ELIZABETH A. GORDON, Ph.D.
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EDUCATION:

1996 Executive M.S., Technology Management, University of Maryland University College, College Park, Maryland.

1987-1990 Post-doctoral Research Fellow, Uniformed Services University of the Health Sciences, Bethesda, Maryland.

1987 Ph.D., Microbiology, University of Rhode Island, Kingston, Rhode Island.

1981 B.A., Microbiology, University of New Hampshire, Durham, New Hampshire.

WORK EXPERIENCE:

2015-2021 *Amplyx Pharmaceuticals, Inc.*
Senior Vice President, Regulatory Affairs (August 2019-June 2021)
Vice President, Regulatory Affairs (December 2015-July 2019)

Responsible for global regulatory strategy, operations and activities; preparation of all regulatory submissions [preIND submissions, scientific advice dossiers, IND applications and amendments/reports, clinical trial applications (CTA), investigation medicinal product dossiers (IMPD), orphan drug applications, expedited program applications for serious conditions, expanded access programs]; project and strategic planning to support development of Fosmanogepix, a first-in-class small molecule drug candidate that targets and inhibits the conserved fungal enzyme Gwt1, compromising fungal growth of major fungal pathogens, including *Candida* and *Aspergillus,* including species that are intrinsically resistant to antifungal drugs, as well as activity against rare, hard-to-treat molds including *Fusarium, Scedosporium* and fungi from the Mucorales order. Also, project and strategic planning to support development of Phase 2 asset, anti-BK virus (BKV) monoclonal antibody, MAU868, for the treatment and prevention of BKV disease in immunocompromised patients, specifically kidney transplant recipients and hematopoietic cell transplant recipients. Key member of the management team supporting the nonclinical, manufacturing, quality, clinical and regulatory programs; medical writer (clinical protocols, other clinical documents, including briefing documents to support meetings of clinical advisors, investigator brochures); implement, maintain and train users on complete product development document management system for the Company; key member of the business development team which resulted in successful acquisition by Pfizer Inc. in 2021.

2015-Present *EG Consulting, Inc.*
2000-2014 President

Provide full program strategic, regulatory, and technical advice to the pharmaceutical and biotechnology industry in all areas of product development from discovery through post-marketing. Provide expert strategic and regulatory advice on issues related to expedited drug development programs, interactions with the FDA and other Health Authorities, and regulatory procedures and policies. Provide training in regulatory affairs and advanced issues related to pharmaceutical development. Act as liaison with FDA and Health Authorities on behalf of client pharmaceutical and biotechnology companies. Technical areas of expertise include: preparation and/or evaluation of nonclinical and clinical data; chemistry, manufacturing, and controls information; and pharmacology and toxicology data submitted to FDA and global health authorities to support the safe and effective use of drug and biological products required by Investigational New Drug (IND), Clinical Trial Application (CTA), Biologics License Application (BLA), and New Drug Application (NDA) requirements; responsible for preparation of all regulatory submissions to FDA and global regulatory authorities including orphan product designation applications, expedited program designation applications, expanded access and other treatment options programs, Investigational Medicinal Product Dossier (IMPD), briefing packages to support communications with the health authority, IND, BLA, and NDA applications, applications in the electronic Common Technical Document (CTD) format, amendments, supplements, and advisory committee briefing packages. Interact with review divisions within FDA and other regulatory authorities. Provide medical writing services including clinical protocols, Investigator Brochures, and other scientific reports. Therapeutic experience: infectious diseases, oncology, urology, dermatology, gastroenterology, metabolic and endocrine, and cardiovascular. Product experience: small molecules, recombinant and therapeutic proteins, monoclonal antibodies, cellular therapies, immunotherapies, and vaccines.

