## BIOGRAPHICAL SKETCH

**NAME:** Daniel L. Black BS, RQAP-GLP (Photo: As President RMRCSQA, Introducing FDA speakers at USDA/APHIS Colorado)

**PROFESSIONAL HISTORY** I have held positions in Pharmaceutical, Biopharmaceutical, Chemical and Agricultural, and Preclinical Contract Industries. A list of some of my responsible duties/positions follow:

**Developmental and Reproductive Toxicology (DART) related responsible duties/positions include:** Lead Supervisor working under World-Renowned Teratologists including Jim Schardien, Mildred Christian, Alan Hoberman, and Dean Rodwell; President, MidWest Teratology Association; Program Director Midwest Teratology Group Supervisor of Teratology; Unit Supervisor of Teratology

**Preclinical Research/Pharmacology related responsible duties/positions include:** Vice President; Board Member; Director of Toxicology and PK (2 companies); Supervisor of Toxicology (2 companies); Supervisor of Live Phase GLP Safety Assessment and Molecular Markers; Senior Scientist, Research Scientist; Associate Scientist; Training Manager, Study Director; Study Monitor; Senior Research Scientist; Senior Biologist; Senior Research Associate; and Research Associate. I am proficient and have been the designated trainer in most live-phase technical procedures in large and small animals (mice to Primates).

**Quality Assurance-related responsible duties/positions include:** I am a Registered Quality Assurance Professional (RQAP-GLP) since 2001 (one of the original certified QA professionals) and a Quality Assurance Consultant. Past-President (former President), Rocky Mountain Regional Chapter Society of Quality Assurance: Director of Quality Assurance; Preclinical drug Safety Training Manager; GLP Systems Assessor; Business Project Manager of Biopharmaceutics System Validation; Coordinator/Manager and Primary Author of Preclinical Standard Operating Procedures (3 companies); Preclinical and Human Clinical Drug Safety Quality Assurance and Quality

Control Auditor; Contract Consultant Quality Assurance Auditor; Director on the Board, Rocky Mountain Regional Chapter of the Society of Quality Assurance (elected three times)

**Nominated/appointed duties/positions include:** Director on the Board of CARE research, Inc.; RMRCSQA Chair of Membership Committee, and Nominating Committee; National SQA Membership, Retention, and Development Committee, Nomination Task Force, and Tellers Committee; Corporate 21 CFR Part 11 Working Group GLP member; IACUC Scientific Member; Preclinical Toxicology Project Team Member for Oncology NDA candidates.

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Website: www.preclinicalsciencesllc.com

**RELEVANT EMPLOYMENT HISTORY: (references on request)**

**I am the Founder of CARE Research, Inc. as a Non-Clinical laboratory in October 2007. CARE Research Inc. was purchased by CARE Research, LLC on 25 March 2010. Care Research LLC was purchased by Mountain West Research in 2020 (CARE Research LLC is currently used as the company name during transition). I am currently Vice President, Director of Toxicology and PK**

As Vice President and Director of Toxicology and Pharmacokinetics; I am a primary point of control for all preclinical research conducted at CARE Research, Inc.

**CARE Research, Inc., 6200 E County Rd 56, Inc., Ft. Collins, CO, Vice President, Director of Toxicology and Pharmacokinetics**

As Vice President and Director of Toxicology and PK I was the primary point of control for all preclinical research conducted at CARE Research, Inc. I was a member of the Board.

**Contract Consultant: Quality Assurance Auditor and GLP Consultant**

Various companies, including facility and study/project auditing, writing of SOPs, creating training program and drafting training documents, system validation, etc.,

**Preclinical Research Services, Inc., Ft. Collins, CO**
**Director of Toxicology and PK (formerly Director, Quality Assurance)**

On 31 December 2006, OSI Pharmaceuticals, Inc. down-sized and eliminated their GLP preclinical safety assessment and molecular markers live-phase toxicology group. I was Senior Scientist and Supervisor of that group. I and my group were laid off. I was retained until 31 January 2007 to close out the GLP functions at OSI. I was hired by Preclinical Research Services 15 February 2007 as Director of Quality Assurance.

