# Curriculum Vitae

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## SUMMARY OF PROFESSIONAL BACKGROUND

I have over 40 years of professional experience in the non-clinical aspects of biological product development including technology assessment, business development, research, product & process development, technology transfer, quality control, and regulatory affairs. This experience includes the 8 years at the FDA, 16 years in industry at both small and large companies, 5 years as a consultant with the Biologics Consulting Group, and 12 years as an independent consultant.

While at the FDA and in the biotech/vaccine industry much of the work was with peptide-protein conjugates, purified capsular polysaccharide-protein conjugates, purified lipo-oligosaccharides-protein conjugates, purified native and recombinantly expressed proteins, live attenuated viral and bacterial organisms and with vectors such as attenuated Salmonella. This provided a broad experience with many vaccine candidates for viral pathogens (Influenza, RSV, HSV, HIV, HPV), bacterial pathogens (*Bordetella pertussis*, *Streptococcus pneumoniae*, Group A and Group B Steptococcus, encapsulated and non-encapsulated *Haemophilus influenzae*, *Moraxella catarrhalis*, Niesseria, Helicobacter, Chlamydia), and for metabolic (Alzheimer's) diseases. Over this time period, I also had the responsibility for managing and directing departments with expertise in all the technical functions and methods for vaccine candidate identification and for biological product production, formulation, characterization, assay development and QC testing clinical trial materials.

Over a 24-year period at the FDA and in industry at Praxis, Lederle-Praxis, Wyeth-Lederle, and Wyeth I was actively involved in the successful development of acellular pertussis vaccines, and bacterial saccharide-protein conjugate vaccines for *Haemophilus influenzae* type b (HibTiter), *Neisseria meningitidis* type C (Meningitec), and *Streptococcus pneumoniae* (7 valent and 13 valent formulations). All of these vaccines became successful commercial products with the licensure of HibTiter in 1988, Acel-Immune (DTaP) in 1991, Meningitec in 1999, Prevnar 7 Valent in 2000 and Prevnar 13 Valent in 2010. All have been very important for the control of the infectious diseases caused by these bacteria and have made major contributions to improving global public health.

As Scientific Director of Discovery Research at Lederle-Praxis & Wyeth-Lederle from 1989 to 1997, I directed and managed the scientific efforts of several research departments and scientific programs for the discovery and early development of vaccine candidates for bacterial and viral pathogens. This required a very active participation in proprietary technology development and assessment including the review and preparation of patents for vaccine candidates developed internally and licensed in from external academic laboratories. The strategic interaction with patent attorneys, business development staff and technical research personnel was an important aspect of developing and managing an effective R&D technology portfolio.

In the five years in the Vaccine Development Group of Wyeth, I obtained valuable first hand experience with cGMP issues for facility design and for production of clinical trial materials at laboratory, pilot and manufacturing scale. Also, at the FDA and in industry I gained much experience in the preparation and review of CMC and nonclinical pharmacology & toxicology data sections of regulatory submissions for biologics.

## INDEPENDENT CONSULTING FOCUS

**1)** Provide technical & regulatory advice on chemistry, manufacturing and control (CMC) technologies for all phases of biotech and vaccine product development from non-clinical through Phase I, II, III and Biological License Application (BLA) submission. **2)** Review and provide advice on the science, manufacturing technology and regulatory issues for assessments by emerging biotech companies & venture capital firms for business development decisions on a variety of vaccine technologies. **3)** Provide CMC advice for Pre-IND meetings, IND submissions, End-of-Phase 2 (EOP2) meetings and BLA submissions for biotech and vaccine products. **4)** Provide review and advice on the design of Phase I/II and commercial production facilities for biotech and vaccine products. **5)** Provide technical and business management assistance for the evaluation and selection Contract Manufacturing Organizations (CMOs) by clients and provide technical and project management assistance for technology transfer, process and analytical assay development and production of clinical trial materials by CMOs.