2011-2015 *Shire*
Lumena Pharmaceuticals, Inc.
Vice President, Regulatory Affairs (April 2014 – June 2015)
Head of Regulatory Affairs (Consultant from August 2011 – March 2014)

Oversee and lead all global regulatory strategy and operations and activities; preparation of all regulatory submissions [preIND submissions, scientific advice dossiers, IND applications and amendments/reports, clinical trial applications (CTA), investigation medicinal product dossiers (IMPD), orphan drug applications, pediatric investigational plans (PIPs) and waivers]; project and strategic planning from candidate selection through Phase 2 clinical studies to support development of LUM001 and LUM002, which are both inhibitors of the apical sodium-dependent bile acid transporter (ASBT), primarily responsible for recycling bile acids from the intestine to the liver; products in development for the treatment of cholestatic disease (10 clinical studies in 9 countries). Key member of the administrative/operations team supporting the nonclinical, manufacturing, quality, clinical and regulatory programs; critical member of the clinical operations team supporting design and implementation of the clinical program, lead medical writer (all clinical protocols, other clinical documents, including briefing documents to support meetings of clinical advisors, investigator brochures); implement, maintain and train users on

complete product development document management system for the Company; key member of the business development team; data room selection, implementation and management to support diligence and transition activities; business development activities resulted in successful acquisition by Shire plc in June 2014.

2008-2012 *Excaliard Pharmaceuticals, Inc.*
Head of Regulatory Affairs and Project Management (Consultant)

Oversee and lead all US regulatory operations and activities; preparation of all regulatory submissions (preIND, IND application and amendments/reports); project and strategic planning from candidate selection through successful completion of Phase 2 clinical studies to support development of an antisense oligonucleotide for the treatment of skin fibrosis (skin scarring); key member of the administrative/operations team supporting the nonclinical, manufacturing, quality, clinical and regulatory programs; critical member of the clinical operations team supporting design and implementation of the clinical program, lead medical writer (all clinical protocols, clinical study reports, other clinical documents, including briefing documents to support meetings of clinical advisors); implement, maintain and train users on complete product development document management system for the Company; key member of the business development team; data room selection, implementation and management to support diligence and transition activities; assisted CEO in the management of potential partners reviewing asset; business development activities resulted in successful acquisition by Pfizer Inc., in December 2011.

2001-2004 *University of California at San Diego/Extension*
Department of Bioscience
Advisory Board Member/Regulatory Affairs

1999-2000 *San Diego State University*
Department of Sciences/General Studies
Center for Bio/Pharmaceutical & Biodevice Development
Adjunct Professor

1996-2000 *Quintiles, Inc., San Diego, CA*
Regulatory and Technical Services
Senior Director, Regulatory Affairs (September 1999- June 2000)
Director, Regulatory Affairs (September 1998 – August 1999)
Senior Technical Adviser (June 1996 – August 1998)

Responsible for providing strategic, regulatory, and technical advice to clients and internal clinical trials project teams related to the development of biological, biopharmaceutical drug products. Provide expert advice on issues related to the interface between Regulatory Affairs and the science of the clinical trial design and development of clinical trial programs, giving the in-depth knowledge of FDA policies and programs, in all aspects of drug development from discovery through post-marketing. Provide regulatory support for successful communications with regulatory authorities. Technical areas of expertise include: preparation and/or evaluation of nonclinical and clinical data; chemistry, manufacturing, and controls information; and pharmacology and toxicology data submitted to FDA to support the

safe and effective use of drug and biological products required by Investigational New Drug (IND), Biologics License Application (BLA), and New Drug Application (NDA) requirements.

1995 - 1996 *U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review*
Special Assistant to the Director

Assisted the Office Director in carrying out the diverse responsibilities related to the regulatory review and compliance missions of the Office and performed special assignments. Other responsibilities included the development, implementation and clarification of regulatory review and compliance policies and procedures; identification of emerging, standing, complex, or precedent-setting issues and advised on the need to formulate appropriate program responses in support of new initiatives; working closely with the Office Director in guiding, controlling, and coordinating overall regulatory review and compliance workload and work product; performing special assignments often on an emergency basis and of complex need; development of briefing papers and/or speeches, covering any and all issues involving or impacting the Office.

