

DAVID (DAVE) G. SEROTA

Education

- B.S. Pharmacy – Auburn University, Auburn, AL 1969
- Ph.D. Toxicology – University of Tennessee Center for the Health Sciences, Memphis, TN, 1976

Professional History

- President & Owner – 7th Inning Stretch Consulting LLC, Kalamazoo, MI, 2016-present
- Senior Vice President & Director of Research/Senior Principal Study Director, MPI Research, Mattawan, MI, 2013-16
- Senior Vice President of Drug Safety Development/Senior Principal Study Director, MPI Research, Mattawan, MI, 2012-2013
- Senior Scientific & Business Advisor/Senior Principal Study Director, MPI Research, Mattawan, MI, 2010-12
- Senior Vice President of Drug Safety Evaluation/Senior Principal Study Director, MPI Research, Mattawan, MI, 2009-10
- Vice President of Toxicology & Pathology/Senior Principal Study Director, MPI Research, Mattawan, MI, 2005-09
- Director of Toxicology/Senior Principal Study Director, MPI Research, Mattawan, MI, 2001-05
- Director of Toxicology/Senior Study Director, MPI Research, Mattawan, MI, 1999-2001
- Senior Study Director, MPI Research, Mattawan, MI, 1997-99
- Director, Toxicology Department, Southern Research Institute, Birmingham, AL, 1993-97
- Assistant Director, Toxicology Department, Southern Research Institute, Birmingham, AL, 1991-93
- Program Manager/Senior Staff Scientist, Hazleton Laboratories Washington Inc., Vienna, VA, 1990-91
- Director, Laboratory Operations/Senior Staff Scientist, Hazleton Laboratories America Inc., Vienna, VA, 1985-90
- Director, Small Animal Laboratory Operations/Senior Staff Scientist, Hazleton Laboratories America, Inc., Vienna, VA, 1983-85
- Associate Director, Operations/Senior Staff Scientist, Hazleton Laboratories America, Inc., Vienna, VA, 1982-83
- Section Supervisor/Senior Staff Scientist, Hazleton Laboratories America, Inc., Vienna, VA, 1979-82
- Section Supervisor/Staff Scientist, Hazleton Laboratories America, Inc., Vienna, VA 1976-79
- Assistant Professor, College of Pharmacy, Washington State University, Pullman, WA, 1975-76
- Ph.D. Candidate, University of Tennessee Center for the Health Sciences, Memphis, TN, 1971-75
- Graduate Research Assistant, University of Tennessee Center for the Health Sciences, Memphis, TN, 1969-71
- Laboratory Assistant, Medicinal Agents Laboratory, Auburn University, Auburn, AL, 1968-69

Board Certifications

- Diplomate, American Board of Toxicology, 1981; recertification 1986, 1991, 1996, 2001, 2006, 2011, 2016,2021

University and Society Affiliations

- Affiliate Professor of Drug Discovery & Development, Auburn University, Auburn, AL, 2022-present
- American College of Toxicology – 40+-year member
 - Appointed Chairperson of the 40th Anniversary Committee, 2018-19
 - Appointed a charter member of the Endowment Committee, 2015-16
 - Nominated as a candidate for the IUTOX Council but lost election, 2016
 - Elected to the Nominations Committee, 2015
 - Chair of the Resource Committee, 2013-15
 - Past President, 2013
 - President, 2012
 - President-Elect, 2011
 - Elected Vice President, 2010
 - Elected as a Councilor, 2007-09
 - Elected to the Membership Committee, 2004-06
- Society of Toxicology – 40+-year member
 - Appointed as a member on the Public Communications Committee
 - Appointed as a member of the Placement Committee
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
 - Board of Trustees, 2010-16
 - Global 3Rs member, 2015-16
 - Nominations Committee Chair, 2016
- MichBio Board of Directors,2014-16
- Southwest Michigan SPCA
 - Board of Directors, 2012-present
 - Board President, 2018
- Auburn University, Harrison College of Pharmacy, appointed member to the Dean’s Council, 2009-11, reappointed 2012-15, 2016-20, 2021-present