## EXPERIENCE

**Independent Consultant,** January 2008 to present

- Provided product development and CMC advice for the development of methamphetamine-protein conjugate vaccines to S. Michael Owens, PhD of the University of Arkansas (April 2008 to August 2012).
- Provided due diligence technology & product development assessments for Calvert Research, Cary, NC (www.calvertholdings.com) for a broad range of small molecule and biological molecules being developed by emerging small companies for many therapeutic diseases for Calvert to consider entering a Service Equity Business Deal with early stage companies (April 2008 to August 2012).
- WHO expert consultant for the review & comment on revised WHO recommendations for acellular pertussis vaccine, September 2009 to June 2010.
- Provide technology transfer, manufacturing (CMC), and general regulatory advice to Heat Biologics, Chapel Hill, NC (heatbio.com) for the development of an allogeneic whole cell cancer vaccine for NSCLC (March 2012 to 2016). This included assistance with three different CMOs for technology transfer, process and analytical assay development and production of clinical trial materials and with writing the CMC sections of two successful IND's to the FDA for the initiation of clinical trials for two different cancer vaccines.
- Conducted a brief review and provided a report to Equitas BioPharma Solutions on the GSK program for the developmentof a vaccine for *Staphylococcus aureus*. (January 2016)
- Member of the Scientific Advisory Committee of VaxYnethic (September 2016 to December 2019).
- Scientific Advisor and Consultant with Citranvi BioSciences, LLC (February 2019 to present).

**The Biologics Consulting Group, Inc.** *Sr. Consultant* (July 2007 to December 2007)

- Performed product development and regulatory consulting work on chemistry, manufacturing and control (CMC) issues for a variety of biological products including subunit and viral vector vaccines for cancer, allergies, and infectious diseases; and with monoclonal antibody and cytokine biological products.
- Performed due diligence product development assessments of a variety of potential biological products or technologies for a variety of clients including Venture Capital Fund Groups

**The Biologics Consulting Group, Inc.** *Head of North Carolina Office*
Cary, North Carolina (Jan. 2003 to July 2007)

- Coordinated administrative operations of North Carolina office
- Interacted with potential BCG clients, prepared Work Proposals to meet their needs, and if needed distribute work among Regulatory Associates
- Attended various Biotech meetings to promote BCG services to interested clients
- Performed product development and regulatory consulting work on chemistry, manufacturing and control (CMC) issues for a variety of biological products including subunit and viral vector vaccines for cancer, allergies, and infectious diseases; and with monoclonal antibody and cytokine biological products.

- Performed due diligence product development assessments of a variety of biological products and technologies.
- WHO expert consultant on serotype composition of pneumococcal conjugate vaccines, WHO HQ, Geneva, SUI, 26-27 October 2006.

**Wyeth Vaccines Research**, *Assistant Vice President, Vaccine Development*
Sanford, North Carolina (2001 to 2003)

- Directed and managed several functional departments at three sites (Sanford, NC; Pearl River, NY; and Marietta, PA) in the development, scale-up, and technology transfer of bacterial and viral vaccine products, including the production of cGMP clinical trial materials for clinical testing.
- During this time period, important product development activities that my staff and I worked on were the development of a live attenuated influenza vaccine with Aviron/MedImmune and the development of a 13-valent pneumococcal capsular PS-CRM197 conjugate vaccine, each of which were eventually brought to commercial licensure by MedImmune in 2003 (FluMist Influenza vaccine) and by Pfizer in 2010 (13-valent pneumococcal conjugate vaccine, Prevanr 13).
- Supervised six director-level direct reports with a total staff of about 200 and the management of a 50- to 60-million dollar budget for the production of clinical trial materials for phase I to III clinical trials.
    - Functional departments under my direction included Process Development (cell culture, fermentation, purification, conjugation chemistry, and formulation), Analytical Development (assay development and QC testing), and Clinical Manufacturing and Distribution, all of which functioned according to good laboratory practices (GLP) and current good manufacturing practices (cGMP) guidelines.

