



Toxicology Regulatory Services

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Curriculum Vitae

Louan C. Fisher

PROFESSIONAL REGISTRATION

Registered Quality Assurance Professional – GLP; 2001 - Present

EXPERIENCE

Scientific & QA Program Director; 2008 to present

Senior Scientist/QA Auditor; 1999 to 2007

Toxicology Regulatory Services, Inc., Charlottesville, VA

Responsible for coordination of the scientific and QA monitoring programs within the company which involves the development and implementation of internal standard operating procedures and training of TRS personnel involved in the study monitoring and quality assurance tasks. Also responsible for monitoring the conduct of various toxicology studies from protocol development through final reporting, including physical chemical property and environmental fate studies; and aquatic, genetic and mammalian toxicology studies. Study monitoring responsibilities include: performing experimental phase audits at the testing laboratories; conducting quality assurance audits and scientific reviews of raw data and reports; and preparing audit reports.

Additional responsibilities include assisting in the preparation of US and international registrations/submissions; preparing summaries of toxicology data; conducting laboratory facility inspections for US and international GLP compliance; and developing training programs for GLP compliance.

Senior Supervisor; 1993 to 1995

Supervisor; 1991 to 1992

Scientist; 1987 to 1990

Research Technologist; 1983 to 1986

Master Technologist; 1979 to 1982

Union Carbide Corporation, Bushy Run Research Center, Export, PA

Developed methodologies, computerization (including validation), statistical analyses, summarization and reporting methods for developmental toxicology and reproduction studies. Developed new procedures to increase productivity while maintaining quality. Directed internal quality improvement committees including the Standard Operating Procedures Team and Archival Standardization Team. Established the marketing and business strategies for the research facility. Designed marketing presentations including

computer demonstrations for prospective clients. Additional responsibilities and accomplishments included:

- Developed and improved procedures for GLP compliance laboratory-wide;
- Established the Developmental Toxicology Department at Bushy Run Research Center with a team of scientists;
- Supervised approximately 20 reproduction and over 100 developmental toxicity studies;
- Managed and scheduled numerous concurrent projects totaling over \$1M;
- Supervised approximately 30 technicians; responsible for operation of small animal toxicology studies including gross pathology and histopathology;
- Summarized data and wrote reports for studies in various toxicology disciplines;
- Prepared cost estimates for studies and human resource allocations;
- Standardized methodologies among several toxicologic disciplines (including inhalation, acute, dermal, developmental and reproductive toxicology and neurotoxicology); and
- Facilitated the laboratory shutdown by maintaining the integrity of data storage and retention for past clients (sole supervisor chosen to remain until the final closing date of the facility).

EDUCATION

Laboratory Animal Technologist, American Association for Laboratory Animal Sciences; 1989
Allegheny College, Meadville, PA; B.S., Biology, Psychology; 1979

SOCIETY MEMBERSHIPS

Society of Toxicology (SOT); 2001 to present

Teratology Society; 2002 to present

Middle Atlantic Reproduction and Teratology Association (MARTA); 2001 to present

Society of Quality Assurance (SQA); 2001 to present

National Capital Area Regional Chapter of the SQA (NCARSQA); 2002 to present

North Carolina Chapter of the SQA (NCCSQA); 2007 to present

PROFESSIONAL DEVELOPMENT

Society of Quality Assurance

Global Regulatory Compliance Challenges Symposium: 2009

Navigating the Global Regulated Environment: Advanced GLP Training for Managing Multi-Site Studies: 2009

Study Director Training: SQA Fall Training Session 2007

Current Topics in Good Laboratory Practice: SQA Fall Training Session 2007

Advanced concepts in Computer Validation: SQA Fall Training Session 2007

NCARSQA Training Session: Comparison of FDA, EPA and OECD Regulations; 2002

NCARSQA Training Session: Auditing Animal Facilities; 2002

Pre-Conference Training: Advanced Concepts in Computer Validation; 2001

Annual Meeting Attendance: 2001

Teratology Society

Education Course: Advances in Reproductive and Developmental Toxicity Risk
Assessment of Biopharmaceuticals: 2007
Education Course: Epidemiology: The Basics, 2004
Education course: Experimental Design and Biostatistics; 2002
Education Course: Mechanisms, Biomarkers, Data Interpretation: an Integrative Risk
Assessment using Developmental Neurotoxicity as a Model; 2002
Annual Meeting Attendance: 2002, 2004, 2007