Special Awards and Presentations

- American College of Toxicology Distinguished Service Award, 2015
- Commencement Speaker, Auburn University Harrison School of Pharmacy 2016 Graduating Class, May 10, 2016

Scientific Meeting Attendance

- Society of Toxicology Annual Meeting - 1970, 1977-2019
- American College of Toxicology Annual Meeting - 1987, 2001, 2006-19, 2021 (virtual)
- Toxicology Roundtable Annual Meeting - 1978-84, 1988, 1994-2014, 2016-19, 2020 (virtual), 2021

- Roundtable of Toxicology Consultants Annual Meeting – 2019-20

Peer Reviewer

- Toxicology Research and Application – 2017-present

Continuing Education Courses Taken

1. The What, When, and How of Nonclinical Support for an IND Submission, 52nd SOT Annual Meeting, San Antonio, TX, 2013
2. Writing for Regulatory Authorities, 34th ACT Annual Meeting, San Antonio, TX, 2013
3. Introduction to Translational Imaging in Nonclinical Safety Assessment: A Technology and Applications Perspective, 32nd ACT Annual Meeting, Phoenix, AZ, 2011
4. Clinical Pathology for the Toxicologist – Looking Beyond the Asterisks, 32nd ACT Annual Meeting, Phoenix, AZ, 2011
5. Design and Performance of Carcinogenicity Studies, 31st ACT Annual Meeting, Baltimore, MD, 2011
6. Consulting in Toxicology, 30th ACT Annual Meeting, Palm Springs, CA 2010
7. Stress as a Confounding Factor in Toxicology Studies, 48th SOT Annual Meeting, Baltimore, MD, 2009
8. Study Monitoring at CROs: Keeping Your Sanity and Achieving the Best Product (Best Practices, Pitfalls, and Keys to Efficiency), 29th ACT Annual Meeting, Tucson, AZ, 2009
9. Medicine – Coming Soon to a Refrigerator Near You, 29th ACT Annual Meeting, Tucson, AZ, 2009
10. Study Director Training, 28th ACT Annual Meeting, Charlotte, NC, 2008
11. Application of the Human Relevance Framework to the Analysis of Rodent Tumor Data, 28th ACT Annual Meeting, Charlotte, NC, 2008
12. Clinical Pathology – The Granddaddy of Biomarkers, 44th SOT Annual Meeting, New Orleans, LA, 2005
13. International Harmonization of Technical Requirements for Conducting Non-clinical Safety Studies of Human Pharmaceuticals: Guidelines, Case Studies, and Challenges, 44th SOT Annual Meeting, New Orleans, LA, 2005
14. Evaluation of Immunomodulation in Safety Assessment, 42nd SOT Annual Meeting, Salt Lake City, UT, 2003
15. Practical Approaches to Applying the Immunotoxicology Guidelines to Safety Assessment, 22nd ACT Annual Meeting, Washington D.C., 2001
16. International Harmonization of Non-clinical Toxicology Requirements: Regulations vs. Practice, 37th SOT Annual Meeting, Seattle, WA, 1998
17. Basic Risk Assessment: Current Developments, 32nd SOT Annual Meeting, New Orleans, LA, 1993
18. Toxicity of Halogenated Hydrocarbons, 31st SOT Annual Meeting, Seattle, WA, 1992

