



Richard M. Lewis, PhD

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## **CURRICULUM VITAE**

### **EXPERIENCE**

**Access BIO, L.C.** 2004-present

**Chief Executive Officer**

Consulting services to biologics corporations and universities

Novel approval strategies

Unique investigational approaches

Regulatory strategies

Interpretation of FDA Regulations and Guidance documents

Strategic planning for FDA meetings and interactions

Rapid and uninterrupted clinical development

GMPs

Process Validation

Strategies for counter terrorism products

To include use of the Animal Rule

### **Recent consulting engagements:**

Program development for recombinant enzymes

Successful preparation of Fast Track Designation requests

Successful request for Comparability decision

Development and launch of phase III studies

Preparation of materials and preparations for FDA meeting for phase III initiation

Pre-IND meeting request and preparation

Orphan Drug Application

Cost Recovery for IND studies

Combination Product jurisdiction decision

Plasma fractionation facility audit

see [www.accessbio.com](http://www.accessbio.com) for Corporation Competencies and abbreviated summary.

**Scientific member of a Central IRB 2004-present**

Chesapeake Research Review, Inc. Columbia, MD

Participate in the review of protocols for clinical trials

Review Informed Consent documents

Evaluate Principal Investigators

**Program Chair, Drug Information Association Meeting**

Regulatory and Scientific Issues that Challenge Comparability Assessment of Biopharmaceuticals, February, 2009

**Member, Loudoun County, Virginia, Science Cabinet****Member, Advisory Board, Inova Health System, Medical Innovation and Transformation Institute, 2006-2009.****Lecturer, George Washington University/Shenandoah University course on Pharmacogenomics – 2007, 2008, 2009****Member, Advisory Board, Biotechnology Program, Northern Virginia Community College, 2006-2008.****CITI Course in The Protection of Human Research – 2006, 2008****Advisory Member, Loudoun County, VA, Economic Development Commission -2006**

**Author: Demonstration of Comparability of a Licensed Product after a Manufacturing Change, 2008**, in *Preclinical Safety Evaluation of Biopharmaceuticals*, ed., Joy A. Cavagnaro, A. John Wiley and Sons. New Jersey.

**Chair, DIA Conference. Comparability Challenges: Regulatory and Scientific Issues in the Assessment of Biopharmaceuticals, February, 2009.**

## **FDA - Center for Biologics Evaluation and Research 1989-2004**

### **REGULATORY EXPERIENCE :**

#### **FDA, Center for Biologics Evaluation and Research**

In the position as Deputy Director, Office of Blood Research and Review (OBRR), was involved in all aspects of the office activities; was personally responsible for the management of the immediate office, day to day oversight of the budget process, approximately \$3.5m per year, and have been the office lead in a number of issues including medical errors and blood supply. Represented OBRR in a number of CBER and FDA committees including counterterrorism efforts, patient safety, information management and reviewer training.

As Branch chief for the Hematologic Products Branch of the Division of Blood Applications, supervised 5 clinical reviewers and 5 regulatory coordinators. The clinical reviewers were responsible for the design of clinical trials for blood INDs and license applications. The regulatory coordinators reviewed product labeling submissions, tracking of all submissions for timeliness of review and for completion of all files.

As Acting Branch Chief for the Hybridoma and Hematologic Products Branch of the Division of Application Review and Policy in the Office of Therapeutics, CBER, FDA, supervised 5 product reviewers who were responsible for chemistry and manufacturing review and for the regulatory-related aspects of BLAs and INDs.

Review of License Applications (BLA), Establishment License Applications and IND submissions for monoclonal antibodies, thrombosis and hemostasis products (coagulation factors, immune globulins, et al.) and hematologic growth factors (IL-3, 11-6 stem cell factor et al.)

Initial FDA laboratory-based position included basic review. Among the review assignments were responsibilities for chairing a number of original licensing submissions and amendments. In addition, acted as a committee member for over 20 different applications pertaining to hemostasis and thrombosis products.

#### **Office of Blood Research and Review**

**1998-2004** Deputy Director, Office of Blood Research and Review

Office Lead for Medical Errors Initiative

Office Lead for Counter-Terrorism Issues

Member of Team Biologics Core Governing Team

Represented Office in Center wide committees.

Information Management Coordinating Committee

Regulatory Management coordinating Committee

Responsible for the day-to-day operation of personnel (160 employees) and budget (\$3-4.5m)

Regularly “acted” as Office Director.

**1995-1998** Division of Blood Applications

Chief, Hematologic Products Branch

Review and policy responsibilities

Managed Review

Supervised Project Managers, Office of Blood

Supervised Clinical review section, Office of Blood

Assure application of consistent clinical evaluation

Member of FDA wide committee to develop Guidance for implementation of FDA Modernization Act.