1994-1995 *U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutics Research and Review*
Acting Associate Director for Regulatory Policy

Served as the senior official to the Office Director on issues of a regulatory, policy, or public interest nature. Advised the Office Director on the precedent setting issues that involve any area of biologics regulatory product review activity. Performed assignments of special interest to the Office Director, policy research, coordination, and advisory duties with assigned organization. Served as Office Director's agent for providing scientific and technical advice and assistance in developing, implementing and analyzing the effects of Center and Agency regulatory review policies and programs having potential impact on the Office. Required knowledge of management and regulatory principles and practices in the government and regulated industry necessary to plan, implement, coordinate and evaluate long-range and extensive programs.

1993-1996 *U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review*
Microbiologist

Reviewed and evaluated preclinical and clinical data; chemistry, manufacturing and controls information; and pharmacology and toxicology data submitted as part of an Investigational New Drug Application (IND) or Product License Application (PLA). The review was intended to assure that the data submitted satisfy the requirements to support safe and effective use of new vaccines, without undue risk to the phase and duration of the clinical trials and the eventual clinical use. Developed and implemented regulatory programs, policies, issues and standard operating procedures applicable to the Office. Participated in special projects of a regulatory or sensitive nature pertaining to biological products.

1991-1993 *U.S. Food and Drug Administration, Center for Drug Evaluation and Research*; *Office of Drug Evaluation II, Division of Anti-Infective Drug Products*
Reviewing Microbiologist; and Microbiology Advisor to the FDA San Antonio Resident Post (SARP)

Reviewed and evaluated all microbiological data submitted as part of New Drug Applications (NDAs), and INDs, including supplements and amendments for a broad range of antimicrobial agents which include antibiotic and non-antibiotic drug products. Review responsibilities included nonclinical efficacy, clinical efficacy, and manufacturing and controls. In addition to responsibilities as a reviewing microbiologist (FDA, Rockville, MD), worked independently at SARP (1992-1993), acted as temporary advisor to the FDA investigators at SARP, accompanied investigators on routine and pre-approval inspections of pharmaceutical, biological, and medical device manufacturing facilities, provide microbiological technical expertise as needed.

1990 - 1991 *U.S. Agency for International Development, Bureau for Science and Technology, Office of Health, Health Services Division*
AAAS Science, Engineering and Diplomacy Fellow

Provided technical and program support in diarrheal disease control projects, with particular emphasis on oral rehydration therapy and other pharmaceutical issues. Assisted in discussions with FDA regarding product specifications, testing methodologies, and quality assurance of centrally and locally procured oral rehydration salts and other pharmaceuticals. Provided technical assistance to WHO's Action Programme on Essential Drugs and UNICEF's Bamako Initiative to ensure the regular supply of safe and effective drugs and vaccines of acceptable quality at the lowest possible cost and to promote the rational use of drugs. Provided technical assistance to the Expanded Programme on Immunization to control vaccine preventable diseases in developing nations through national health programs.

PUBLICATIONS:

Cohen, Paul S., **Elizabeth A. Wadolkowski** and David C. Laux. 1986. Adhesion of a human fecal Escherichia coli strain to a 50.5 kDal glycoprotein present in mouse colonic mucus. Microecology and Therapy **16**:231-241.

Laux, David C., Edward F. McSweegan, Taffy J. Williams, **Elizabeth A. Wadolkowski** and Paul S. Cohen. 1986. Identification and characterization of mouse small intestine mucosal receptors for Escherichia coli K-12(K88ab). Infection and Immunity **52**:18-25.

Wadolkowski, Elizabeth A., David C. Laux and Paul S. Cohen. 1988. Colonization of the streptomycin-treated mouse large intestine by a human fecal Escherichia coli strain: role of adhesion to mucosal receptors. Infection and Immunity **56**:1036-1043.