19. Naturally Occurring Toxins, 30th SOT Annual Meeting, Dallas, TX, 1991
20. Toxicity of Agents: Pesticides, 29th SOT Annual Meeting, Miami, FL, 1990
21. Neurotoxicology, 28th SOT Annual Meeting, Atlanta, GA, 1989
22. Gastrointestinal Toxicology, 27th SOT Annual Meeting, Dallas, TX, 1988
23. Respiratory Tract Toxicology by Classes of Agents, 27th SOT Annual Meeting, Dallas, TX, 1988
24. Clinical Chemistry of Laboratory Animals, 26th SOT Annual Meeting, Washington D.C., 1987
25. Naturally Occurring Toxins, 26th SOT Annual Meeting, Washington D.C., 1987
26. Environmental Toxicology, 25th SOT Annual Meeting, New Orleans, LA, 1986
27. Developmental Toxicology for the General Toxicologist, 25th SOT Annual Meeting, New Orleans, LA, 1986
28. Current Concepts and Mechanisms of Carcinogenesis, 23rd SOT Annual Meeting, Atlanta, GA, 1984
29. Selection of Tests for Assessment of Hepatotoxicity, 23rd SOT Annual Meeting, Atlanta, GA, 1984
30. Basic Concepts of Immunotoxicology, 21st SOT Annual Meeting, Boston, MA, 1982

Presentations

1. Furman GM and **Serota DG**. November 16, 2021, Workshop Co-chair – So, You Want to Be a Consultant?. Presentation at the 42nd Annual Meeting of the American College of Toxicology (virtual presentation).
2. **Serota DG**. October 18, 2021, The Story of Ebola Reston from the Perspective of the CRO, Presentation at the Toxicology Roundtable Meeting, White Sulphur Springs, WV.
3. **Serota DG**. November 11, 2020, Hannah's Hope Foundation and the Role of MPI Research in Supporting Orphan Disease Testing, Presentation at Northern Biomedical Research Laboratories, Norton Shores, MI.
4. **Serota DG**. October 16, 2019, The Story of Ebola Reston from the Perspective of the CRO, Presentation at Covance Laboratories, Madison, WI.
5. **Serota, DG**. October 14, 2019, Industrial Biotest and How We Got to GLPs, Toxicology Presentation at the Toxicology Roundtable Meeting, Lake Geneva, WI.
6. **Serota, DG**. September 26, 2019, Do You Have a Face in Research, Keynote Speaker Presentation at the Academy of Surgical Research Annual Meeting, Clearwater, FL.

7. **Serota DG.** September 5, 2019, American College of Toxicology Webinar - An Overview of the History of ACT and How the College Has Become What It Is Today.
8. **Serota, DG.** October 16, 2018, Consolidation in the Preclinical CRO Industry– Who Benefits and Who Loses, Presentation at the Toxicology Roundtable Meeting, Galveston, TX.
9. **Serota DG.** March 14, 2018. Maximizing Your Experience and Relationship with Your CRO. Exhibitor-hosted session Presentation for WuXi-AppTec at the 57th Annual Meeting of the Society of Toxicology, San Antonio, TX.
10. **Serota DG** and Bartoe JE. November 7, 2017. Symposium Co-chair – The Eyes Have It: Considerations on Design and Interpretation of Preclinical Ocular Safety Studies. Presentation at the 38th Annual Meeting of the American College of Toxicology, Palm Springs, CA.
11. **Serota DG.** November 5, 2017. Continuing Education Course – Study Monitoring at CROs, What You Need To Know And Do To Be An Effective Study Monitor. Presentation at the 38th Annual Meeting of the American College of Toxicology, Palm Springs, CA.
12. **Serota DG** and Baird TJ. November 7, 2016. Symposium Co-chair – Small Compartment Toxicity: ‘CN VIII’: Hearing Loss, Tinnitus, and Balance Disorders. Presentation at the 37th Annual Meeting of the American College of Toxicology, Baltimore, MD.
13. **Serota DG** and Gad SC. November 8, 2016. Symposium Co-chair – Current Issues in Evolving Regulatory Systemic Toxicology Study Design and Conduct. Presentation at the 37th Annual Meeting of the American College of Toxicology, Baltimore, MD.
14. **Serota DG.** May 6, 2016. From Bench to Bedside. Searching for Health Symposium Presentation at the Annual Conference of the Kalamazoo Area Mathematics and Science Center, Kalamazoo, MI.
15. **Serota DG.** November 12, 2014. PETA Questions the Value of AAALAC Accreditation – What is Going on Here? Hot Topics Presentation at the 35th Annual Meeting of the American College of Toxicology, Orlando, FL
16. **Serota DG.** November 8, 2013. Putting a Face on Research. Keynote Speaker Presentation at the Annual Michigan AALAS Awards Banquet, Jackson, MI.
17. **Serota DG.** November 2, 2013. Optimizing Interactions Between Toxicology Consultants and the CRO. Presented at the Biennial Roundtable of Toxicology Consultants Meeting, San Antonio, TX.
18. **Serota DG.** April 2, 2011. A Retrospective View of the Study Director in a GLP World – A Journey of Over 30 Years. Presented at the 27th Annual Meeting of the Society of Quality Assurance, San Antonio, TX.

