

Curriculum Vitae

L. Bruce Pearce, Ph.D.

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Senior Consultant

Biologics Consulting Group, Inc.

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EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant

Hudson, NH (July 2010 - present)

Therapeutics Development Sciences Consultant, (2009-2010)

- Provided expertise in therapeutics development including; non-clinical and clinical pharmacology, program strategic/technical design, management and assessment, quantitative outcomes analysis, safety signal detection, and benefit-risk balance assessment.
- Developed methods to provide blinded assessment of safety and benefit-risk balance at all phases of clinical development and in support of regulatory requirements for RMAPs, and REMs.
- Provided project and program risk/uncertainty assessment to reduce costs and minimize timelines based on execution algorithms supporting evidence-based decision making at all levels of development, non-clinical through post marketing surveillance.
- Advisory group member for biopharmaceutical companies developing new therapeutics. Development of Scoring in Benefit-Risk Assessment website (<http://www.SIBRA.org>) dedicated to promoting the development of quantitative methods for outcome analysis and benefit-risk assessment in clinical trials.

Biopure Corporation, (Developer, manufacturer, and marketer of hemoglobin-based oxygen therapeutic products.), Cambridge, Massachusetts, (1996-2008)

Director, Clinical Research & Pharmacology (2005-2008)

Supervised personnel, including statisticians and scientists to define product efficacy and safety characteristics. Developed relative efficacy theory to explain safety findings for product suite. Conducted data analyses and authored responses to questions from FDA regarding preclinical and clinical issues. Coauthored meta-analysis of results for 22 clinical trials, providing 1st integrated safety analysis. Prepared responses to all clinical efficacy and safety issues arising from MHRA critique of marketing application. Represented company clinical research and pharmacology to FDA and MHRA in UK. Administered and coauthored submissions to FDA, addressing efficacy, safety and risk/benefit profile issues.

- Teamed with biostatistician to achieve acceptance of database by regulatory authorities through coauthoring report on data cleaning and restructuring safety database and comprehensive conferences/meetings with FDA.
- Collaborated with biostatistician and clinical scientists to reanalyze results from phase 3 clinical trial, which was basis for new drug license application and was stopped due to safety issues; determined root cause for safety signals in study and presented explanations in publication.
- Provided 1st comprehensive explanation for major safety issues identified for other products within field; presented results to FDA Advisory Committee (9/08).
- Co-developed method for quantitative analysis of benefit/risk assessment (Sibra.org), which has proven to be more cost effective and provides major advances over current, non-quantitative approaches; method incorporates clinical contextualization and system for scoring of benefit and risk outcome. Presented to Office of Translational Sciences at FDA (2009).
- Managed and authored 2008 version of clinical investigator's brochure.
- Acted as primary author of clinical protocol for treatment of life-threatening severe anemia due to acute myeloid leukemia in Jehovah Witness patients; functioned as project team leader and regulatory affairs representative.

Trauma Program Manager (2003-2008)

Acted as principal investigator, directing all studies performed under DoD grants. Oversaw preclinical animal research in support of trauma program, including protocol design, data analysis, and report/publications preparation. Directed development of in-hospital phase 2 safety protocol to study hemorrhagic shock patients; chaired Trauma Studies Committee. Designed and coauthored clinical protocols, including trials proposed under waiver of informed consent for emergency research. Functioned as lead author on SBIR grant applications.

- Provided \$27M+ in federal funding through authoring and negotiating cooperative research and development agreement (CRADA) with US Naval Medical Research Center for product development and clinical trails.
- Played integral role as coauthor and co-principal investigator in design and development of phase 2/3 protocol for investigating product use in treatment of hemorrhagic shock in out-of-hospital setting based on CRADA.

Director, Pharmacology & Physiology (2002-2004)

Led product development as adjunct to radiation therapy in glioblastoma. Designed and authored phase 1 protocol in tandem with medical scientists; prepared CRF study reference manual and analysis plan. Held project management accountability for all functions supporting clinical trails, including CRA recruitment, initiation visits, and progress status. Designed and reviewed PK and population PK studies in support of preclinical and clinical studies, and coauthored section 6 of biologics license application (BLA).

- Collaborated with leading scientists to establish mechanism of teratology findings in rodents leading to white paper describing false positive finding in lower mammals and symposium at Teratology Society Meeting.
- Prepared abstracts and tabular summaries for 150+ studies and authored Nonclinical Pharmacology and Toxicology section 5 of BLA.
- Teamed with mathematician/biostatistician to reanalyze data from 22 clinical trials to address FDA queries regarding safety and efficacy issues following regulatory review of BLA.