Wadolkowski, Elizabeth A., David C. Laux and Paul S. Cohen. 1988. Colonization of the streptomycin-treated mouse large intestine by a human fecal Escherichia coli strain: role of growth in mucus. Infection and Immunity 56:1030-1035

Sung, L.M., M.P. Jackson, **E.A. Wadolkowski** , D.L. Weinstein, R.K. Holmes and A.D. O'Brien. 1989. Regulation studies and structure-function analyses on Shiga toxin and the Shiga-like toxins of Escherichia coli. In Fourth European Workshop on Bacterial Protein Toxins.

Jackson, Matthew, Debra Weinstein, **Elizabeth Wadolkowski**, Randall Holmes and Alison O'Brien. 1989. Subunit activities of Shiga toxin and the Shiga-like toxins. In Proceedings of the Twenty-Fourth Joint US-Japan Cholera Conference.
Jackson, M.P., **E.A. Wadolkowski,** D.L. Weinstein, R.K. Holmes, and A.D. O'Brien. 1990. Functional analysis of the Shiga toxin and Shiga-like toxin type II variant binding subunit by using site-directed mutagenesis. J. Bacteriol **172**:653-658.

Wadolkowski, Elizabeth A., Jennifer A. Burris and Alison D. O'Brien. 1990. Mouse model for colonization and disease caused by enterohemorrhagic Escherichia coli 0157:H7. Infection and Immunity **58**:2458-2445.

Wadolkowski, Elizabeth A., Lawrence M. Sung, Jennifer A. Burris, James E. Samuel, and Alison D. O'Brien. 1990. Acute renal tubular necrosis and death of mice orally infected with Escherichia coli strains that produce Shiga-like toxin type II. Infection and Immunity 58:3959-3965.

Wadolkowski, Elizabeth A., and Alison D. O'Brien. 1990. Mouse model for disease caused by Escherichia coli that produce Shiga-like toxins. In Proceedings of the U.S.-Japan Panel on Cholera and Related Diarrheal Diseases.

Tesh, Vernon L., Jennifer A. Burris, Jennie W. Owens, Valery M. Gordon, **Elizabeth A. Wadolkowski**, Alison D. O'Brien, and James E. Samuel. 1993. Comparison of the relative toxicities of Shiga-like toxins type I and II for mice. Infection and Immunity **61**:3392-3402.

ABSTRACTS:

1990 "Role of Shiga-like Toxin II in the Pathogenesis of Escherichia coli 0157:H7 in a Streptomycin-Treated Mouse Model." **Elizabeth A. Wadolkowski**, L.M. Sung, and A.D. O'Brien. Presented at the Annual Meeting of the American Society for Microbiology (ASM), Meeting in Anaheim, CA.

1989 "Colonization of the streptomycin-treated mouse intestine by E.coli 0157:H7." **Elizabeth A. Wadolkowski** and A.D. O'Brien. Presented at ASM Meeting in New Orleans, LA.

1989 "Functional analyses of the Shiga toxin binding subunit by site-directed mutagenesis." M.P. Jackson, **Elizabeth A Wadolkowski** and A.D. O'Brien. Presented at ASM Meeting in New Orleans, LA.

1988 "Role of growth in mucus and adhesion to mucosal receptors in the colonization of the mouse large intestine by a human fecal E. coli strain." **Elizabeth A Wadolkowski**, David C. Laux and Paul S. Cohen. Presented at ASM Meeting in Miami Beach, FL.

1987 "Identification of mouse colonic and cecal mucosal receptors for a human fecal strain of E. coli." **Elizabeth A. Wadolkowski**, D.C. Laux and P.S. Cohen. Presented at ASM Meeting in Atlanta, GA.

1986 "Identification of a mouse colonic mucus glycoprotein receptor specific for a human fecal Escherichia coli strain." **Elizabeth A. Wadolkowski**, D.C. Laux and P.S. Cohen. Presented at the ASM meeting in Washington, D.C.

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