Society of Toxicology

Annual Meeting Attendance: 2000, 2004, 2008, 2009

Workshops, courses and seminars:

Genetic and Molecular Toxicology Workshop at BioReliance; 2000
Using Microsoft® Windows™; 1995
First Things First: Quadrant II Time Management; 1993
How to Handle People with Tact and Skill; 1992
Empowering Leader; 1992
Coaching and Teambuilding Skills for Managers; 1992
Management Skills for New Supervisors; 1991
Introduction to Microcomputers, Pennsylvania State University, Monroeville, PA; 1984
Statistics, University of Pittsburgh, Greensburg, PA; 1982

PROFESSIONAL HONORS

Special Recognition Award; 1994. Developed and improved procedures for Good Laboratory Practice compliance.

Special Recognition Award; 1991. Enhanced operations of the Reproduction/Developmental Toxicology area and maintained customer satisfaction during an 18-month period with numerous management and personnel changes. Implemented and managed the safety program and ensured the overall improvement of the safety program.

Special Recognition Award; 1988. Reduced cost of developmental and reproduction studies by greater than 12% through the design and implementation of new computer software to collect, analyze and report data.

PUBLICATIONS

Christian, M.S., R. G. York, A. M. Hoberman, L. C. Fisher, W. R. Brown and D. M. Creasy (2002). Oral (Drinking Water) Two-Generation Reproductive Toxicity Study of Dibromoacetic Acid (DBA) in Rats. *International Journal of Toxicology*, 21 (4):237-276.

Christian, M.S., R. G. York, A. M. Hoberman, L. C. Fisher and W. R. Brown (2002). Oral (Drinking Water) Two-Generation Reproductive Toxicity Study of Bromodichloromethane (BDCM) in Rats. *International Journal of Toxicology*, 21:115-146.

PUBLICATIONS (continued)

Christian, M.S., R. G. York, A. M. Hoberman, R. M. Diener, and L. C. Fisher (2001). Oral (Drinking Water) Developmental Toxicity Studies of Bromodichloromethane (BDCM) in Rats and Rabbits. *International Journal of Toxicology*, 20:225-237.

Christian, M.S., R. G. York, A. M. Hoberman, R. M. Diener, L. C. Fisher, and G. A. Gates (2001). Biodisposition of Dibromoacetic Acid (DBA) and Bromodichloromethane (BDCM) Administered to Rats and Rabbits in Drinking Water During Range-Finding Reproduction and Developmental Toxicity Studies. *International Journal of Toxicology*, 20:239-253.

Tyl, Rochelle W., L. C. Fisher, D. E. Dodd, I. M. Pritts, M. F. Kubena, P. E. Losco, C. M. Troup, J. P. Lyon and T. D. Landry (1999). Developmental Toxicity Evaluation of Inhaled Toluene Diisocyanate Vapor in CD Rats. *Toxicol. Sciences*. 52:248-257.

Tyl, Rochelle W., T. L. Neeper-Bradley, L. C. Fisher, D. E. Dodd, I. M. Pritts, P. E. Losco, J. P. Lyon and T. D. Landry (1999). Two-Generation Reproduction Study of Inhaled Toluene Diisocyanate Vapor in CD Rats. *Toxicol. Sciences*. 52:258-268.

Bevan, C., R. W. Tyl, T. L. Neeper-Bradley, L. C. Fisher, R. D. Panson, J. F. Douglas and L. S. Andrews (1997). Developmental Toxicity Evaluation of Methyl Tertiary-Butyl Ether (MTBE) by Inhalation in Mice and Rabbits. *J. Appl. Toxicol.* May;17(Suppl. 1):S21-29.

Neeper-Bradley, T. L., R. W. Tyl, L. C. Fisher, M. F. Dubena, M. A. Vrbanic and P. E. Losco (1995). Determination of a no-observed-effect level for developmental toxicity of ethylene glycol administered by gavage to CD rats and CD-1 mice. *Fundam. Appl. Toxicol.* Aug;27(1):121-130.

