

PERSONAL INFORMATION:

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SUMMARY OF EXPERTISE:

Over, twenty-five years of experience in infectious disease including food microbiology, chemical/ biological defense and regulatory science. Provide guidance on microbiology and regulatory affairs for clients developing antimicrobials and biologics allowing clients to navigate through the FDA regulatory process. Provide advice for developing protocols and strategies; review and advise on IND, NDA and ANDA submissions and meeting minutes; advise on regulations, guidelines and guidance documents; assist in dispute resolution; advise on labeling; support clients in strategic meetings; accompany clients in face-to-face FDA meetings; and prepare clients for Advisory Committee meetings. Serve as an expert witness in litigation concerning scientific data in clinical trials by biotech companies, drug codes in wrongful death, and causation in food poisoning. Have written reports, given oral reports and testified in hearing.

PROFESSIONAL WORK EXPERIENCE:

Antimicrobial Regulatory Consulting LLC

Owner and sole member, September 2016 to present

Microbiology and Regulatory Consultant

- Provide regulatory and scientific guidance for clients developing antibiotics, topical antiseptics, medical devices, botanicals, biologics, bacteriophage therapy, generic drugs and dietary supplements to navigate through the FDA regulatory process;
- Provide advice for developing protocols and strategies; review and advise on IND, NDA and ANDA submissions and meeting minutes;
- Advise on regulations, guidelines and guidance documents;
- Assist in dispute resolution;
- Advise on labeling;
- support clients in strategic meetings and accompany them in face-to-face FDA meetings; Assist in preparation for FDA Advisory Committee meetings;
- Serve as an expert witness in litigations and provide assessment scientific and data integrity for the biotech and financial industries;
- Write technology reports that include: analysis of scientific studies, funding, regulatory environment and intellectual property

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- Perform operational, financial and marketing functions of this consultancy as needed.

CARB-X

Scientific Advisory Board, March 2017-January 2020

- Review scientific merit of short form and long form submissions for companies developing antimicrobial products. These products are at either the hit-to-lead, lead optimization or preclinical stage.
- Meet with board members to discuss and decide whether to fund submissions from Sponsors.

National Institutes of Health

Biodefense Contract Reviewer, December 2019 to present

- Evaluate scientific merits of biodefense contracts for applicants developing antimicrobials at the lead optimization, pre-clinical and clinical studies stages.

BioScience Laboratories, Inc.

Director of Regulatory Affairs, February 2015-August 2016

- Provided regulatory guidance to staff for various FDA and EPA regulatory issues (topical antiseptics and disinfectants);
- Provided contractual consultation and regulatory advice for various clients including meeting for strategy sessions and support during face-to-face FDA meetings;
- Provided regulatory guidance to study directors for study protocols;
- Trained laboratory and administrative personnel in FDA regulations including INDs and Bioequivalence/Bioavailability.

Food and Drug Administration

Microbiologist, October 2002-February 2015

- Reviewed and evaluate all microbiological data submitted as part of New Drug Applications (NDAs), Investigational New Drug Applications (INDs), including supplements, special protocol assessments and amendments for a broad range of antimicrobial agents which include antibiotic and non-antibiotic drug products;
- Preclinical evaluation reviews of the antimicrobial agents for preclinical efficacy by *in vitro* methods which assess the mechanism of action, antimicrobial spectrum of activity, mechanism(s) of resistance, and epidemiological studies and by *in vivo* methods which include pharmacokinetics and pharmacodynamics, animal prophylactic and therapeutic studies;
- Reviewed clinical efficacy by examining effectiveness in clinical trials and establish *in vitro* clinical interpretation criteria;
- Reviewed manufacturing and control processes including package inserts;
- Conducted special studies and consultations including participation in *ad hoc* task forces and professional meetings.
- Completed dozens of pre-IND and IND reviews and/or special protocols;

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- eight NDA review.
- Completed thirteen training courses and attended 13 Scientific Rounds.
- Co-chair Healthcare Antiseptic Committee and writing guidance document for Topical Healthcare Antiseptics;
- Consulted with independent laboratories on protocols for these antiseptics.
- Attended four national professional meetings;
- Presented at three Anti-Infective Advisory Committee Meetings;
- Presented at two Anti-Infective Workshops;
- Involved in professional development focus group;
- Participated in interviews for candidates for open Microbiology Reviewer positions; Mentored new reviewer;
- Consultations performed for other centers including: Center for Devices and Radiological Health (CDRH), Center for Veterinary Medicine (CVM), Center for Biologicals Evaluation and Research (CBER) and Center for Food Safety and Nutrition (CFSAN) as well as other divisions including Ophthalmology, Dermal and Gastrointestinal.