Sign-off on all IND and BLA correspondence, for Division of Hematology

Product Review (IND and BLA)

Participated in the review for Hematologic Products, including development of Advisory Committee materials

Review comment sign-off

Finalization of Summary Basis of Approval for licensed products.

**Office of Therapeutics Research and Review**

**1993-1995** Division of Application Review and Policy

Acting Chief , Hybridoma and Hematologic Products Branch (HHPB)

Hematologic Products

Thrombolytics, e.g., tPA, Streptokinase, Eminase,

Anti-thrombotics (e.g., AT III, protein C)

Hematologic growth factors (e.g., G-, GM-CSF, 11-3)

Monoclonal Antibodies

Review and policy responsibilities

Managed Review

Product Review (IND and BLA)

**Office of Research**

**1989-1993** Division of Hematology, Laboratory of Thrombosis and Hemostasis

Product areas: Blood and Plasma Fractions (e.g., factor VIII, Factor IX, AT 111)

Thrombolytic agents (e.g., Alteplase)

Regulatory Responsibilities

Review

Biologics Inspections: Plasma fractionation, Recombinant proteins

Research Responsibilities

Immunologic - Studies of Tissue Factor Pathway Inhibitor (TFPI)

von Willebrand factor binding to platelets

regulation of surface antigen expression by monocytes

**U.S. Army -- Civilian Chemist****1983-1989 United States Army Research Institute of Infectious Diseases****Professional Societies:**

American Association of Blood Banks  
American Heart Association  
International Society for Thrombosis and Hemostasis  
American Society of Hematology

**Patent:** The use of conformation specific antibodies to purify vitamin K dependent coagulation proteins.

**EDUCATION:**

**Ph.D.** University of North Carolina, Chapel Hill  
Department of Experimental Pathology,  
December, 1980

**Dissertation title:** Studies on the Binding of Human Anti - Factor IX  
Antibodies to Factor IX Protein.

**M.S.** University of Miami, Miami, FL  
Department of Microbiology, December, 1976

**Thesis title:** Studies on the Origin of a C4 Inactivator from the Nurse  
Shark

**B.S.** Spring Hill College, Mobile, AL  
Biology, May, 1971

**RESEARCH EXPERIENCE:**

Characterization of the tissue factor pathway inhibitor of the extrinsic coagulation cascade.

Influence of hemorrhagic fever viruses on the hemostatic mechanism.

Effects of mycotoxin(s) on hemostasis.

Development of hybridoma cells producing antibodies to the coagulation protein, prothrombin; identification of clones producing conformation-specific antibodies.

Radioimmunoassay of coagulation factor IX; comparison of acquired human antibodies; isolation of conformation-specific alloantibodies (Doctoral Dissertation).

Immunochemical studies of a component of shark serum which inactivates the fourth component of human complement (Master's Thesis).

## **RECOGNITION AND PROFESSIONAL STATURE:**

### **Awards or other honors:**

(As examples of participation in FDA and HHS initiatives.)

#### **Secretary's Award for Distinguished Service**

For leadership, teamwork and dedication in coordinating the integration of existing HHS Programs and systems to collect data on patient safety. June 2003

#### **FDA Award of Merit**

For outstanding effort in the continued safety of the Nation's blood supply during a West Nile virus infection epidemic. May 2003

#### **Commissioner's Special Citation**

For extraordinary efforts that led to the approval of the first of a new class of rapid HIV tests. May 2003

#### **FDA Award of Merit**

For exceptional responsiveness to provide a policy statement on urgent collection, shipment, and use of whole blood and blood components intended for transfusion on September 11, 2001. May 2002

#### **FDA Policy Development Award**

For outstanding effort in enhancing regulatory oversight and the safety of the nation's blood supply by developing and publishing numerous rulemakings and guidance documents. June 2002

#### **Secretary's Award for Distinguished Service**

For outstanding performance and teamwork in the development and implementation of the Device Action Plan contributing to the continued safety of the nation's blood supply. June 2001

#### **Group Recognition Award**

For exceptional performance in response to predictions of severe shortages in blood supply. June 2001

#### **FDA Commendable Service Award**

For superlative teamwork and exceptional performance during the creative development and implementation of the CBER's Device Action Plan for the improvement of device review performance. June 2000

**Group Recognition Award**

For contributions to the training of Team Biologics Investigators in preparation for the transfer of the biennial inspection responsibility from CBER to the Field.