Tyl, R. W., B. Ballantyne, L. C. Fisher, D. L. Fait, D. E. Dodd, D. R. Klonne and I. M. Pritts and P. E. Losco (1995). Evaluation of the developmental toxicity of ethylene glycol aerosol in CD-1 mice by nose-only exposure. *Fundam. Appl. Toxicol.* Aug;27(1):49-62.

Tyl, R. W., B. Ballantyne, L. C. Fisher, D. L. Fait, T. A. Savine, D. E. Dodd, D. R. Klonne and I. M. Pritts (1995). Evaluation of the Developmental Toxicity of Ethylene Glycol Aerosol in the CD[®] Rat and CD[®]-1 Mouse by Whole-Body Exposure. *Fundam. Appl. Toxicol.* 24:57-75.

Neeper-Bradley, T. L., L. C. Fisher and B. Ballantyne (1994). Evaluation of the Developmental Toxicity Potential of 2-Ethyl-1,3-Hexanediol in the Rat by Cutaneous Application. *Cut. and Ocular Tox.* 13(3):203-214.

Hendrick, A.G., P. E. Peterson, R. W. Tyl, L.C. Fisher, L. G. Fosnight, M. F. Kubena, M. A. Vrbanic and G. V. Katz (1993). *Fundam. Appl. Toxicol.* 20:199.

Tyl, R. W., B. Ballantyne, I. M. Pritts, R. H. Garman, L. C. Fisher, K. A. France and D. J. McNeil (1990). An evaluation of the developmental toxicity of 2,4-pentanedione in the Fischer 344 rat by vapour exposure. *Toxicol. Ind. Health* May-Jul;6(3-4):461-474.

PUBLICATIONS (continued)

- Tyl, R. W., B. Ballantyne, K. A. France, L. C. Fisher, D. R. Klonne and I. M. Pritts (1989). Evaluation of the Developmental Toxicology of Ethylene Glycol Monoethyl Ether Vapor in Fischer 344 Rats and New Zealand White Rabbits. *Fundam. Appl. Toxicol.* 12:269-280.
- Tyl, R. W., B. Ballantyne, L. C. Fisher, D. J. Tarasi and D. E. Dodd (1989). Dominant Lethal Assay of 2,4-Pentanedione Vapor in Fischer 344 Rats. *Toxicol. Ind. Health* 5(3):463-477.
- Tyl, R. W., I. M. Pritts, K. A. France, L. C. Fisher and T. R. Tyler (1988). Developmental Toxicity Evaluation of Inhaled 2-Ethoxyethanol Acetate in Fischer 344 Rats and New Zealand White Rabbits. *Fundam. Appl. Toxicol.* 10(1):20-39.
- Tyl, R. W., K. A. France, L. C. Fisher and B. Ballantyne (1988). Developmental Toxicity Evaluation of Beta(3,-Epoxyethyl) Ethyltrimethoxysilane in Fischer 344 Rats and New Zealand White Rabbits. *Fundam. Appl. Toxicol.* 10(3):439-452.
- Tyl, R. W., I. M. Pritts, K. A. France, L. C. Fisher and T. R. Tyler (1988). Developmental Toxicity Evaluation of Inhaled 2-Ethoxyethanol Acetate in Fischer 344 Rats and New Zealand White Rabbits. *Fundam. Appl. Toxicol.* 10(1):20-39.
- Tyl, R. W., K. A. France, L. C. Fisher, D. E. Dodd, I. M. Pritts, J. P. Lyon, F. O. O'Neal and G. Kimmerle (1987). Developmental Toxicity Evaluation of Inhaled Nitrobenzene in CD Rats. *Fundam. Appl. Toxicol.* 8:482-492.
- Tyl, R. W., L. C. Fisher, K. A. France, R. H. Garman and B. Ballantyne (1986). Evaluation of the Teratogenicity of Bis(2-Dimethylaminoethyl)Ether after Dermal Application in New Zealand White Rabbits. *J. Toxicology - Cutaneous and Ocular Toxicology* 5(4):263-284.
- Tyl, R. W., B. Ballantyne, I. M. Pritts, K. A. France, L. C. Fisher and D. J. McNeil (1986). The Teratogenic Potential of 2,4-Pentanedione Vapor in Fischer 344 Rats. *J. American College of Toxicology* 5:600.
- Tyl, R. W., G. Millicovsky, D. E. Dodd, I. M. Pritts, K. A. France and L. C. Fisher (1984). A Teratologic Evaluation of Ethylene Glycol Monobutyl Ether in Fischer 344 Rats and New Zealand White Rabbits Following Inhalation Exposure. *Environmental Health Perspectives* 57:47-68.