Associate Director, Pharmacology & Physiology (1999-2001)
Senior Scientist (1996-1999)

Administered preclinical research efforts with CROs, universities, military organizations, and foundations. Negotiated contracts and licensing agreements. Contributed to design and execution of study protocols. Presented data analysis to regulatory agencies. Managed preclinical section of BLA. Drafted SBIR grant applications.

- Instituted preclinical trauma program, heading design, execution, analysis, report preparation and submission, and publication of study findings.
- Established and chaired Trauma Studies Committee, which encompassed advisory panel of clinical/non-clinical experts in trauma and emergency medicine; chaired meetings.
- Spearheaded design, development, and management of pharmacology, pharmacokinetics, teratology, genotox, cardiotox, and general toxicology protocols.

Interactive Biologics Associates

(Joint venture with Associated Synapse Biologics; developer and manufacturer of therapeutic botulinum toxin.)

Cambridge, Massachusetts, (1992-1995)

Director, R&D (1994-1995) –

Lead Basic Science Investigator/Co-Founder—Associated Synapse Biologics (1992-1994)

Managed investigations for development of botulinum toxin for treating neurologic disorders; participated in development and design of phase 1 and 2 clinical trials and corresponding meetings with FDA. Contributed to business strategic development, negotiation, and joint venture functions. Designed and led all preclinical research and managed contract research, formulation development, and manufacturing supporting clinical trials. Defined new unit of biologic activity to assess efficacy and potency of clinical formulations of botulinum toxin. Invented patent describing unique efficacy of mixtures of botulinum toxin serotypes. Played key role in contracting and licensing universities and foundations.

Also acted as Adjunct Associate Professor and Assistant Professor (Department of Pharmacology) for Boston University.

EDUCATION

Postdoctoral *Pharmacology*, Harvard University, (1985-1987)

Postdoctoral *Pharmacology*, Yale University, (1983-1985)

Ph.D. *Pharmacology*, State University of New York (1984)

B.A. *Chemistry/Biology*, University of Massachusetts, (1978)

PUBLICATIONS

1. **Pearce, LB**, Pitman A., Greenburg, AG, Freilich, DA, and Kaplan L. Application of a unique scoring system for numerical determination of a benefit risk ratio in clinical trials. (*Manuscript In preparation*), 2010
2. Pitman, AN and **Pearce, LB**. A Flexible Outcome Scoring System for Clinical Trials. (*Manuscript in preparation*), 2010
3. **Pearce, LB** and Pitman, A. The Design of Clinical Trials Investigating the Treatment of Perioperative Anemia. (*Manuscript in preparation*), 2010
4. **Pearce, LB**, Pitman, A., and Connolly, M. The Coupling of Efficacy and Safety in Clinical Trials of Hemoglobin-Based Oxygen Carriers: Evidence from a Logistic Model of the Contribution of Low Total Hb Concentrations to the Risk of Adverse Events (*Manuscript in preparation*), 2009
5. **Pearce, LB**, Pitman, AN, and Greenburg, AG. Results of Research with Haemoglobin-Based Oxygen Carriers (HBOCs): Evidence of Toxicity or Failure to Assess Relative Efficacy? (submitted for publication), 2010
6. Berzins, M., Bebris, L., Ahlers, S., and McCarron, R., et al. HBOC-201 vasoactivity in a Phase III clinical trial in orthopedic surgery subjects-extrapolation of potential risk for acute trauma trials. *J. Trauma Feb;66(2):365-76,2009*
7. Greenburg, AG, Pitman, A., **Pearce, LB**, and Kim, HW. Clinical Contextualization and the Assessment of Adverse Events in HBOC Trials. *Artif Cells Blood Substit Immobil Biotechnol.* Nov 27:1-10, 2008
8. Jahr, JS, Mackenzie, C., **Pearce, LB**, Pitman, A., and Greenburg, AG. HBOC-201 as an alternative to blood transfusion: efficacy and safety evaluation in a multicenter phase III trial in elective orthopedic surgery. *J Trauma.* Jun;64(6):1484-97, 2008
9. Malkevich, NV, Dong, F., Vandermolen, CA, Philbin, NB, Rice, JP, Scultetus, A., Hong, J., Arnaud, F., Hall, CH, McGwin, G. Jr, **Pearce, LB**, Handrigan, M., Ahlers, S., McCarron, RM, and Freilich, D. Innate immune response after resuscitation with