I was Director of Quality Assurance until 01 Sept 2007. My Director of Quality Assurance duties were to write all SOPs and implement all procedures and documentation necessary to bring the former Non-GLP preclinical CRO into GLP compliance. I have been responsible (and successful) for similar tasks in 3 other companies.

Beginning 01 Sept 2007 I became Director of Toxicology and PK for the company. As Director of Toxicology and PK, I was responsible for all aspects of the design, conduct, and reporting of protocol-driven preclinical studies of all types in large and small animals.

**OSI Pharmaceuticals, Inc., Boulder, CO**
**Title: Senior Research Scientist, Supervisor of Safety Assessment and Biomarkers (including GLP Toxicology and Teratology)**

*Note: OSI purchased Preclinical drug safety and Oncology Assets and Preclinical Toxicology from Gilead Sciences 01 January 2002*.
Duties while at OSI included but were not limited to:

1) Senior Scientist and Supervisor of Live Phase Safety Assessment and Molecular Markers Standard duties included: Supervised a staff of 5 Research Associates, Study Director for GLP and Non-GLP preclinical studies, Protocol author for preclinical toxicology studies, Author of Final Reports for GLP and Non-GLP preclinical toxicology studies, and Study Monitor for contracted studies.

In addition to Senior Scientist and Supervisor responsibilities, I voluntarily took on the following additional responsibilities:

2) Quality Assurance Auditor/Inspector assistance for the GLP Compliance Department for assigned contracted GLP studies and in-house studies on which I have no investigational or management involvement, and for CRO site inspections.
3) IACUC Scientific Member.
4) Coordinator/Manager of Standard Operating Procedures (SOP's).
5) Primary author of Standard Operating Procedures (SOP's).
6) Preclinical (Life Sciences) Training Documentation and Coordinator.
7) 21 CFR Part 11 Corporate Working Group member representing GLP Compliance.
8) GLP Systems Assessor.
9) Project Team Preclinical Toxicology Member for the Aptosyn Project.
10) Business Project Manager of Biopharmaceutics HPLC and MS/MS Systems Validation.
11) Business Project Manager of SOP Migration to EDMS.
12) Electronic Data Management System (EDMS by Qumas) GXP Project Team Member.
13) Advisor to management and to the Quality Assurance Unit regarding preclinical drug safety regulatory requirements.
14) Backup for Preclinical Quality Assurance relevant to regulatory inspections.
15) Provide review and expert opinion with respect to regulatory agency and laboratory management questions concerning Developmental and Reproductive Toxicology (DART) Studies.
16) Managed the GLP toxicology Reserve Sample collection, storage, and documentation function until I delegated the responsibility to one of my employees.
17) .Designated trainer DART and general toxicology procedures.
18) Assist non-toxicology areas in the design of studies and protocols for those studies intended to be for submitted to regulatory agencies.
19) Design and implement nonclinical drug safety toxicology study raw data forms.
20) Designated GLP Trainer for GLP raw data recording and correction.

**Berthoud High School, Berthoud, CO**
**Title: Assistant Track Coach**

Coach of Men's and Women's middle and long distance units

**Gilead Sciences, Inc., Boulder, CO**
**Title: Associate Scientist**

*Note: Prior my hire January 2000, the preclinical drug safety laboratory of Gilead Sciences was strictly exploratory (Non-GLP). The primary purpose of my hire was to determine what was required to change to a GLP nonclinical drug safety laboratory, and then to take action toward that goal in a reasonable amount of time. Most of the following activities were directed toward that goal. The preclinical drug safety laboratory became GLP compliant January 2001 (including AAALAC accreditation).*