June 2000

**Certificate of Appreciation**

For outstanding contribution to the Team Biologics Core Team Combined Training Course at Rockville, Maryland. March 27 - April 6, 2000

## PUBLICATIONS:

### Articles

Lewis, R.M., Reisner, H.M., Chung, K.S. and Roberts, H.R. (1980). Detection of Factor IX antibodies by radioimmunoassay: effect of calcium on antibody-factor IX interaction. *Blood* 56:608.

Lewis, R.M., Zeitler, K.D., Blatt, P.M., Reisner, H.M. and Roberts, H.R. (1980). Immunology of inhibitors to clotting proteins. In: Rose, N.R. and Friedman, H. (eds.) *Manual of Clinical Immunology*, second edition. Washington, p. 750.

Lewis, R.M., Furie, B.C., and Furie, B. (1983). Conformation specific monoclonal antibodies directed against the calcium-stabilized structure of human prothrombin. *Biochemistry* 22:948.

Owen, J., **Lewis, R.M.**, Cantor, A., Furie, B.C. and Furie, B. (1984). Monoclonal antibodies against human abnormal (Des-q-carboxy) prothrombin specific for the metal-free conformer of prothrombin. *J. Biol. Chem.* 259:13800.

Lewis, R.M., Cosgriff, T.M., Peters, C.J., and Morrill, J.C. (1987). Differentiation of a human monocytic line is associated with increased production of Rift Valley fever virus infected cells. *J. Med. Virol.* 23:207.

Cosgriff, T.M., Jahrling, P.B., Chen, J.P., Hodgson, L.A., **Lewis, R.M.**, Green, D.E., and Smith, J.I. (1987). Studies of the coagulation system in arenaviral hemorrhagic fever: experimental infection of strain 13 guinea pigs with Pichinde virus. *Am. J. Trop. Med. Hyg.* 36:424-431.

Cavagnaro, J. and Lewis, R.M. (1987). Toxicological evaluation of drugs. In: M. Williams and J.B. Malick (eds.), *Drug Discovery and Development*, Humana Press, Clifton, p. 259.

Cavagnaro, J., Waterhouse, G.A.W. and **Lewis, R.M.** (1987). Neuroendocrine-immune interactions: immunoregulatory signals mediated by neurohumoral agents. In J.M. Cruse and R.E. Lewis, Jr. (eds.), *The Year in Immunology*, (1986-1987) Vol. 3, Karger, Basel, p.228.

Lewis, R.M., Cosgriff, T.M., Griffin, B.Y., Rhoderick, J. and Jahrling, P.B. (1988) Immune serum increases arenavirus replication in monocytes. *J. Gen. Virol.* 69:1735-40.

Cavagnaro, J., and Lewis, R.M. (1987-88). Neuroendocrine immune interactions In J.M. Cruse and R.E. Lewis, Jr. (eds.), *The Year in Immunology*, Karger, Basel, p. 273.

Cavagnaro, J., and Lewis, R.M. (1989). Bidirectional circuit between the immune and neuroendocrine systems. J.M. Cruse and R.E. Lewis, Jr. (eds.), *The Year in Immunology*, Vol. 4, Karge, Basel, pp. 241-252.

Lewis, R.M., Morrill, J.C., Jahrling, P.B. and Cosgriff, T.M. (1989) Hemorrhagic fever virus replication in monocytic cells. *Rev. Inf. Dis.* 11:S736-S741.

Cosgriff, T.M., and Lewis, R.M. (Guest Editors). (1989). Hemostatic impairment associated with hemorrhagic fever viruses. *Rev. Inf. Dis.* volume 11, Suppl 4.

Lewis, R.M., Lee, H.W., See, A.F., Parrish, D.B., Moon, J.S., Kim, D.J. and Cosgriff, T.M. (1990). Changes in populations of immune effector cells during the course of hemorrhagic fever with renal syndrome. *Royal Soc. Trop. Med. and Hyg.* 85:282-286.

Lewis, R.M. and Cavagnaro, J. (1989). Basic studies in age-related changes in immune function. In: R.L. Cooper, J.M. Gordman and T.J. Harbin. (eds.), *Aging and Environmental Toxicology: Biological and Behavioral Perspectives.*, The Johns Hopkins University Press, Baltimore.

Cosgriff, T.M. Lee, H.W., See, A.F., Parrish, D.B., Moon, J.S., Kim, D.J. and **Lewis, R.M.**, (1991). Platelet dysfunction contributes to the haemostatic defect in haemorrhagic fever with renal syndrome. *Trans. Royal Soc. Trop. Med. and Hyg.* 85, 660-663.

