CURRICULUM VITAE

PERSONAL

Name: Juan Luis Arciniega

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SUMMARY STATEMENT

Dr. Juan L. Arciniega performs consulting on biological products. He retired in 2018 as a Microbiologist from the Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration (FDA), after 29 years of government service. He received an undergraduate degree in Chemistry, Bacteriology and Parasitology in 1982; a Master of Science degree in Clinical Biology in 1985; and a Doctor of Science degree in the same specialty in 1987, all from the National School of Biological Sciences in Mexico City.

Before joining the Laboratory of Pertussis at CBER in 1989 as a Visiting Fellow, he worked for nine years at the Mexican National Public Health Laboratory, most recently as Deputy Director for Biological Control, in charge of two departments with responsibility for sanitary testing of food and biologics. He is also a founding member of the Permanent Commission of the Mexican Pharmacopoeia (Biologics; Bioassay and Statistics Committees).

His research and regulatory activities focused on pertussis (whooping cough), diphtheria and anthrax vaccines, and the development of alternatives to animal testing. Dr. Arciniega's last position at CBER was as a CMC consult reviewer, with special emphasis on methods development, validation, and quality control. Additionally, he participated in other regulatory activities, such as batch release, as a member of the Laboratory of Respiratory and Special Pathogens, Division of Bacterial, Parasitic, and Allergenic Products. Previously (2010-2015) he acted as a CBER/FDA liaison with the US Pharmacopeia (Biologics and Biotechnology 2 Expert Committee).

He has published more than 30 papers in his field and cooperated with the World Health Organization (WHO) and the Pan American Health Organization (PAHO) as a Temporary Advisor; with the European Center for the Validation of Alternative Methods (ECVAM); and with the European Directorate for the Quality of Medicines and Healthcare (EDQM).

Dr. Arciniega has also mentored several young Latin American vaccine regulators and other scientists.

EXPERIENCE – UNITED STATES (1991 – PRESENT)

Consultant. Developing Countries Vaccine Manufactures Network (DCVMN). Preparation of training material, 2020.

Consultant. American and Indian Vaccine companies, through Biologics Quality & Regulatory Consultants, LLC and DCVMN, 2019.

Microbiologist. Laboratory of Respiratory and Special Pathogens. Bethesda, MD, 2016-2018.

Coordination of activities for the official release of acellular pertussis (aP) and anthrax vaccines.

Advice on manufacturing and testing issues related to pertussis vaccine regulation.

Microbiologist. Laboratory of Respiratory and Special Pathogens. CBER/FDA. Bethesda, MD, 2010-2016.

Coordination of activities for the official release of acellular pertussis (aP) and anthrax vaccines.

Coordination and performance of research and development activities related to the quality control testing of aP and anthrax vaccines, including the production of reference materials.

Chairman of forty-six committees for product license supplements related to changes in product testing (aP, anthrax, and tetanus and diphtheria vaccines).

Member of nine review committees for product license supplements related to changes in product testing or manufacturing (aP, anthrax, and tetanus and diphtheria vaccines).

Member of one product license application review committee for a Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP), Inactivated Poliovirus (IPV), Haemophilus b Conjugate (Hib) and Recombinant Hepatitis B Vaccine (HepB) application for infant indication. Quality control testing issues.

FDA Establishment Inspection Program. Participated in one bi-annual inspection (Product Specialist) in 2011.

Research Microbiologist. Laboratory of Methods Development and Quality Control and Laboratory of Respiratory and Special Pathogens. CBER/FDA. Bethesda, MD, 2008-2010.

Coordination of activities for the official release of acellular pertussis (aP) and anthrax vaccines.

Coordination and performance of research and development activities related to the quality control testing of aP and anthrax vaccines, including the production of reference materials.

Chairman of nine committees for product license supplements related to changes in product testing (aP and anthrax vaccine).

FDA Establishment Inspection Program. Participated in one bi-annual inspection (Product Specialist) in 2010.

Microbiologist. Laboratory of Methods Development and Quality Control. CBER/FDA. Bethesda, MD, 2007-2008.

Coordination of activities for the official release of acellular pertussis (aP) and anthrax vaccines.

Coordination and performance of research and development activities related to the quality control testing of aP and anthrax vaccines, including the production of reference materials.

Member of one product license application review committee for a Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine and Inactivated Poliovirus Vaccine (DTaP + HIB + IPV) application for infant indication. Quality control testing issues.

Member of one product license application review committee for a Haemophilus b conjugate vaccine reconstituted with DTaP combined with IPV application for infant indication. Quality control testing issues.

Chairman of seven committees for product license supplements related to changes in product testing (aP and anthrax vaccine).