- hemoglobin-based oxygen carrier and recombinant factor VIIA in uncontrolled hemorrhagic shock in a swine model. *J Trauma*. Jun;64(6):1498-510, 2008
10. Stern, S., Rice, J., Philbin, N., McGwin, G., Arnaud, F., Johnson, T., Flournoy, WS, Ahlers, S., Pearce, LB, McCarron, R., and Freilich, D. Resuscitation with the Hemoglobin-based Oxygen Carrier, HBOC-201, in a swine model of severe uncontrolled hemorrhage and traumatic brain injury. *Shock*. May 19; [Epub ahead of print], 2008
 11. Rice, J., Philbin, N., Light, R., Arnaud, F., Steinbach, T., McGwin, G., Collier, S., Malkevich, N., Moon-Massatt, P., Rentko, V., Pearce, LB, Ahlers, S., McCarron, R., Handrigan, M., and Freilich, D. The effects of decreasing low-molecular weight hemoglobin components of hemoglobin-based oxygen carriers in swine with hemorrhagic shock. *J Trauma*. May;64(5):1240-57, 2008
 12. **Pearce, LB**, Pitman, AN, and Connolly, M. Risk of adverse outcome due to acute anemia in the orthopedic surgical setting. *Clin Pharmacol & Thera*. 83(Suppl 1):S39, 2008
 13. **Pearce, LB**, Pitman, AN, and Greenburg, AG. Breaking the rules: misinterpretation of dose-response relationships in clinical trials. *Clin Pharmacol & Thera*. 83(Suppl 1):S87, 2008
 14. **Pearce, LB**, Pitman A., Greenburg, AG, Freilich, DA, and Kaplan L. Application of a unique scoring system for numerical determination of a benefit risk ratio in clinical trials. *Clin Pharmacol & Thera*.83(Suppl 1):S87-88, 2008
 15. Pitman, AN and **Pearce, LB**. A flexible outcome scoring system for clinical trials. *Clin Pharmacol & Thera*. 83(Suppl 1):S87, 2008
 16. VanderMolen, C., Malkevich, N., Philbin, N., Rice, J., Collier, S., Hall, C., Ahlers, S., McCarron, R., Freilich, D., McGwin, G., and Pearce, LB. Immune effects of decreasing low-molecular weight hemoglobin components of hemoglobin-based oxygen carriers (HBOC) in a swine model of severe controlled hemorrhagic shock. *Artif Cells Blood Substit Immobil Biotechnol*.35(5):507-17, 2007
 17. Hall, C., Malkevich, N., Handrigan, M., Vandermolen, C., Arnaud, F., Hong J., Dong, F., Rice, J., Philbin, N., Ahlers, S., McCarron, R., Freilich, D., McGwin G, Flournoy, WS, and Pearce, LB. Innate immune responses in Swine resuscitated from severe traumatic hemorrhagic shock with hemoglobin-based oxygen carrier-201. *Artif Cells Blood Substit Immobil Biotechnol*. 35(3):259-74, 2007
 18. Rice J, Philbin N, Handrigan M, Hall C, McGwin G, Ahlers S, Pearce LB, Arnaud F, McCarron R, Freilich D. Vasoactivity of bovine polymerized hemoglobin (HBOC-201) in swine with traumatic hemorrhagic shock with and without brain injury. *J Trauma*. Nov;61(5):1085-99, 2006