19. **Serota DG.** May 1, 2009. MPI Research – Helping to Develop New Medicines. Presentation to the Biology and Chemistry Classes of Gobles High School, Gobles, MI.
20. **Serota DG.** October 21, 2007. Aiming for Preclinical Success – CRO Expectations of the Sponsor. Presented at the 2007 Annual AusBiotech Meeting, Brisbane, Australia.
21. **Serota DG.** October 28, 2006. The Role, Responsibilities, and Required Qualifications of the Study Director in the Successful Conduct of GLP Studies. Presented at the 10th Healthcare Industry Forum, China Opportunity in the Industrial Globalization, Beijing, China.
22. **Serota DG.** June 27, 2006. Managing the Sponsor/Provider Relationship in Preclinical Outsourcing: Best Practices and Trends. Presented at the 2nd Annual Optimizing Preclinical Outsourcing Meeting, Boston, MA.
23. **Serota DG.** October 13, 2004. Preclinical GLP Studies: The Study Director Perspective. Presented at the Regulatory Affairs Professional Society Annual Conference & Exhibition, Washington, D.C.
24. **Serota DG.** March 18, 2002. How to Market Yourself as a Toxicologist. Presented at the Society of Toxicology Meeting Placement Service Symposia at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN.
25. **Serota DG.** September 8-9, 1986. Guest Lecturer and Invited Speaker. Presented at the Food and Drug Administration Seminar on Good Laboratory Practices, The National Center for Toxicological Research (NCTR), Jefferson, AR.
26. **Serota DG.** October 6-10, 1985. Methylene Chloride. Presented at Living in a Chemical World, The Collegium Ramazzini, Bologna, Italy.
27. **Serota DG.** September 11, 1984. Effective Communications Between the Joint Venture Sponsor and the Contract Laboratory-The Contract, the Data and the Report. Presented at the Joint Venture Testing Seminar, Sponsored by McKenna, Conner & Cuneo, and Hazleton Laboratories, Washington, DC.
28. **Serota DG.** May 15-17, 1984. The Results of a Rat Three-Generation Reproduction Study with Caprolactam. Presented at Symposium on an Industrial Approach to Chemical Risk Assessment, Sponsored by the Industrial Health Foundation, Arlington, VA.
29. **Serota DG.** March 8-9, 1984. Chronic Toxicity and Oncogenicity Testing of Methylene Chloride in Rats and Mice. Presented at Food Solvents Workshop I: Methylene Chloride, Sponsored by the Nutrition Foundation, Bethesda, MD.
30. **Serota DG,** Mense MA, Ulland BM. March 1984. Two-Year Drinking Water Study of Methylene Chloride in B6C3F1 Mice. Presented at the 23rd Annual Meeting of the Society of Toxicology, Atlanta, GA.