Member of one review committee for a product license supplement related to a change in product testing (diphtheria and tetanus toxoids).

Reviewer of four Investigational New Drug submissions (pertussis antibody testing).

FDA Establishment Inspection Program. Participated in one bi-annual inspection (Product Specialist) in 2008.

Microbiologist. Laboratory of Methods Development and Quality Control. CBER/FDA. Bethesda, MD, 2000-2006.

Coordination of activities for the official release of acellular pertussis (aP) and anthrax vaccines, including laboratory testing of aP vaccines when required.

Coordination and performance of research and development activities related to the quality control testing of aP and anthrax vaccines, including the production of reference materials.

Coordination and performance of research and development activities related to the in vivo and in vitro testing of diphtheria antitoxin, in animal and human sera.

Member of one product license application review committee for a Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine and Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine (DTaP + HIB + IPV) application for infant indication. Quality control testing issues.

Member of one product license application review committee for a Haemophilus b conjugate vaccine reconstituted with DTaP combined with IPV application for infant indication. Quality control testing issues.

Member of two product license application review committees for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) application for adolescents. Quality control testing issues.

Chairman of twelve committees for product license supplements related to changes in product testing (DTaP, DTaP + HIB + IPV, Tdap and anthrax vaccine).

Member of nine review committees for product license supplements related to a change in product testing (DTaP, Tdap and AVA).

FDA Establishment Inspection Program. Participated in one pre-license inspection (Product Specialist) in 2005 and three bi-annual inspections in 2002, 2004 and 2006.

Visiting Scientist. Laboratory of Methods Development and Quality Control. CBER/FDA. Bethesda, MD, 1999-2000.

Coordination of activities for the official release of pertussis and anthrax vaccines, including laboratory testing when required.

Coordination and performance of research and development activities related to the quality control testing of pertussis vaccines, including the production of reference materials.

Member of one product license application review committee for a Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine (DTaP) application for infant indication. Quality control testing issues.

Chairman of two review committees for product license supplements related to a change in product (DTaP) testing.

Member of eight review committees for product license supplements related to a change in product (DTaP) testing.

FDA Establishment Inspection Program. Participated in one pre-license inspection (Product Specialist) in 1999.

Visiting Scientist. Applied Immunology and Vaccine Evaluation Section. Laboratory of Pertussis (1994-1999)/Laboratory of Respiratory and Special Pathogens (1999). CBER/FDA. Kensington/Bethesda, MD.

Coordination of testing activities for the official control of pertussis vaccines.

Coordination and performance of research and development activities related to the quality control testing of pertussis vaccines, including the production of reference materials.

Member of four product license application review committees for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine (DTaP) applications for infant indication. Quality control testing issues.

Chairman of four review committees for product license supplements related to a change in product (DTaP) testing.

Member of seven review committees for product license supplements related to a change in product (DTaP) testing.

FDA establishment inspection program. Participated in three pre-license inspections (Product Specialist) in 1997 and one in 1998.

Visiting Associate. Applied Immunology and Vaccine Evaluation Section. Laboratory of Pertussis. CBER/FDA. Kensington, MD, 1992-1993.

Coordination of testing activities for the official control of acellular pertussis vaccines.

Coordination and performance of research and development activities related to the quality control testing of acellular pertussis vaccines, including the production of reference materials.

ADDITIONAL REGULATORY ACTIVITIES (1991-2018)

Designing and periodical updating Product Testing Plans (Combination Vaccines containing an aP component and anthrax vaccine --AVA).

Occasional review of Biological Deviation Reports (BPDR; DTaP and anthrax vaccines).

Management of the reference materials program (pertussis and anthrax vaccines).

EXPERIENCE – POST-DOCTORAL (1989-1991)

Visiting Fellow. Biochemistry Section. Laboratory of Pertussis. CBER/FDA. Bethesda, MD 1989-1991.

Participation in studies aimed at characterizing putative protective antigens of Bordetella pertussis, and their immunogenicity.

EXPERIENCE – MEXICO (1977-1989)

Assistant Director for Analysis and Biological Control. National Public Health Laboratory. Mexico City, Mexico, 1986-1989:

Management of the technical activities of the Department for Evaluation of Microbial and Parasitic Risks and the Department for Evaluation of Biologics, supervising approximately 70 employees; establishment of programs for operation; organization of research and publication of technical manuals and papers; participation in training.

Head of Bacterial Vaccines and Hemoderivatives Section. Department of Biologics Evaluation. National Reference Laboratory. Mexico City, Mexico, 1982-1986:

Organization and supervision of the work related to official control of vaccines and blood derivatives; updating of analytical techniques related to these products; supervision of approximately 20 employees.

