** |
  Applied Biotechnology graduate program curriculum, College of Natural and Mathematical Sciences
- **Biotechnology Career Forum Panelist (2008)**
  *"From Bench to Business: Biotechnology Career Opportunities"*
- **Biotechnology Graduate Program Course Guest Faculty (2001 – Present)**

GMP Course Class: *"Test Method Development and Validation"*
GMP Course Class: *"Laboratory Quality Practices: R&D, GLP and GMP"*

**Johns Hopkins University Graduate School of Biotechnology**

- Biotechnology Graduate Program Course Speaker (2007)
  Regulatory Affairs Class: *"CMC Analytical and Stability Studies for Biotech Products"*

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

- Member (1993 – 2006)
- Co-Founder and Chairman, Quality and Compliance Committee (1996-1998)
- ABRF-NIST Peptide Standards Committee (2001 – 2006)
- ABRF Annual Professional Society Meeting, Co-Chair (1999)

**Association for Women in Science**

- AWIS Board Member (various roles), Houston (1984-1990)
- Chapter President, Houston AWIS (1990-1992)
- AWIS Board Member (various roles), Chicago (1994-1997)
- Chapter President, Chicago AWIS (1997-1998)

## Publications

### Books and Chapters

**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, Second Edition (A.S. Rathore and G. Sofer, eds), CRC Press, Taylor and Francis Group, Boca Raton, FL, **2012**.

**Ritter N. M**. "Characterization of Biotechnological/Biological/Biosimilar Products." In: Murray Moo-Young (ed.), Comprehensive Biotechnology, Second Edition, volume 3 Biologics, pp. 459–466. Elsevier (**2011**)

**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. "*R&D Laboratory Quality Policies to Support Product CMC Development Activities",* (*manuscript in progress*).

Rios, M., Montgomery, S.A., and **Ritter, N.M.** *"Strategies for Successful Sample Transfer"*, BioProcess Intl, 15(4) April **2017**

Shahrokh, Z, Schmalzing, D. Rawat, R, Sluzky, V, Ho, K, Engelbergs, J, Bishop, J, Friedl, E, Bruce Meiklejohn, B, and **Ritter, N** *"Current Perspectives on Host Cell Protein Analysis and Control",* Proceedings of the CMC Strategy Forum, BioProcess Intl, Sept, **2016**

**Ritter, N.,** Russell, R., Schofield, T., Graham, L., Dillon, P., Maggio, F., Bhattacharyya, L., Schmalzing, D., Zhou, W-M., Miller, K. and Yang, H. *"Bridging Analytical Methods for Release and Stability Testing: Technical, Quality and Regulatory Considerations"* Proceedings of the CMC Strategy Forum, BioProcess Intl. Feb **2016**

Ridgway, A, **Ritter, N.M.**, Scheistl, M., and Schrietmuller, T. *"Biosimilar Products: Scientific Principles, Challenges, and Opportunities,"* Proceedings of the CMC Strategy Forum, BioProcess Intl, 13(10), Nov **2015**.

**Ritter, N**., Edwards, J, Plushkell, S, Stella, S., Logan, R., Fuchs, C., Nassabeh, W., Mahtre, R. *"Expanded Change Protocols: Benefits, Cost Considerations and Regulatory Views,"* Proceedings of the CMC Strategy Forum; BioProcess Intl. 13(3) March **2015**

Mire-Sluis, A, **Ritter, N**, Cherney, B, Schmalzing, D, and Blumel, M, *"Reference Standards for Therapeutic Proteins, Part 1: Current Regulatory Trends, Scientific Best Practices and Remaining Needs,"* Proceedings of the CMC Strategy Forum; BioProcess Intl. 12(3) March **2014**

Mire-Sluis, A, **Ritter, N**, Cherney, B, Schmalzing, D, and Blumel, M, *"Reference Standards for Therapeutic Proteins, Part 2: Current Regulatory Trends, Scientific Best Practices and Remaining Needs,"* Proceedings of the CMC Strategy Forum; BioProcess Intl. 12(5) May **2014**

A. T. Menendez, **N. M. Ritter**, D. Jani and J. Goyal "*Recommendations for the Preparation, Characterization and Storage of Cell Banks Used in GXP Assays for Biopharmaceutical Products*", BioProcess Intl (Jan **2012**)

J. Patel, R. Kothari, R. Tunga**, N. Ritter**, and B. Tunga**,** "Stability Considerations for Biopharmaceuticals - Overview of Protein and Peptide Degradation Pathways" BioProcess Intl. (Jan **2011**) pp. 2-10

**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**).

Sampson, H.W., Vogel, J., **Ritter, N.M.**, Hakim, F. *Changes in sphingomyelin and non-collagenous proteins during intervertebral disk mineralization in progressive ankylosis mice"* Bone and Mineral 17 (2):309 **(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. 3 5:957-965 (**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**).

## Public/Community Scientific Activities

**Montgomery County Public Schools (Maryland)**

- Invited speaker on careers in science, Seneca Valley H.S. (2004-present)
- Invited guest lab teacher in biology, Martin Luther King M.S.(2002-2005)

**Lake County School District (Chicago)**

- Invited speaker on careers in science, Lake Forest H.S. (1996-98)

**Houston Museum of Natural Science (Houston)**

- Performed weekend public chemistry demonstrations in the Welch Hall of Chemistry (1984-1988)
- Revised and updated the chemistry demonstration experiment book for HMNS (1988)

**Children's Museum of Houston (Houston)**

- Museum Program Development Task Force Member for Science Exhibits, Planning Stages (1988)

## Professional Honors and Awards

- Who's Who of American Professional Women – 2005 to present
- Pharmaceutical Training Institute Trainer of the Year - 2002
- Pharmaceutical Training Institute Trainer of the Month - 2001
- BioPharm International 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
- NIH Young Investigator Award, University of Texas Health Science Center – 1988-92
- Rice University Graduate Fellow Award – 1984-86
- Outstanding Young Women of America –1979