CURRICULUM VITAE

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BUSINESS EXPERIENCE

1990-Present

New England Biomedical Research, Inc.
Northborough, Massachusetts
President

Founded NEBR to provide Regulatory Affairs and Product Development consulting services to the Pharmaceutical, Medical Device and Biotechnology Industries. Serve many international and domestic clients. Have managed clinical development programs; critically reviewed, prepared and submitted multiple regulatory documents on behalf of clients; and assisted with the development of regulatory strategy for several pharmaceuticals and medical devices. Provide GMP, GCP and GLP compliance advice and audit services.

1981-1990

Astra Pharmaceutical Products, Inc.
Westborough, Massachusetts
Vice President, Regulatory Affairs and Product Development

Responsible for Regulatory Affairs, the Medical Department, the Medical Computer Systems Department, the Pharmaceutical Development Laboratory and the Analytical Development Laboratory. Developed and obtained regulatory approval for over 150 medical products, including drugs used in AIDS and AIDS related illnesses.

1980-1981 Director, Worcester Production
1978-1980 Director, Project Coordination
1977-1978 Director, Quality Assurance

Three Director level positions held during the time indicated at Astra. The positions provided a variety of experience in regulatory compliance, production, quality control and project coordination at the management level. Responsible for large budgets and line operations.

1972-1977 Manager, Scientific Communications and Regulatory Affairs
1970-1972 Manager, Drug Regulatory Affairs
1968-1970 Head, Regulatory Affairs Group

Three other management positions at Astra. Formed and managed a centralized regulatory affairs function. Formed and managed a centralized technical information center providing information to Astra's customers and inside scientists.

1966-1968 *US Food and Drug Administration*
Div. of Neuropharmacological Drug Products
Arlington, Virginia
Reviewer

Reviewed new drug applications and related documents. Coordinated own review with that of other members of review team. Corresponded with regulated firms.

PROFESSIONAL SKILLS *Regulatory Affairs*

- Regulatory Affairs Certified (RAC). Nearly thirty years experience in planning regulatory strategy, in preparing regulatory submissions, and in negotiating at all levels of the FDA

Product Development

- Ten years as a line manager with overall responsibility for the development of drug products at a $230 million US subsidiary of a multinational pharmaceutical firm

Other

- Experienced in press briefings, and with congressional interactions
- Experienced at evaluation of product and company acquisitions from the research perspective
- Experienced with production, quality assurance and project management concepts

EDUCATION *The Massachusetts College of Pharmacy*
Boston, Massachusetts

B.S. in Pharmacy, 1966
Registered Pharmacist-Commonwealth of Massachusetts - License No. 14637

BUSINESS AND PROFESSIONAL SOCIETIES

Regulatory Affairs Professional Society
Parenteral Drug Association