Cosgriff, T.M., **Lewis, R.M.**, (1991). Mechanisms of disease in hemorrhagic fever with renal syndrome. *Kid. Int.* 40 (Supp. 35), S72-S79.

Lewis, R. M., 2008, Demonstration of Comparability of a Licensed Product after a Manufacturing Change, 2008, in *Preclinical Safety Evaluation of Biopharmaceuticals*, ed., Joy A. Cavagnaro, A. John Wiley and Sons. New Jersey.

### Abstracts

Lewis, R.M., Reisner, H.M., Chung, K.S. and Roberts, H.R. (1979). Radioimmunoassay for antibodies to human factor IX. *Fed. Proc.* 38:1410. FASEB Annual Meeting, Dallas, TX.

Lewis, R.M., Reisner, H.M., Chung, K.S. and Roberts, H.R. (1980). Isolation of Ca<sup>++</sup> dependent human antibodies to human factor IX. *Circulation* **62(Suppl):III-279**.

Lewis, R.M., Reisner, H.M., Abels, B.C., Jr., and Roberts, H.R. (1981). The effect of metal ions to human factor IX antigenicity. *Thromb. Haemost.* 46:137.

Lewis, R.M., Reisner, H.M., Chung, K.S. and Roberts, H.R. (1979). Calcium dependent antigenicity of human F.IX. *Blood* **54(Suppl):289a**. Annual Meeting, American Heart Association, Miami, FL.

Lewis, R.M., Reisner, H.M., Lundblad, R.L., Chung, K.S. and Roberts, H.R. (1979). A radioimmunoassay for factor IX (f.IX) using staph A. *Thromb. Haemostat.* 42:363. International Society of Thrombosis and Haemostasis, London, England.

Lewis, R.M., Furie, B.C. and Furie, B. (1981). Hybridoma produced conformation-specific monoclonal antibodies to human prothrombin. *Blood* **58(Suppl):220a**. Annual Meeting, American Heart Association, San Antonio, TX.

Lewis, R.M., Johnson, E.D., Jahrling, P.B., Edgell, C.-J., Cosgriff, T.M. and Peters, C.J. (1984). In vitro infection of endothelial cells by Ebola, Lassa, and Marburg viruses. For Annual Meeting, American Society of Microbiology, 3-8 March 1985, Las Vegas, NV

- Lewis, R.M., Hodgson, L.A. and Cosgriff, T.M. (1985). The effect of T-2 mycotoxin on tissue factor production by human monocytes and U937 cells. International Society of Thrombosis and Hemostasis, San Diego, CA.
- Lewis, R.M. (1986). In vivo and in vitro effects of T-2 toxin on coagulation. Presented at the FASEB Conference on Tricothecene Mycotoxins, Copper Mountain, Colorado, July
- Reisner, H.M., Lewis, R.M., Strand, E.A., Chung, K.S. and Roberts, H.R. (1979). Binding of allo- and heteroantibodies to human factor IX (*f.IX*). *Thromb. Haemost.* 42:364.
- Borowski, M., Furie, B.C., Goldsmith, G.H., **Lewis, R.M.**, Owen, J. and Furie, B. (1983). Isolation and characterization of partially carboxylated human prothrombin. *Fed. Proc.* 42:1862.
- Cosgriff, T.M., Hodgson, L.A., **Lewis, R.M.** and Driessen, J.L. (1984). Familial thrombopathy with increased activity of factors V, VII, and VIII. American Society of Hematology, 1-4 December, Miami, FL.
- Cosgriff, T.M., Hodgson, L.A., **Lewis, R.M.**, Fair, D.S. and Marlar, R.A. (1985). Familial protein S deficiency associated with increased activity of Factors V, VII, VIII, and recurrent thrombosis. For Xth Congress on Thrombosis and Hemostasis, 6-11 July, San Diego, CA.
- Johnson, E.D., McKee, K.T., Jr., Jaax, N., Dixon, S., **Lewis, R.M.**, and Cosgriff, T.M. (1985). Experimental Ebola hemorrhagic fever (EHF): a model for rational therapy. For 4th International Congress on Impact of Viral Diseases on the Development of the African and Middle-East Countries, 13-19 April, Rabat, Morocco.
- Lewis R.M., Jahrling P.B., Griffin B.P., and Cosgriff T.M. (1987). The effect of hemorrhagic fever virus infection of endothelial cells. *Thromb. Haemostas.* 58:553A.
- Lewis, R.M., Schneider, M.J., Fricke, W.A., (1991). Neutralization of tissue factor pathway inhibitor corrects the clotting time of hemophilic plasma in vitro. *Blood* 78:724.
- Gordon Research Conference: Thrombosis and Hemostasis, 1982, 1984.