31. **Serota DG**. September 27, 1983. Quality Assurance From a Toxicologist's Point of View. Presented at the Fourth Annual Quality Assurance Roundtable Meeting (now the Society of Quality Assurance), Houston, TX.
32. **Serota DG**, Fezio WL, Ulland BM. March 1983. Two-Year Drinking Water Study of Methylene Chloride in Fischer 344 Rats. Presented at the 22nd Annual Meeting of the Society of Toxicology. Las Vegas, NV.

Book Authorship

1. Contract Research and Development Organizations – Their History, Selection, and Utilization. Shayne C. Gad, Charles B. Spainhour, and **David G. Serota** – Editors. Springer Nature Switzerland, 2020.

Book Chapters

1. Caruso, MJ, Pachta, TC, Papagiannis CN, Lloyd Z, Cooper DM, **Serota DG**. Humane care and use of laboratory animals in toxicology research. Hayes' Principals and Methods in Toxicology, 7th Edition (planned publication if 2023), Chapter 21.
2. **Serota, DG**. The history of CROs: including CRO snapshots. Contract Research and Development Organizations – Their History, Selection, and Utilization. Shayne C. Gad, Charles B. Spainhour, and **David G. Serota** – Editors, (2020), Chapter 2, pp.37-69.
3. **Serota, DG**. Study and project monitoring. Shayne C. Gad, Charles B. Spainhour, and **David G. Serota** – Editors, (2020), Chapter 12, pp. 299-313.
4. **Serota, DG**. Optimizing your experience and relationship with your preclinical CRO. Shayne C. Gad, Charles B. Spainhour, and **David G. Serota** – Editors, (2020), Chapter 15, pp. 34--349.
5. Cooper DM, Craig L, Papagiannis CN, Poage DW, Ruppert GW, **Serota DG**. Humane care and use of laboratory animals in toxicology research. Hayes' Principals and Methods in Toxicology, 6th Edition (2014), Chapter 20, pp. 1023-1080.
6. MacKenzie SA, Ruppert GW, **Serota DG**. Facilities, operations, laboratory animal Care, and veterinary services. The role of the study director in nonclinical studies (2014), edited by William S. Brock, Chapter 4, pp. 43-72.
7. **Serota, DG**, Ghost-Wrote the Forward by Dr. Edwin I Goldenthal in The role of the study director in nonclinical studies (2014), edited by William S. Brock, pp. ix-x.

8. **Serota, DG.** Wrote the Forward to a Comprehensive guide to toxicology in preclinical drug development (2013) and Second Edition (2016), edited by Ali S. Faqi, p. xiii.

Publications

1. Kim, TW, Papagiannis, C, Capaldi, D, McPherson, AK, Mahdi, F, Luu, N, Rodriguez, A, Hoffmaster, C, **Serota, D**, Henry, SP: Impurity qualification toxicology study for a 2'-O-methoxyethyl-modified antisense inhibitor in mice, Nucleic Acid Therapeutics. 30, 14-21, 2020.
2. **Serota, DG.** History of the American College of Toxicology: The 15-year period from 2004 through 2018, International Journal of Toxicology. 39, 1, 4-19, 2020.
3. Zanardi, T, Kim, TW, Shen, L, **Serota, D**, Papagiannis, C, Park, SY, Henry, S. Chronic toxicity assessment of 2'-o-methoxyethyl antisense oligonucleotides in mice, Nucleic Acid Therapeutics. 28, 233-41, 2018.
4. Kovalcsik R, Devlin T, Loux S, Martinek M, May J, Pickering T, Tapp R, Wilson S, **Serota D.** (2006). Animal reuse: Balancing scientific integrity and animal welfare. Lab Animal. 35(9), 49.
5. Germann N, Urien S, Rodgers AH, Ratterree M, Struck RF, Waud WR, **Serota DG**, Bastian G, Jursic BS, Morgan LR. (2005). Comparative preclinical toxicology and pharmacology of isophosphoramidate mustard, the active metabolite of ifosfamide. Cancer Chemother Pharmacol. 55, 143.
6. Kilpatrick JM, Morris PE, **Serota DG**, Phillips D, Moore DR, Bennett JC, Babu YS. (2003). Intravenous and oral pharmacokinetic study of BCX-1777, a novel purine nucleoside phosphorylase transition-state inhibitor. In vivo effects on blood 2'-deoxyguanosine in primates. International Immunopharmacology. 3(4), 541.
7. Wan XS, **Serota DG**, Ware JH, Crowell JA, Kennedy AR. (2002). Detection of Bowman-Birk inhibitor and anti-Bowman-Birk inhibitor antibodies in sera of humans and animals treated with Bowman-Birk inhibitor concentrate. Nutrition and Cancer, 43(2), 167.
8. Morgan LR, Rodgers AH, Hooper CL, Ratterree M, **Serota D**, Beis R, Schwartz SL. (2001). Comparative dermal pharmacology and toxicology of 4,4'-dihydroxybenzophenone-2,4-dinitrophenylhydrazine (A-007) in rodents and primates. In Vivo 15(6), 479.