**Wyeth-Lederle Vaccines**, *Senior Director, Bacterial Vaccine Development*
Sanford, North Carolina (1997-2000)

- Directed and managed several functional departments at the Sanford, NC, facility in the development, scale-up, and technology transfer of bacterial vaccine products.
- During this period I participated in the technology transfer to manufacturing, and the US and international regulatory submissions for the commercial licensure in 1999 of the Meningococcal C polysaccharide-CRM197 conjugate vaccine (Meningitec) and the licensure in 2000 of the 7-valent Pneumococcal polysaccharide-CRM197 conjugate vaccine (Prevnar).
- Produced bulk concentrates of the drug substance or active biopharmaceutical ingredient under cGMP conditions for clinical trials.
- Supervised five associate director/manager-level direct reports with a total staff of 50 to 60 and the management of a 10- to 15-million dollar budget. Functional departments that reported to me included Fermentation, Purification, Conjugation Chemistry, Analytical, and Compliance.

**Lederle-Praxis Biologicals and Wyeth-Lederle Vaccines**, *Scientific Director, Vaccine Discovery Research*
Rochester, New York (1989 to 1997)

- Directed and managed the scientific efforts of several research departments and scientific programs for the discovery and early development of vaccine candidates for bacterial and viral pathogens.
- Supervised five to six manager or associate director-level direct reports with a total staff of 40 to 50 and a budget of 8- to 12-million dollars. Functional departments reporting to me included Molecular Biology and Genetics, Protein Chemistry, Bacteriology, Carbohydrate Chemistry, Immunology, and External Technology Assessment.
- Provided technical and regulatory advice to the Lederle, Pearl River, NY staff on data for the FDA review and successful licensure of the Takeda Acellular Pertussis Vaccine in 1991 as a component of the DTaP vaccine (Acel-Imune).
- Provided technical and regulatory guidance to Rochester research staff for the development of a HibTiter stability assay for a DTP-HibTiter combination vaccine (TETRAMUNE) that was important for the successful licensure of this vaccine by the FDA in 1993.
- Participated in the scientific review of the DNA vaccine technology of Apollon for the possible acquisition of Apollon by Wyeth-Lederle Vaccines. This aquistion occurred in 1998.

**Praxis Biologics, Inc.**, *Manager, Bacteriology Research Department*
Rochester, New York (1986-1989)

- Managed, directed, and supervised Ph.D. level and non-Ph.D. level scientific employees in the discovery and early development of vaccine candidates against bacterial pathogens.

**Praxis Biologics, Inc.**, *Interim Director, Quality Control and Quality Assurance*
Sanford, North Carolina (July 1988 to December 1988)

- Coordinated and directed QC and QA staff in the preparation for an FDA pre-license inspection of the Praxis manufacturing facility for the production of HibTiter, the Praxis Haemophilus Conjugate Vaccine.
- Acted as responsible head of the Sanford facility for the FDA inspection
- Directed and coordinated QC and QA activities and correspondence leading to the granting of an Establishment License and Product License in 1988 for the Praxis Haemophilus b Conjugate Vaccine, HibTiter.

**Food and Drug Administration, Office of Biologics Research and Review,** *Research Microbiologist* Bethesda, Maryland (1978-1986)

- Planned, designed, conducted, and directed research projects with *Bordetella pertussis* directed toward the development of acellular pertussis vaccines.
- Published several research papers establishing that the filamentous hemagglutinin (FHA), a toxoid of pertussis toxin, and fimbriae were important vaccine candidates to include in an acellular vaccine formulation.
- Participated in the inspection of licensed manufacturers and the review of Investigational New Drug applications.

**New York University School of Medicine**, *Research Fellow, Department of Microbiology*
New York, New York (1974-1978)

- Planned, designed, and conducted basic research studies on the characterization of bacterial cytolytic toxins.
- Participated in the laboratory & lectures to medical students covering bacterial pathogenic mechanisms and laboratory detection & identification methods for bacterial pathogens.

**Cornell University**, *Research Fellow, Department of Biochemistry*
Ithaca, New York (1972-1974)

- Planned, designed, and conducted basic research studies with bacterial membrane bound enzymes and peptide transport systems.