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20. Arnaud, F., Handrigan, M., Hammett, M., Philbin, N., Rice, J., Dong, F., Pearce, LB, McCarron, R., and Freilich, D. Coagulation patterns following hemoglobin-based oxygen carrier resuscitation in severe uncontrolled hemorrhagic shock in swine. *Transfus Med*. Aug;16(4):290-302, 2006
21. Johnson, T., Arnaud, F, Dong, F., Philbin, N., Rice, J., Asher, L., Arrisueno, M., Warndorf, M., Gurney, J., McGwin, G., Kaplan, L., Flournoy, WS, Apple, FS, Pearce, LB, Ahlers, S., McCarron, R., and Freilich, D. Bovine polymerized hemoglobin (hemoglobin-based oxygen carrier-201) resuscitation in three swine models of hemorrhagic shock with militarily relevant delayed evacuation—effects on histopathology and organ function. *Crit Care Med*. May;34(5):1464-74, 2006
22. Dong, F., Hall, CH, Golech, SA, Philbin, NB, Rice, JP, Gurney, J., Arnaud, FG, Hammett, M., Ma, X., Flournoy, WS, Hong, J., Kaplan, LJ, **Pearce, LB**, McGwin, G., Ahlers, S., McCarron R., and Freilich D. Immune Effects of Resuscitation with HBOC-201, A Hemoglobin-based Oxygen Carrier, in Swine with Moderately Severe Hemorrhagic Shock from Controlled Hemorrhage. *Shock*. 25(1):50-55, 2006
23. **Pearce, LB**, Gawryl, MS, Rentko, VT, Moon, P., and Rausch, CW. HBOC-201, [hemoglobin glutamer-250 (bovine), Hemopure®]: Clinical Studies 2005 In: *Blood Substitutes* Ed. Robert M. Winslow, Eslevier, Amsterdam, 437-450, 2005
24. Rentko, Gawryl, MS, **Pearce, LB**, and Moon-Massat, PF. Hemopure®, [HBOC-201, hemoglobin glutamer-250 (bovine), Hemopure®]: Pre-clinical Studies In: *Blood Substitutes* Ed. Robert M. Winslow, Eslevier, Amsterdam, 424-450, 2005
25. Holson, JF, Stump, DG, **Pearce, LB**, Watson RE, and DeSesso, JM. Mode of action: yolk sac poisoning and impeded histiotrophic nutrition--HBOC-related congenital malformations. *Crit Rev Toxicol*. 35(8-9):739-45, 2005
26. Arnaud, F., Hammett, M., Asher, L., Philbin, N., Rice, J., Dong, F., **Pearce, LB**, Flournoy, WS, Nicholson C., McCarron R., and Freilich, D. Effects of bovine polymerized hemoglobin on coagulation in controlled hemorrhagic shock in swine. *Shock*. 24(2):145-52, 2005
27. Warndorf, Matthew, Dong, Feng, Philbin, Nora B., Rice, Jennifer, P., Arnaud, Francoise, G, **Pearce, LB**; McCarron, Richard, M., and Freilich, Daniel. A Role of HBOC-201 resuscitation in ischemic-reperfusion injury in major organs from swine with hemorrhagic shock. *ASAIO Journal*. 51(2):6A, 2005

28. Arnaud, F., Hammett, M., Dong, F., Rice, J., **Pearce, LB**, McCarron, R., Nicholson, C., and Freilich, D. Hemostatic effects of HBOC-201 in a swine hemorrhagic shock model of controlled hemorrhage. *ITACCS*, 2005
29. Philbin N., Rice, J., Gurney, J., McGwin, G., Arnaud, F., Dong, F., Johnson, T., Flournoy, WS, Ahlers, S., **Pearce, LB**, McCarron, R, and Freilich, D. A hemoglobin-based oxygen carrier, bovine polymerized hemoglobin (HBOC-201) versus hetastarch (HEX) in a moderate severity hemorrhagic shock swine model with delayed evacuation. *Resuscitation*. 66(3):367-78, 2005
30. Philbin, N., Rice, J., Gurney, J., Arnaud, F., Dong, F, **Pearce, LB**, McCarron, RM, and Freilich, D. HBOC-201 Reduces fluid requirements in a controlled hemorrhagic shock swine model with delayed evacuation. *ASAIO*, 2004
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33. **Pearce, LB**, Rentko, VT, Moon-Massat, PF, and Gawryl, MS. The pharmacokinetics of a hemoglobin-based oxygen carrier, HBOC-201, does not change during second trimester pregnancy. *Acad Emerg Med*. 2003;10(5):494
34. Holson, JF, **Pearce, LB**, and Stump, DG. A probable false positive finding of prenatal toxicity in the rodent model with a high molecular weight protein oxygen therapeutic: Evidence and implications. *Birth Defects Res Part A Clin Mol Teratol* 2003 May;67(5):345
35. Katz, L., Manning, J., McCurdy, S., **Pearce, LB**, Gawryl, M., Wang, Y., and Brown C. HBOC-201 Improves Survival in a Swine Model of Hemorrhagic Shock and Liver Injury. *Resuscitation*. 2002;54(1):77-87
36. Manning, J., Katz, L., **Pearce, LB**, Batson, N., McCurdy, SL, Gawryl, MS, and Baker CC. Selective Aortic Arch Perfusion With Hemoglobin-Based Oxygen Carrier-201 For Resuscitation from Exsanguinating Cardiac Arrest In Swine. *Crit Care Med*. 2001;29(11):2067-2074
37. Katz, LM, Manning, JE, and **Pearce, LB**, et al. An Outcome Model of Severe Hemorrhage And Liver Injury In Swine. SAEM. May 2001. Abstract.