Duties included but were not limited to:
1) Coordinator and Author of Standard Operating Procedures (SOP's).
2) Preclinical (Life Sciences) Training Documentation and Coordinator (I designed the Life Sciences Training Program).
3) Primarily responsible for the development, organization, and implimentation of the Gilead Sciences, Inc., Boulder, CO Quality Assurance Unit.
4) Conducted or provided assistance with the conduct of Quality Assurance and Quality Control audits of preclinical and human clinical drug safety studies.
5) Conducted GLP site inspection of contracted laboratories.
6) Provided review and expert opinion with respect to regulatory agency and laboratory management questions concerning Gilead Sciences, Inc. Developmental and Reproductive Toxicology Studies.
7) I was an advisor to management and to the Quality Assurance Unit regarding preclinical drug safety regulatory requirements.
8) Managed the GLP toxicology Reserve Sample collection, storage, and documentation function.
9) Helped re-design the nonclinical toxicology GLP Master Schedule and assist the Research Planner and Quality Assurance Unit in its maintenance.
10) Study Director (GLP and Non-GLP) for studies on which I had no QA activities.
11) Final protocol and report author for studies on which I was assigned as the Study Director.
12) Drafted protocols and final reports (materials and methods and live phase results) for all in-house GLP toxicology studies, and those in-house Non-GLP toxicology studies intended for submission to regulatory agencies on which I was not assigned as Study Director. In addition, I drafted protocols and aid in the monitoring for some contracted nonclinical drug safety studies.
13) I directed and conducted all in-house developmental and reproductive toxicology studies.
14) Assisted non-toxicology areas in the design of studies and protocols for those studies intended to be for submitted to regulatory agencies.
15) Designed and implemented nonclinical drug safety toxicology study raw data forms.

16) I provided in-life and necropsy assistance whenever needed.

**Primedica Redfield Laboratories (Div. of Charles River, formerly Div. of Argus Labs), Redfield, Arkansas**
**Training Manager, Toxicology/Teratology Supervisor**

Responsibilities Included but were not limited to:

1) Manager of toxicology and teratology GLP study conduct training program.
2) Toxicology and Teratology Technical Trainer.
3) Oversaw (supervisor of) the toxicology and developmental and reproductive toxicology (teratology) program.
4) Conducted GLP and Non-GLP developmental and reproductive toxicology studies, and GLP juvenile and neonatal toxicology studies in species including primates.
5) Assisted in study conduct functions.
6) Interfaced with regulatory officers during regulatory inspections.
7) Interfaced with Sponsors and Study Directors regarding study conduct.

**The Upjohn (Pharmacia & Upjohn) Company, Kalamazoo, MI**
**Research Biologist II/III/IV/Senior Biologist/Study Director**
**Toxicology Operations - North America**
**Worldwide Drug Safety**

Responsibilities included but were not limited to:

1) Study Director, developmental and reproductive toxicology.
2) Principal Investigator, developmental and reproductive toxicology.
3) Senior Biologist, developmental and reproductive toxicology (rats, mice, rabbits, and primates).
4) Study Monitor of assigned outsourced developmental and reproductive toxicology studies.
5) Primary author of the reproductive and Developmental Toxicology Training Manual.
6) Merger Team member.
7) Weinberg Computer Validation Team member.

**Otsego High School, Otsego, MI**
**Title: Head Cross Country Coach**

Coach of Men's and Women's teams

**Rohm and Haas Company, Spring House, PA**
**Scientist II, Teratology**

Responsibilities included but were not limited to:

1) Principal Investigator responsible for the conduct of GLP and Non-GLP chemical safety studies in accordance with EPA and all relevant guidelines and regulations.
2) Training of technical staff, data collection, data tabulation, data interpretation, protocol preparation, final report preparation.
3) The primary purpose of my hire by Dr. Jean Hirsekorn was to help set up an in-house developmental and reproductive toxicology laboratory – which I did successfully.