BOOK CHAPTER:

Acknowledgment in book chapter entitled: "Developmental Toxicity in Toxicologic Research and Testing" by R. W. Tyl In: *Perspectives in Basic and Applied Toxicology* (B. Ballantyne, Editor), John Wright and Sons, Year Book Publishers, 1988, for compilation and analysis of historical control data from CD[®] and Fischer 344 rats and New Zealand White rabbits for fetal body weights by litter size.

ABSTRACTS/PRESENTATIONS

Neeper-Bradley, T. L., L. C. Fisher, B. L. Butler, M. F. Kubena and B. Ballantyne (1994). Developmental Toxicity Evaluation of Triethylene Glycol (TEG) Administered by Gavage to CD[®] Rats and CD[®]-1 Mice. *Toxicologist* 14(1):160.

Neeper-Bradley, T. L., L. C. Fisher, D. L. Fait, M. F. Kubena, D. A. Neptun and B. Ballantyne (1993). Dominant Lethal Assay of Tetraethylene Glycol (TTEG) in the Drinking Water of Fischer 344 Rats. *Toxicologist* 13(1):96.

Neeper-Bradley, T. L., L. C. Fisher, D. J. Tarasi, E. H. Fowler and B. Ballantyne (1992). Developmental Toxicity Evaluation of Diethylene Glycol (DEG) Administered by Gavage to CD[®] (Sprague-Dawley) Rats. *Toxicologist* 12(1):102.

Neeper-Bradley, T. L., L. C. Fisher, B. L. Butler and B. Ballantyne. (1991). Developmental Toxicity Evaluation of 2-Ethyl-1,3-Hexanediol (EHD) Administered Cutaneously to CD[®] (Sprague-Dawley) Rats. *Toxicologist* 11(1):341.

Wilson, R. E., L. C. Fisher and J. P. Van Miller (1991). Dosing Developmental Cutaneous Toxicity Studies Using an Automated Dual Delivery System. *Toxicologist* 11(1):342.

Neeper-Bradley, T. L., R. W. Tyl, L. C. Fisher, D. J. Tarasi, D. L. Fait, D. E. Dodd, I. M. Pritts, R. S. Panson and S. A. Ridlon (1990). Developmental Toxicity Study of Inhaled Methyl Tertiary Butyl Ether (MTBE) in New Zealand White Rabbits and CD[®]-1 Mice. *Toxicologist* 10(1):41.

Fisher, L. C., R. W. Tyl, B. L. Butler, M. A. Vrbanic, J. P. Van Miller and C. R. Stack (1990). Developmental Toxicity Evaluation of 1,2,4,5-Tetrachlorobenzene (TCB) Administered by Gavage to Fischer 344 (F-344) Rats and New Zealand White (NZW) Rabbits. *Teratology* 41(5):556.

Neeper-Bradley, T. L., R. W. Tyl, L. C. Fisher, D. L. Fait, M. A. Vrbanic, J. P. Van Miller, P. E. Losco and C. R. Stack (1990). Reproductive Toxicity Study of 1,2,4,5-Tetrachlorobenzene (TCB) in the Diet of CD[®] Rats. *Teratology* 41(5):580.

Fisher, L. C., R. W. Tyl, L. J. Fosnight, M. F. Kubena and M. A. Vrbanic (1989). Development Toxicity of 2-Ethylhexanoic Acid (2-EHA) by Gavage in Fischer 344 Rats and New Zealand White Rabbits. *Toxicologist* 9(1):269.

Tyl, R. W., B. Ballantyne, L. C. Fisher, D. L. Fait, T. A. Savine, D. R. Klonne, I. M. Pritts and D. E. Dodd (1989). Developmental Toxicity of Ethylene Glycol (EG) Aerosol by Whole-Body Exposure in CD[®] Rats and CD[®]-1 Mice. *Toxicologist* 9(1):270.