## EDUCATION

Ph.D., Microbiology, University of Illinois, Urbana, IL (1972)
M.S., Biology, St. John's University, Jamaica, NY (1968)
B.S., Biology, King's College, Wilkes-Barre, PA (1966)

## HONORS AND AWARDS

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| 1985 | FDA Award of Merit |
| 1973-1975 | NIH Postdoctoral Fellowship |
| 1968-1972 | USPH Traineeship in Microbiology |
| 1966-1968 | NSF Traineeship |
| 1962-1966 | King's College Scholarship |

## PROFESSIONAL SOCIETIES

American Society for Microbiology
American Chemical Society (2001 to 2015)
American Association for the Advancement of Science
Regulatory Affairs Professionals Society (RAPS) 2003 to 2008

## AD HOC GUEST REVIEWER

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| 1985-1990 | Journal of Infectious Diseases |
| 1984-1990 | Infection and Immunity |
| 2003-2007 | Clinical Infectious Diseases |
| 2016 | Synthetic and Systems Biotechnology |

## PUBLICATIONS

1. Peterson EC, Hambuchen MD, Tawney RL, Gunnell MG, Cowell JL, Lay JO Jr, Blough BE, Carroll FI, Owens SM. Simple radiometric method for accurately quantitating epitope densities of hapten-protein conjugates with sulfhydryl linkages**.** Bioconjugate Chemistry. 25: 2112-2115, 2014

2. Dai-Fang Liu, Eric Phillips, T. M. Wizemann, M. M. Siegel, K. Tabei, James L. Cowell, and Elaine Tuomanen. Characterization of a Recombinant Fragment that Contains a Carbohydrate Recognition Domain of the Filamentous Hemagglutinin. Infect. & Immun., 65:3465-3468, 1997.

3. Chen, D., McMichael, J.C., Vandermeid, K.R., Hahn, D., Mininni, T., Cowell, J., and Eldridge, J.H. Evaluation of purified UspA from *Moraxella catarrhalis* as a vaccine in a murine model after active immunization. Infect. & Immun., 64:1900-1905, 1996.

4. Green, B.A., Doyle, W.J., and Cowell, J.L. Chinchilla model of experimental otitis media for study of nontypable *Haemophilus influenzae* vaccine efficacy. Methods in Enz. 235:59-68, 1994.

5. Shahin, R.D., and Cowell, J.L. Mouse respiratory infection models for pertussis. Methods in Enz. 235:47-58, 1994.

6. Gotto, J.W., Eckhardt, T., Reilly, P.A., Scott, J.V., Cowell, J.L., Metcalf III, T.N., Mountzouros, K., Gibbons Jr., J.J., and Siegel, M. Biochemical and immunological properties of two forms of pertactin, the 69,000-molecular-weight outer membrane protein of *Bordetella pertussis*. Infect. Immun. 61(5):2211-2215, 1993.

7. Green, B.A., Vazquez, M.E., Zlotnick, G.W., Quigley-Reape, G., Swarts, J.D., Green, I., Cowell, J.L., Bluestone, C.D., and Doyle, W.J. Evaluation of mixtures of purified *Haemophilus influenzae* outer membrane proteins in protection against challenge with *Nontypeable H. influenzae* in the chinchilla otitis media model. Infect. & Immun. 61(5):1950-1957, 1993.

8. Mountzouros, K.T., Kimura, A., and Cowell, J.L. A bactericidal monoclonal antibody specific for the lipooligosaccharide of *Bordetella pertussis* reduces colonization of the respiratory tract of mice after aerosol infection with *B. pertussis*. Infect. & Immun. 60(12):5316-5318, 1992.

9. Cowell, J.L., Deich, R.A., and Kimura, A. Development of nontoxic immunogenic analogs of toxins for vaccines with emphasis on pertussis toxin. In R. Isaacson (Ed.), Recombinant DNA Vaccines: Rationale and Strategies. Marcel Dekker, Inc., NY, p. 49-71, 1992.

10. Kimura, A., Mountzouros, K.T., Schad, P.A., Cieplak, W., and Cowell, J.L. A pertussis toxin analog with reduced enzymatic and biological activities is a protective immunogen. Infect. Immun. 58(10):3337-3347, 1990.

11. Kimura, A., Mountzouros, K.T., Relman, D.A., Falkow, S., and Cowell, J.L. *Bordetella pertussis* filamentous hemagglutinin: Evaluation as a protective antigen and colonization factor in a mouse respiratory infection model. Infect. Immun. 58(1):7-16, 1990.