**International Research and Development Corporation,**
**Mattawan, MI**
**Research Associate, Large Animal Toxicology, Research Associate in Teratology, Unit Supervisor Teratology, Group (Head) SupervisorTeratology**

Responsibilities Included but were not limited to:

1) Head supervisor of a very large teratology laboratory (laboratory staff of 18 associates and 2 unit supervisors.
2) Primary trainer of laboratory staff in teratology procedures.
3) Numerous large and small animal procedures (mice to primates).
4) Developmental and reproductive toxicology procedures (including but not limited to dam, sire, fetus, and neonatal necropsy procedures, sperm analysis, estrous monitoring, and functional/behavioral development).

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Other work: I have been a substitute teacher for elementary, Jr. high, and high school (mostly biology classes), and for special needs children. In college, among other jobs, I was supervisor for student maintenance employees and was the fieldhouse supervisor.

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**EDUCATION: DEGREES AND CERTIFICATION:**

Aquinas College, B.S., Environmental Studies (Major #1)
Aquinas College, B.S., Biology (Major #2)
Registered Quality Assurance Professional Certification (RQA-GLP)
CHSAA Coaching Certification
Turner Flight School, Pilot Certification

**SIGNIFICANT HONORS, PROFESSIONAL & RESEARCH SOCIETY MEMBERSHIPS**

**(PAST and PRESENT):**

National Society of Quality Assurance
RMRC of the Society of Quality Assurance
OSI 21 CFR PART 11 Working Group Member (GLP Expert)
National Teratology Society
AALAS (National)
Midwest Teratology Association
Elected to Director on the Board, Rocky Mountain Regional Chapter of the Society of Quality Assurance (RMRCSQA)
RMRCSQA Membership Committee (Chair)
RMRCSQA Nominating Committee
National SQA Membership, Retention, and Development Committee
Mid-Atlantic Chapter of the Society of Toxicology
Middle Atlantic Reproduction Teratology Association
Nominated to Run for Office (Secretary/Treasurer), Midwest Teratology Association
Elected to Program Director, Midwest Teratology Association
Elected President Elect, Midwest Teratology Association
Elected Vice President RMRCSQA
President, Midwest Teratology Association
Nominated Midwest Teratology Association Constitution & By-Laws Chairperson
Midwest Teratology Association Hotline Captain
Reviewer for Teratology, Journal of Abnormal Development
OSI Pharmaceuticals, Inc., Performance Award (for Facility GLP Compliance)
Gilead Sciences, Inc., Spot Award for helping with the European registration of Viread
P&U DART Merger Team Member
The Upjohn Company (TUC) Buck Award
Member, Weinberg Computer Validation Team
Multiple Award Winner in the Dale Carnegie Class (Highest Award for Achievement, Outstanding Performance Award, Reporting Award, Special Award for Achievement, and Human Relations Award
Coach of the Year (Upjohn Corporate Olympics - running), 1995,96,97
Ranked #4 Master Marathon Runner in USA (Running Times Magazine), 1994
Third Place, National Canoe Triathlon (USCA) Championship (Tandem), 1989
Runner-Up, National Canoe Triathlon (USCA) Championship (Tandem), 1988
Overall Medal Winner, The Boston Marathon, 1986, 1987, 1988, 1994

State #1 Finisher, The Boston Marathon, 1988
National College Scholar Athletes of the Year
High School and College Team Captain and MVP
All-State High School Cross Country
All-State High School Track
National High School RRCA Cross Country Champion

**Relevant Post-Graduate Course Work and Training Summary Available on Request**

**PUBLICATIONS:**

Novel: The Banana People, accepted for marketing by ST Literary Agency. Current

Steven Smith, Dan Black, Di Song, and Anthony Ford. A Novel Method to Estimate AF-219 Levels in Bladded Interstitium Derived from Drug Excreted into the Urine, FASEB J., April 9, 2013, 27:887.5