9. Kossor DC, Han S, Kemp FW, Slaughter RW, **Serota D**, Rajaskarian D, Milner N, Davidovich A, Bogden JD. (2001). Administration of the oral antibiotic frenolicin-B selectively alters copper nutrition in male rats. Journal of Nutrition, 131(12), 3247.
10. Agrawal S, Zhad Q, Jiang Z, Oliver C, Giles H, Heath J, **Serota DG**. (1997). Toxicologic effects of an oligodeoxynucleotide phosphorothioate and its analogs following intravenous administration in rats. Antisense & Nucleic Acid Drug Development, 7, 575.
11. **Serota DG**, Hoberman AM, Friedman MA, Gad SC. (1988). Three-generation Reproduction Study with Caprolactam in Rats. Journal of Applied Toxicology, 8, 285.
12. Gad SC, Robinson KR, Colpean BR, **Serota DG**. (1987). Developmental Toxicity Studies of Caprolactam in the Rat and Rabbit. Journal of Applied Toxicology, 7, 317.
13. **Serota DG**, Thakur AK, Ulland BM, Kirschman JC, Brown NM, Coots RH, Morgareidge K. (1986). A two-year drinking water study of dichloromethane in rodents: I. Rats. Food & Chemical Toxicology, 24, 951.
14. **Serota DG**, Thakur AK, Ulland BM, Kirschman JC, Brown NM, Coots RH, Morgareidge K. (1986). A two-year drinking water study of dichloromethane in rodents: II. Mice. Food & Chemical Toxicology, 24, 959.
15. Parker CM, Van Gelder GA, Chai EY, Gellatly JBM, **Serota DG**, Voelker RW, Vesselinovitch SD. (1985). Oncogenic evaluation of tetrachlorovinphos in the B₆C₃F₁ mouse. Fundamental & Applied Toxicology, 5, 840.
16. **Serota DG**, Meyer MC, Autian J. (1972). Effect of Structure on Permeability of Substituted Anilines from Aqueous Solutions through Polyethylene. Journal of Pharmacology and Science, 61, 416.

Reports

- Responsible for the generation of over 1,300 technical reports for commercial and government clients relating to toxicity studies conducted at Hazleton Laboratories, Southern Research Institute, and MPI Research. The substance of these reports is proprietary to the clients sponsoring the research and is thus confidential and not available for publication.
- Served as Principal Investigator for National Toxicology Program (NTP) contracts for sub-chronic and/or carcinogenicity studies in rats and/or mice on Theophylline, D&C Yellow, t-Butyl Hydroquinone, and Emodin. (Southern Research Institute)
- Served as Co-Principal Investigator and Study Director for National Cancer Institute (NCI) Chemopreventive Branch subchronic and chronic studies in mice and dogs on Bowman-Birk Inhibitor concentrate (BBIC). (MPI Research)