12. Askelof, P., Rodmalm, K., Wrangsell, G., Larsson, U., Svenson, S.B., Cowell, J.L., Unden, A., and Bartfai, T. Protective immunogenicity of two synthetic peptides selected from the amino acid sequence of *Bordetella pertussis* toxin subunit S1. Proc. Natl. Acad. Sci. USA 87:1347-1351, 1990.

13. Hewlett, E.L., and Cowell, J.L. Evaluation of a mouse model for study of encephalopathy in pertussis vaccine recipients. Infect. Immun. 57(3):661-663, 1989.

14. Brennan, M.J., Li, Z.M., Cowell, J.L., Bisher, M.E., Steven, A.C., and Manclark, C.R. Comparison of agglutinogens on serotype 3 and serotype 6 strains of *Bordetella pertussis*. In: S. Mebel (Ed.), Proceedings of the FEMS Symposium-Pertussis, p. 183-195, 1989.

15. Kenimer, J.G., Kim, K.J., Probst, P.G., Manclark, C.R., Burstyn, D.G., and Cowell, J.L. Monoclonal antibodies to pertussis toxin: Utilization as probes of toxin function. Hybridoma 8(1):37-51, 1989.

16. Li, Z.M., Cowell, J.L., Brennan, M.J., Burns, D.L., and Manclark, C.R. Agglutinating monoclonal antibodies that specifically recognize lipooligosaccharide A of *Bordetella pertussis*. Infect. Immun. 56:699-702, 1988.

17. Black, W.J., Munoz, J.J., Peacock, M.G., Schad, P.A., Cowell, J.L., Burchall, J.J., Lim, M., Kent, A., Steinman, L., and Falkow, S. ADP-ribosyltransferase activity of pertussis toxin and immunomodulation by *Bordetella pertussis*. Science 240:656-659, 1988.

18. Li, Z.M., Brennan, M.J., David, J.L., Carter, P.H., Cowell, J.L., and Manclark, C.R. Comparison of type 2 and type 6 fimbriae of *Bordetella pertussis* by using agglutinating monoclonal antibodies. Infect. Immun. 56:3184-3188, 1988.

19. Brennan, M.J., Li, Z.M., Cowell, J.L., Bisher, M.E., Steven, A.C., Novotny, P., and Manclark, C.R. Identification of a 69-kilodalton nonfimbrial protein as an agglutinogen of *Bordetella pertussis*. Infect. Immun. 56:3189-3195, 1988.

20. Cowell, J.L., Zhang, J.M., Urisu, A., Suzuki, A., Steven, A.C., Liu, T., Liu, T.Y., and Manclark, C.R. Purification and characterization of serotype 6 fimbriae from *Bordetella pertussis* and comparison of their properties with serotype 2 fimbriae. Infect. Immun. 55:916-922, 1987.

21. An der Lan, B., Cowell, J.L., Burstyn, D.G., Manclark, C.R., and Chrambach, A. Characterization of the filamentous hemagglutinin from *Bordetella pertussis* by gel electrophoresis. Mol. Cell. Biochem. 70:31-55, 1986.

22. Steven, A.C., Bisher, M.E., Trus, B.L., Thomas, D., Zhang, J.M., and Cowell, J.L. The helical structure of fimbriae of *Bordetella pertussis*. J. Bacteriol. 167:968-974, 1986.

23. Urisu, A., Cowell, J.L., and Manclark, C.R. Filamentous hemagglutinin has a major role in mediating adherence of *Bordetella pertussis* to human WiDr cells. Infect. Immun. 52:695-701, 1986.

24. Cowell, J.L., Urisu, A., Zhang, J.M., Steven, A.C., and Manclark, C.R. The filamentous hemagglutinin and fimbriae of *Bordetella pertussis*: properties and roles in attachment. In L. Leive (ed.), Microbiology-1986. American Society for Microbiology, Washington, DC, p. 55-58, 1986.