38. Katz, LM, Manning, JE, and **Pearce, LB**, et al. Resuscitation With HBOC-201 Allows 96-Hour Survival After Severe Hemorrhagic Shock. *Acad Emerg Med.*;8(5):534-535, 2001
39. **Pearce, LB** and Gawryl, M. The Pharmacology of Tissue Oxygenation By Biopure's Hemoglobin-Based Oxygen Carrier, Hemopure® (HBOC-201). In; Oxygen Transport to Tissues (Eds. Dunn, JF and Swartz, HM) *Adv Expt Med Biol.*, 530:261-270, 2000
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41. Dunn, JF, Nwaigwe, C., Roche, M., Zhu, H., Grinberg, OY, **Pearce, LB**, and Gawryl, MS. Mitigation of Acute Hypoxia In Brain by Infusion of the Acellular Hemoglobin HBOC-201: A Bold MR Imaging Study. ISOTT Proceedings, Abstract, 1999
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44. **Pearce, LB** and Gawryl, MS. Overview of preclinical and clinical efficacy of Biopure's HBOCs. *Blood Substitutes. Vol.2 (Chang, T.M.S., Ed.) Karger Landes Systems*, 1998
45. **Pearce, LB** and Gawryl, MS. Overview of Preclinical and Clinical Efficacy of Biopure's HBOCs. In: Chang TMS, ed. Blood Substitutes: Principles, Methods, Products and Clinical Trials. New York: Karger Langer Systems; 1998:82-100
46. **Pearce, LB**, First, ER, Gupta, A., and MacCallum, RD. The Bioactivity of Botulinum Toxin Formulations. Therapeutic Botulinum Toxins: Oxford Conference 1997
47. **Pearce, LB**, First, ER, Gupta, A., and MacCallum, RD. Pharmacologic Characterization of Botulinum Toxin for Basic Science and Medicine. *Toxicon* 1997;35:1373-1412
48. **Pearce, LB**, Borodic, GE, Johnson, EA, First, ER, MacCallum, R. The Median Paralysis Unit: A More Pharmacologically Relevant Unit of Biologic Activity for Botulinum Toxin. *Toxicon* 1995;33(2):217-27
49. Borodic, GE and **Pearce, LB**, Letter to the Editor. *Neurology* 1995;45:204
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51. Livezey, T., **Pearce, LB**, and Kornetsky, C. The Effect of MK-801 and SCH-23390 on the Expression and Sensitization of Morphine-Induced Oral Stereotypy. *Brain Research*, 692:93-98,1995
52. Borodic, GE and **Pearce, LB**. Letter to the Editor *Neurology*,45:204,1995
53. Borodic, GE, **Pearce, LB**, and Duane, D. Letter to the Editor *Arch Ophthalmology*, 1995
54. **Pearce, LB**, Borodic, GE, and First, ER. Botulinum Toxin: Death Versus Localized Denervation. *J. Royal Soc. Med.* 88(4): 240, 1995
55. **Pearce, LB**, First, ER, MacCallum, RD, and Borodic, GE. The MPU: A More Pharmacologically Relevant Unit of Biologic Activity for Botulinum Toxin. *Toxicon*. 33:1-11, 1995
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57. Borodic, GE, **Pearce, LB**, Farrante, RJ, and Alderson, K. Pharmacology and Histology of the Therapeutic Application of Botulinum Toxin In: *Therapy with Botulinum Toxin* (Ed. by Jankovic J and Hallet M.) 1994;119-157 Marcell Dekker, New York
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60. **Pearce, LB**, First, ER and Borodic, GE. Botulinum Toxin Potency: A Mystery Resolved by the Median Paralysis Unit *J. Royal Soc. Med.* 87:571-572, 1994
61. Borodic, GE and **Pearce, LB**. Current Thinking on the Use of Botulinum Toxin: Do the Risks Outweight the Benefits, *Drug Saftey*, 11 (3):145-152, 1994
62. Borodic, GE and **Pearce, LB**. The Botulinum Toxin Technology: Treatment of Spasmodic Torticollis. *National Spasmodic Torticollis Society Newsletter*, 1994
63. Borodic, GE, **Pearce, LB**, and Johnson, EA. Antibodies to Botulinum Toxin *Ophthalmology*, 101;1158, 1994
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UNPUBLISHED REPORTS



Authored, designed, or coauthored marketing applications, including biologics license application to FDA and European regulatory authorities, IND applications and 50+ clinical study reports, investigator brochures, clinical study protocols, clinical pharmacokinetics, preclinical GLP, and nonGLP studies in areas of pharmacology, pharmacokinetics, safety pharmacology, developmental toxicology, organ systems toxicology, genotoxicity, and general toxicology.