Tyl, R. W., L. C. Fisher and M. F. Kubena (1989). Cutaneous Developmental Toxicity Study of 2-Ethylhexanol (2-EH) in Fischer 344 Rats. *Teratology* 39(5):452.

Tyl, R. W., L. C. Fisher, M. F. Kubena, P. E. Losco and M. A. Vrbanic (1989). Determination of a Developmental Toxicity "No Observable Effect Level" (NOEL) for Ethylene Glycol (EG) by Gavage in CD[®]-1 Mice. *Teratology* 39(5):487.

ABSTRACTS/PRESENTATIONS (continued)

Neeper-Bradley, T. L., L. C. Fisher, D. L. Fait, D. E. Dodd, I. M. Pritts, R. H. Garman and J. A. Barter (1989). Reproductive Toxicity Study of Inhaled Paradichlorobenzene (PDCB) Vapor in CD[®] Rats. *Teratology* 39(5):470.

Fisher, L. C., R. W. Tyl, T. A. Savine and J. M. Charles (1988). Developmental Toxicity Evaluation of 3-Chlorophenoxypropionic Acid (CPA) by Gavage to NZW Rabbits. *Toxicologist* 8(1):244.

Tyl, R. W., B. Ballantyne, L. C. Fisher, D. L. Fait, D. R. Klonne, I. M. Pritts and D. E. Dodd (1988). Developmental Toxicity Evaluation of Ethylene Glycol (EG) Aerosol by Nose-Only (NO) or Whole-Body (WB) Exposure in CD[®]-1 Mice. *Toxicologist* 8(1):242.

Tyl, R. W., L. C. Fisher, M. F. Kubena, M. A. Vrbanic and P. E. Losco (1988). Developmental Toxicity Evaluation of Ethylene Glycol (EG) Applied Cutaneously to CD[®]-1 Mice. *Teratology* 37(5):498.

Fisher, L. C., R. W. Tyl, T. A. Savine and J. M. Charles (1988). Developmental Toxicity Evaluation of 3-Chlorophenoxypropionic Acid (CPA) by Gavage to NZW Rabbits. *Toxicologist* 8(1):244.

Tyl, R. W., B. Ballantyne, I. M. Pritts, D. R. Klonne, L. C. Fisher, T. A. Savine, D. J. McNeil and M. F. Kubena (1987). Developmental Toxicity Evaluation of Inhaled Ethylene Glycol Monoethyl Ether (EGHE) in Rats and Rabbits. *Teratology* 35(2):53-54A.

Tyl, R. W., B. Ballantyne, D. L. Fait, L. C. Fisher, T. A. Savine, I. M. Pritts and D. E. Dodd (1987). Teratogenicity Evaluation of Water Aerosol (AER) or air (AIR) in CD[®]-1 Mice by Nose-Only (NO) or Whole Body (WB) Exposure. *Teratology* 35(2), 39A.

Tyl, R. W., K. A. France, L. C. Fisher, D. E. Dodd, I. M. Pritts, J. P. Lyon, F. O. O'Neal and G. Kimmerle (1986). Developmental Toxicity Evaluation of Inhaled Nitrobenzene (NB) in CD[®] Rats. *Toxicologist* 6:90.

Fisher, L. C., R. W. Tyl, K. A. France, R. H. Garman and B. Ballantyne (1986). Teratogenicity Evaluation of Bis(2-Dimethylaminoethyl) Ether after Dermal Application in New Zealand White Rabbits. *Toxicologist* 6:93.

Tyl, R. W., K. A. France, L. C. Fisher, E. J. Moran and R. D. Phillips (1985). Teratologic Evaluation of Inhaled Methyl Isobutyl Ketone (MIBK) in Fischer 344 Rats and CD[®]-1 Mice. *Toxicologist* 5:120.

Tyl, R. W., I. M. Pritts, K. A. France, L. C. Fisher and T. R. Tyler (1985). Developmental Toxicity Evaluation of Inhaled 2-Ethoxyethanol Acetate (EEA) in Rats and Rabbits. *Teratologist* 31(3):59A.