25. Zhang, J.M., Cowell, J.L., Steven, A.C., and Manclark, C.R. Purification of serotype 2 fimbriae of *Bordetella pertussis* and their identification as a mouse protective antigen. In Manclark, C.R. and Hennessen, W. (ed.) Proceedings of the Fourth International Symposium on Pertussis. Develop. Biol. Standard. Vol. 61. pp. 173-185, S. Karger, Basel, 1985.

26. Urisu, A., Cowell, J.L., and Manclark, C.R. Involvement of the filamentous hemagglutinin in the adherence of *Bordetella pertussis* to human WiDr cell cultures. In Manclark, C.R. and Hennessen, W. (ed.). Proceedings of the Fourth International Symposium on Pertussis. Develop. Biol. Standard. Vol. 61. p. 205-214, S. Karger, Basel, 1985.

27. Oda, M., Cowell, J.L., Burstyn, D.G., Thaib, S., and Manclark, C.R. Antibodies to *Bordetella pertussis* in human colostrum and their protective activity against aerosol infection of mice. Infect. Immun. 47:441-445, 1985.

28. Zhang, J.M., Cowell, J.L., Steven, A.C., Carter, P.H., McGrath, P.P., and Manclark, C.R. Purification and characterization of fimbriae isolated from *Bordetella pertussis*. Infect. Immun. 48:422-427, 1985.

29. Manclark, C.R., and Cowell, J.L. Pertussis vaccine. Bell, R. and Torrigiani, G. (eds.). New approaches to vaccine development. Schwabe and Co., AG, Basel, p. 328-359, 1984.

30. Oda, M., Cowell, J.L., Burstyn, D.G., and Manclark, C.R. Mouse protective activities of the filamentous hemagglutinin and the lymphocytosis-promoting factor of *Bordetella pertussis*. J. Infect. Dis. 150:823-833, 1984.

31. Cowell, J.L., Oda, M., Burstyn, D.G., and Manclark, C.R. Prospective protective antigens and animal models for pertussis. In: Leive, L. and Schlessinger, D. (eds.). Microbiology – 1984, p. 172-175. American Society for Microbiology, Washington, DC, p. 172-175, 1984.

32. Manclark, C.R., and Cowell, J.L. Pertussis. In: Germanier, R. (ed). Bacterial Vaccines. Academic Press, N.Y., p. 69-106, 1984.

33. Fish, F., Cowell, J.L., and Manclark, C.R. Proliferative response of immune mouse T-lymphocytes to the lymphocytosis-promoting factor of *Bordetella pertussis*. Infect. Immun. 44:1-6, 1984.

34. Hewlett, E.L., Sauer, K., Myers, A.G., Cowell, J.L., and Guerrant, R.L. Induction of a novel morphological response in chinese hamster ovary cells by pertussis toxin. Infect. Immun. 40:1198-1203, 1983.

35. Sato, Y., Cowell, J.L., Sato, H., Burstyn, D.G., and Manclark, C.R. Separation and purification of the hemagglutinins from *Bordetella pertussis*. Infect. Immun. 41:313-320, 1983.

36. Sato, Y., Sato, H., Izumiya, K., Cowell, J.L., and Manclark, C.R. Role of antibody to the filamentous hemagglutinin and to the leukocytosis promoting factor-hemagglutinin in immunity to pertussis. In J.B. Robbins, J.C. Hill, J.C. Sadoff (eds.) Seminars in Infectious Disease, Vol. IV, Bacterial Vaccines, Thieme-Stratton Inc., NY, P. 380-385, 1982.

37. Cowell, J.L., Sato, Y., Sato, H., An der Lan, B., and Manclark, C.R. Separation purification and properties of the filamentous hemagglutinin and the leukocytosis promoting factor-hemagglutinin from *Bordetella pertussis*. In J.B. Robbins, J.C. Hill, J.C. Sadoff (eds.) Seminars in Infectious Disease, Vol. IV, Bacterial Vaccines, Thieme-Stratton Inc., NY, p. 371-379, 1982.

38. Sato, Y. Izumiya, K., Sato, H., Cowell, J.L., and Manclark, C.R. Role of antibody to the leukocytosis-promoting factor hemagglutinin and to the filamentous hemagglutinin in immunity to pertussis. Infect. Immun. 31:1223-1231, 1981.