Lisa S. Bertram, Daniel Black, Paul Briner, Rosemary Chatfield, Andrew Cooke, Matthew Fyfe, P. John, Murray, Frederic Naud, Masao Nawano, Martin J. Procter, Gunaj Rakipovski, Chrystelle M. Rasamison, Christine Raynet, Karen Schofield, Vilas K. Shah, Felix Spindler, Amanda Taylor, Roy Turton, Geoffrey M. Williams, Philippe Wong-Kai-In, and Kasuka Yasuda. SAR, Pharmacokinetics, Safety, and Efficacy of Glucokinase Activating, 2-(4-Sulfonylphenyl)-N-thiazol-2-ylacetamides: Discovery of PSN-GK1. Accepted for publication in the Journal of Medicinal Chemistry 22 May 2008.

Black, D. L. One Approach to Raw Data Collection and Correction for both GLP and Non-GLP Nonclinical laboratory Studies. The Journal, Rocky Mountain Regional Chapter of the Society of Quality Assurance, Vol X, Issue 2, June 2002.

Black, D. L. and T.A. Marks. Role of Maternal Toxicity in Assessing Developmental Toxicity in Animals: A Discussion. Regulatory Toxicology and Pharmacology, 16, 189-201 (1992).

Black, D. L., T. A. Marks, D. G. Branstetter, and K. T. Kirton, 1991. Reversal of Bropirimine Developmental Toxicity with Progesterone. Toxicology and Applied Pharmacology, 108:121-128.

Black, D. L. and T. A. Marks, 1986. Inconsistent Use of Terminology in Animal Developmental Toxicology Studies: A Discussion. Teratology 33: 333-338.

Marks, T.A., D.L. Black, and D.E. Tracie. Prevention of Human Recombinant Interleukin-1□ (rhIL-1□) Embryolethality with Progesterone or Indomethacin. In Review.

Marks, T.A., D.L. Black, and R.D. Terry. Counteraction of the Embryolethal Effects, But Not the Maternal Toxicity, of Bropirimine and Tilorone by Coadministration of Indomethacin. Journal of the American College of Toxicology 13(2):93-102 (1994).

Marks, T. A., D. L. Black, R. D. Terry, D. G. Branstetter, K. T. Kirton. Variability in the Developmental Toxicity of Bropirimine with the Day of Administration. Teratology, 42:55-66 (1990).

Poppe, S. M., T. A. Marks, G. M. Mesfin, D. L. Soule, C. I. Shaw, D. F. Morris, D. L. Black. Reproductive and Developmental Effects on Rats After Prenatal, Postnatal or Pre- and Postnatal Exposure to the Hypotensive Agent Losulazine. Teratology, 36:171-180 (1987).

Costlow, R. D., J. M. Hirsekorn, R. G. Steratelli, G. P. O'Hara, D. L. Black, W. K. Kane, S. S. Burke, J. M. Smith and A. W. Hayes. The Effects on Rat Pups When Nitrofen (4[2,4-Dichorophenoxy] Nitro-benzene) was Applied Dermally to the Dam During Organogenesis. Toxicology, Vol. 28, Nos. 1,2:37-50 (1983).

Black D.L. Pharmacia & Upjohn Developmental and Reproductive Toxicology (DART) Training Manual. Revised 25 August 1997. Variations of this manual are in use (with permission) in other companies.

**ABSTRACTS:**

Morris, D. F., T. A. Marks, G. M. Mesfin, S. M. Poppe, D. L. Black, D. L. Soule, C. I. Shaw. The Effects of Losulazine on Development in Rats. Teratology, 33(3):97c-97c (1986).

Poppe, S. M., T. A. Marks, G. M. Mesfin, D. L. Soule, C. I. Shaw, D. F. Morris and D. L. Black, 1986. Reproductive and Developmental Effects on Rats After Perinatal, Postnatal, or Peri-Postnatal Exposure to the Hypotensive Agent Losulazine. Teratology, 33(3):36c-36c (1986).