Microbiology Team Leader (detail performed July-October, 2004)

- Served as principal advisor to the Division Director and team leader in Microbiology; Planned coordinated, and evaluated programs and activities of the Division for Microbiology;
- Maintained personal contact with “state of the science”;
- Assigned and reviewed work of team members;
- Assured requirements for production and accuracy are met;
- Planned work to be performed by team members, set and adjusted short-term priorities, and prepared schedules for the completion of work;
- Assigned work to team members based upon priorities, selective consideration of difficulty and requirements of assignments, and capabilities of team members;
- Gave advice, counsel, and instruction to team members on work matters;
- Found ways to improve production and increase quality of work of team;
- Team completed six consultations, five pre-INDs, 15 INDs, and six NDAs.

Naval Surface Warfare Center, Dahlgren Division

Interdisciplinary Microbiologist, October 2000-October 2002

- Acquired funding for, directed and implemented independent, basic and applied research on:
 1. Enzyme kinetics of synthesis of 2-dimethyl-2-dinitrobutane by peroxidases (sponsor: Office of Naval Research);
 2. Expression of heterologous markers in *Bacillus* sp. for bioremediation (confidential sponsor);
 3. Bacteriocins for a decontamination solution against anthrax (sponsor: Office of Naval Research);
- Served as technical agent for DARPA

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- Advised naval base public works department and developed protocols for pathogen detection in water supply
- Served as naval representative to biological warfare treaty
- Wrote research proposals
- Presented data at national meetings
- Supervised two laboratory technicians.

US Department of Agriculture, Agricultural Research Service-ERRC

Research Chemist/Research Molecular Biologist, January 1998-October 2000

- Directed and implemented independent, basic and applied research projects on:
 1. heterologous expression of antimicrobials in lactic acid bacteria;
 2. expression of food-grade markers in lactic acid bacteria;
 3. construction of secretion cassettes for use as vehicles for vaccine delivery by lactic acid bacteria;
- Supervised one laboratory technician;
- Mentored college student
- Served as judge for county science fairs
- Managed laboratory
- Wrote and edited scholarly research publications
- Presented data to colleagues at national meetings
- Served on the microbiology safety committee
- Served as institution coordinator for U.S. Savings Bonds drive

Arcadia University (Beaver College)

Adjunct Faculty, Biology Department, February 2000-May 2000

Molecular Biology lecture and laboratory to upper classmen.

- Devised and delivered lectures
- Prepared and graded examinations
- Devised laboratory experiments
- Graded laboratory notebooks and reports
- Assigned grades.

POST-DOCTORAL TRAINING:

University of Massachusetts, Boston, 1997

Boston Biomedical Research Institute, 1996

University of Massachusetts Medical Center, 1992-1995

M.D. Anderson Cancer Center, 1990-1992

EDUCATION:

Clark University, MBA, 1996

University of Texas, PhD, Microbiology, 1990

University of Montana, MS, 1981

University of Vermont, BS, 1979

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TECHNICAL SKILLS:

Various **laboratory techniques** including: clinical microbiology, environmental microbiology, molecular biology, protein chemistry, phospholipid biochemistry

TEACHING EXPERIENCE:

Beaver College (Arcadia University), 2000:

Molecular biology lecture and lab

Austin Community College, 1988-1989:

Introductory biology lab (non-majors)

Introductory microbiology (lecture and lab for nursing students)

University of Texas, 1982-1987:

Introductory microbiology lab (majors and non-majors),

Virology lecture and lab

Immunology lecture

Public health microbiology lecture and lab

University of Montana, 1980-1981:

Molecular biology lab

Molecular genetics guest lecturer

University of Vermont, 1979:

Introductory microbiology lab

FEDERAL GOVERNMENT TRAINING:

- CDER Employee Orientation
- Searching Full Text Electronic Journals (Medical Library)
- Basic Drug Law
- IND Regulations and Policies
- NDA Regulations and Policies
- DFS (Divisional Filing System)
- Ethics
- FDA Computer Security
- New Reviewers Workshop (CDER)
- Star Spangled Federal Benefits
- PDUFA III
- Technical Writing Workshop
- Fire Safety, Civil Rights, EEO, Ethics, Sexual Harassment, New SY Orientation- USDA, ARS, North Atlantic Area
- Introduction to Supervision, USDA Graduate School
- Principles of Defense Acquisition and Program Management, Naval Postgraduate School
- Patents and Intellectual Property

OTHER REGULATORY TRAINING:

- Dietary Supplement Labeling
- Electronic Mail Use in FDA Regulated Industries

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- Surviving FDA Audits
- Good Laboratory Practice (GLP) Simplified
- Medical Foods
- Social Media and FDA Products

EXPERT WITNESS TRAINING (SEAK):

- How to Start, Build and Run a Successful Expert Witness Practice, 2024
- How to Be an Effective Expert Witness at Deposition and Trial, 2025
- How to Refine, Improve and Grow Your Expert Witness Practice, 2026

HONORS:

- Special Recognition Award, CDER, FDA, 2004
- Boston Biomedical Research Institute (BBRI) Scholar, 1996
- T.S. Painter Fellowship, University of Texas, 1986
- Graduate Student Representative to the Microbiology Department faculty, 1984-1985
- Outstanding Student Presentation Award, Montana Academy of Sciences, 1981

PROFESSIONAL ORGANIZATIONS:

- American Society for Microbiology, 1975-1981, 1986, 1998-2002, 2016-2019
- Infectious Disease Society of America, 2018
- ASTM, 2016
- Society for Industrial Microbiology, 1998-2000
- Federation of the American Society for Experimental Biology, Glucose Transporter Biology, 1993
- Gordon Conference participant Red Cell Meeting, 1991

ABSTRACTS, PRESENTATIONS, PUBLICATIONS:

1. FDA Workshop: Issues in the Design of Clinical Trials for Antibacterial Drugs for the Treatment of Non-CF Bronchiectasis. 07 September 2012.
2. Anti-Infective Drugs Advisory Committee, NDA 201-688. Tobramycin Inhalation Powder (TIP) (for Cystic Fibrosis); 05 September 2012.
3. FDA Workshop: Issues in the Design of Clinical Trials of Aerosolized Antimicrobials for the Treatment of Cystic Fibrosis, 23 September 2010.
4. Anti-Infective Drugs Advisory Committee, NDA 22-171, Doribax (doripenem) for the treatment of Nosocomial pneumonia (NP) including ventilator-associated pneumonia (VAP); September 2007.
5. Anti-Infective Drugs Advisory Committee, NDA 21-572 SN008, Cubicin (daptomycin for injection) For the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected infective endocarditis; 6 March 2006
6. **Coderre, P.E.**, Cronce, D.T., McCabe, M.A. and J. Kenar. 2001. Peroxidase-catalyzed synthesis of 2,3-dimethyl-2,3-dinitrobutane (DMDNB). A marking

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- agent for moldable explosives. Abstracts, American Chemical Society, Green Chemistry Conference, Washington, D.C.
7. Somkuti, G.A., **Coderre, P.E.** and D.H. Steinberg. 2000. Pediocin production by recombinant *Streptococcus thermophilus*. Abstracts, American Dairy Science Association.
 8. **Coderre, P.E.** and G.A. Somkuti. 2000. Cloning and expression of a pediocin-lysostaphin hybrid gene in *Streptococcus thermophilus* and other bacteria. Abstracts, Society for Industrial Microbiology.
 9. **Coderre, P.E.** and G.A. Somkuti. 1999. Cloning and expression of the pediocin operon in *Streptococcus thermophilus* and other lactic fermentation bacteria. *Curr. Microbiol.* 39:295-301.
 10. **Coderre, P.E.** and G.A. Somkuti. 1999. Cloning and expression of a gelatinase-lysostaphin hybrid in *Escherichia coli*. Abstracts, Society for Industrial Microbiology.
 11. **Coderre, P.E.** and G.A. Somkuti. 1999. Cloning and expression of the pediocin operon in *Streptococcus thermophilus*. Abstracts, American Society for Microbiology.
 12. Zottola, R.J., E.K. Cloherty, **P.E. Coderre**, A. Hansen, D.N. Hebert and A. Carruthers. 1995. Glucose transporter function is controlled by transporter oligomeric structure. A single intramolecular disulfide promotes GLUT1 tetramerization. *Biochemistry* 34:9734-9747.
 13. **Coderre, P.E.**, E.K. Cloherty, R.J. Zottola and A. Carruthers. 1995. Rapid substrate translocation by the multisubunit, erythroid glucose transporter requires subunit associations but not cooperative ligand binding. *Biochemistry* 34:9762-9773.
 14. **Coderre, P.E.** and A. Carruthers. 1993. Exofacial tryptic cleavage of erythroid GLUT1. Federation of the American Society for Experimental Biology, Glucose Transporter Biology Abstract.
 15. **Coderre, P.E.** and A.J. Schroit. 1991. The erythrocyte aminophospholipid transporter. in *Phospholipid and Signal Transduction* (Horrocks, L.A., ed.). NATO ASI series, Springer Verlag, New York.
 16. **Coderre, P.E.** and C.F. Earhart. 1989. The *entD* gene of the *Escherichia coli* K-12 enterobactin gene cluster. *J. Gen. Microbiology* 135:3043-3055.
 17. **Coderre, P.E.** and C.F. Earhart. 1986. Characterization of a plasmid carrying the *Escherichia coli* K-12 *entD*, *fes*, *fepA* and *entF* genes by Tn5 mutagenesis. American Society for Microbiology Abstracts.
 18. **Coderre, P.E.** and C.F. Earhart. 1984. Characterization of a plasmid from *Escherichia coli* K-12 carrying the *entD*, *fepA*, *fes* and *entF* genes. *FEMS Microbiol. Lett.* 25:111-116.

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