39. Sato, Y., Izumiya, K., Sato, H., Cowell, J.L., and Manclark, C.R. Aerosol infection of mice with *Bordetella pertussis*. Infect. Immun. 29:261-266, 1980.

40. Cowell, J.L., Hewlett, E.R., and Manclark, C.R. Intracellular localization of the dermonecrotic toxin from *Bordetella pertussis*. Infect. Immun. 25:896-901, 1979.

41. Cowell, J.L., and Bernheimer, A.W. Role of cholesterol in the action of cereolysin on membranes. Arch. Biochem. Biophys. 190:603-610, 1978.

42. Cowell, J.L., Kim, K.S., and Bernheimer, A.W. Alteration by cereolysin of the structure of cholesterol-containing membranes. Biochem. Biophys. Acta 507:230-241, 1978.

43. Cowell, J.L., and Bernheimer, A.W. Antigenic relationships among thiol-activated cytolysins. Infect. Immun. 16:397-399, 1977.

44. Cowell, J.L., Grushoff-Kosyk, P.S., and Bernheimer, A.W. Purification of cerolysin and the electrophoretic separation of the active (reduced) and inactive (oxidized) forms of the purified toxin. Infect. Immun. 14:144-154, 1976.

45. Cowell, J.L. Energetics of glycylglycine transport in *Escherichia coli*. J. Bacteriol. 120:139-146, 1974.

46. Cowell, J.L., and DeMoss, R.D. Tryptophanase from *Aeromonas liquefaciens*: Subunit structure and aggregation of the enzyme into enzymatically active polymeric species. J. Biol. Chem. 248:6262-6269, 1973.

47. Cowell, J.L., Moser, K., and DeMoss, R.D. Tryptophanase from *Aeromonas liquefaciens*: Purification, molecular weight and some chemical, catalytic, and immunochemical properties. Biochem. Biophys. Acta 315:449-463, 1973.

**INVITED PRESENTATIONS**

1. "Development of Bacterial Capsular Glycoconjugate Vaccines." Presented as part of a symposium on 'Recent Advances in Vaccine Development' at the American Association of Pharmaceutical Sciences Biotechnology Conference, San Diego, California, June 2002.

2. "Development of Nontoxic Mutant CRMs of Pertussis Toxin for Acellular Pertussis Vaccines." Advisory Commission on Childhood Vaccines. Washington, D.C., November 1989.

3. "The Use of Animal Models for Pertussis and Their Relevance to the Development of Acellular Pertussis Vaccines." International Workshop on *Bordetella pertussis*, NIH Rocky Mountain Laboratories, Hamilton, Montana, August 1988.

4. "*Bordetella pertussis*: Virulence Factors, Protective Antigens and Development of Acellular Pertussis Vaccines." UA-UC Conference on Infectious Diseases, Invermere, British Columbia, May 1986.

5. "Filamentous Hemagglutinin and Fimbriae: Physical Characteristics and Roles in Attachment." Seminar on 'Virulence Factors of *Bordetella pertussis* and Their Potential Roles in Pathogenesis.' Annual Meeting, ASM, March 1985.

6. "Involvement of the Filamentous Hemagglutinin in the Adherence of *Bordetella pertussis* to Human WiDr Cell Cultures." Fourth International Symposium on Pertussis, Geneva, September 1984.

7. "Prospective Protective Antigens and Disease Models for Pertussis." Symposium *Bordetella pertussis*: Pathogenesis and Prevention of Whooping Cough. Interscience Conference on Antimicrobial Agents in Chemotherapy. October 1983.

8. "Prospective Protective Antigens and Laboratory Models to Evaluate Vaccine Efficacy." International Workshop: "New Pertussis Vaccines, Laboratory and Clinical Evaluations." National Institutes of Health, February 1982.

9. "Respiratory Infection as a Model to Study Protective Antigens of *Bordetella pertussis*." Seminar on "Immunological Activities of *B. pertussis*." Annual Meeting ASM, March 1981.

10. "Separation and Purification of the Hemagglutinins from *Bordetella pertussis*." International Symposium on Bacterial Vaccines, National Institutes of Health, September 1980.