Poppe, S. M., Marks, T. A., Mesfin, G. M., Soule, D. L., Shaw, C. I., Morris, D. F. and Black, D. L. (1986): A Modified Segment III Peri-Postnatal Study in Rats on the Hypotensive Agent Losulazine. Teratology, 33, 36C.

Black, D. L., T. A. Marks, D. L. Soule, C. I. Shaw, S. M. Poppe, D. F. Morris. A Segment III Peri-Postnatal Study in Rats on the Immunomodulator Bropirimine. Teratology, 35(2):30a-30a (1987).

Marks, T. A., S. M. Poppe, D. L. Black, D. F. Morris, C. I. Shaw, R. D. Terry. Developmental Toxicity of Bropirimine After Oral Administration to Pregnant Rats. Teratology, 35(2):30a-30a (1987).

Marks, T. A., D. L. Black, S. M. Poppe, R. D. Terry. Developmental Toxicity of Bropirimine. The Toxicologist, 8(1):64 (1988).

Branstetter, D. G., T. A. Marks, D. L. Black, S. M. Poppe, R. D. Terry. Bropirimine Induced Necrosis of the Uterine Decidua During Gestation. The Toxicologist, 8(1):237 (1988).

Marks, T. A., Black, D. L., Terry, R. D., Branstetter, D. G. and Kirton, K. T. (1989): Reversal of Bropirimine or Tilorone Developmental Toxicity with Progesterone. V International Congress of Toxicology, Brighton, England, Abstract 461.

Marks, T. A., Black, D. L., Branstetter, D. G. and Kirton, K. T. (1990): Reversal of Bropirimine Embryolethality with Progesterone or Indomethacin. The Toxicologist, 10, 126.

**ORAL PRESENTATIONS:**

Invited Speaker (4-hour oral presentation), Rocky Mountain Regional Chapter of the Society of Quality Assurance (RMRCSQA) Annual Training Session, 28 Sept 2004: Computerized System Validation

Presented an oral presentation on the negative geotaxis parameter as used at Upjohn in the Segment One Reproduction and Teratology Study, at the Midwest Teratology Association Workshop, July 27, 1984.

Guest lecturer on teratology for Temple University graduate students, April 1982, at the Rohm and Haas Company, Spring House, PA.

Presented an oral presentation on the reproductive difficulties experienced by Shetland Sheep Dogs at Morribrook Kennel, at the section meeting, Feb. 1986.

Relevance of Frequently Encountered Fetal Abnormalities in Assessing the Teratogenicity of a Test Substance - The Gray Area, M.A.R.T.A. Meeting, February, 1987.

A Segment III Peri-Postnatal Study in Rats on the Immunomodulator Xxxxx, National Teratology Society Meeting, 16 June 1987.

Malformations and/or Lesions in Animals Procured from Commercial Suppliers, The 36th Meeting of the Midwest Teratology Association, 19 October 1990.

Facilitator, 36th Meeting of the Midwest Teratology Association, 19 October 1990.

Terminal Bleeding Via the Abdominal Aorta in the Rat, The Midwest Teratology Association Workshop, 25 April 1991.

Oral Dosing Via a Rubber Gavage Tube in the Rabbit, The Midwest Teratology Association Workshop, 25 April 1991.

Facilitator, The 37th Meeting of the Midwest Teratology Association, 25 and 26 April 1991.

Increased litter size in Charles River (Portage) Crl:CD[BR] Sprague Dawley Rats, Midwest Teratology Association Meeting. 7-8 May 1991.

Facilitator, The 40th Meeting of the Midwest Teratology Association, 5 November 1992.

Facilitator, The 41st Meeting of the Midwest Teratology Association, 23 April 1993.

On many occasions I have substitute taught various high-school, junior high school, and elementary biology (and other) classes (Otsego, Plainwell and Allegan public schools, Michigan).

GLP Course, Instructor, BioTox Sciences and BioQuant, SanDiego CA, 11 August 2011

GLP Canine Necropsy Procedures, Instructor, BioTox Sciences and BioQuant, SanDiego CA, 12 August 2011