Professor of "Human Ecology and Health." Nursing School, DGAMDF, Mexico City, D.F., Mexico, 1982:

Lecturing (12 hours/week).

Analytical Chemist. National Reference Laboratory. SSA, Mexico City, Mexico, 1980-1982:

Testing of potency (activity) of the following products: Tetanus toxoid, DTP vaccine, Tetanus and Diphtheria Antitoxins; Tetanus Immune globulin.

Translation Supervisor. "Editorial Interamericana." Mexico City, D.F. Mexico, 1980:

Reviewing translations of English-written books into Spanish, considering proper Spanish Grammar.

Chemist. Clinical analysis laboratory "Central de Análisis." Mexico City, D.F., Mexico, 1979:

Performing clinical analysis (hematology, blood chemistry, bacteriology, and parasitology).

Student. Practice without payment and occasional substitutions in the clinical-immunological laboratory of "Clínicas de Alergia." Mexico City, D.F., Mexico, 1977-1978:

Practice without payment of clinical analysis (hematology, blood chemistry, immunology, bacteriology, and parasitology).

EDUCATION

Graduate:	1987 – Doctor of Science Degree in Clinical Biology. Graduate Section. National School of Biological Sciences. National Polytechnic Institute. Mexico City, Mexico.
	1985 – Master of Science Degree in Clinical Biology. Graduate Section. National School of Biological Sciences. National Polytechnic Institute. Mexico City, Mexico.
Professional:	1982 – Q.B.P. (Licensed Bacteriologist, Parasitologist, Chemist). National School of Biological Sciences. National Polytechnic Institute. Mexico City, Mexico.
High School:	1974 – Clinical Laboratory Technician CECYTEMB "Miguel Othón de Mendizábal" (Vocational School 6). National Polytechnic Institute. Mexico City, Mexico.

COURSES

Introduction to Risk Assessment for Biologics. CBER/FDA. White Oak, 2015.

USP Bioassay Workshop. Rockville, MD 2010.

Introduction to the Principles and Practice of Clinical Research (IPPCR). NIH. Bethesda, MD 2006.

ISO Management Systems for The Laboratory. ISO/IEC 17025. Training class participation. Shady Grove, MD 2001.

Symposia in Clinical Trial Course. Rockville, MD 2001.

Inspection Overview and Techniques. DHHS/FDA/CBER. Gaithersburg, MD 1999.

Vaccines and Related Products. DHHS/FDA/CBER. Gaithersburg, MD 1999.

Basic Food and Drug Law Course. FDA/FDLI. Shady Grove, MD 1998.

Good Manufacturing Practices. DHHS/PHS/FDA/CBER. Bethesda, MD 1997.

Reviewer Training Program and IND and PLA Review Issues. DHHS/PHS/FDA/CBER. Rockville, MD 1996.

Introduction to Epidemiology. FAES. Bethesda, MD 1993.

Clinical Trials: Issues in the Design, Conduct and Analysis. CBER/FDA. Bethesda, MD, 1992.

Recombinant DNA Methodology. FAES. Bethesda, MD, 1991.

Inspection of Production and Good Manufacturing Practices on Biologics Production. LNSP/PAHO. Mexico City, D.F., Mexico, 1986.

Laboratory Administration and Biosafety. LNSP/PAHO. Mexico City, D.F., Mexico, 1986.

Biologics Standardization. LNSP/PAHO. Mexico City, D.F., Mexico, 1986.

Quality Assurance Systems in the Production and Evaluation of Biological Products. CDC Mexico City, D.F., Mexico, 1985.

Biostatistics. Public Health School. SSA, Mexico City, D.F., Mexico, 1982.

Parasitology Seminar. National School of Biological Sciences. National Polytechnic Institute. Mexico City, D.F., Mexico, 1979.

Genetics. COFFAA/Graduate Section. National School of Biological Sciences. National Polytechnic Institute. Mexico City, D.F., Mexico, 1978.

Hematology. National School of Biological Sciences. National Polytechnic Institute. Mexico City, D.F., Mexico, 1978.

INVITED LECTURES AND CONSULTATIONS

Invited speaker and organizer. International Alliance for Biological Standardisation (IABS)/US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) Workshop: Implementing Non-animal Approaches to Human and Veterinary Vaccine Testing: Achieving Scientific and Regulatory Success for Rabies and Beyond. Bethesda, Maryland. October 16-17, 2018.

Invited speaker. Biopharmaceutical Emerging Best Practices Association (BEBPA) Annual Bioassay Conference. Dubrovnik, Croatia. September 29-30, 2016.

Invited speaker. IABS conference: 3Rs alternatives and consistency approach in vaccine lot release testing. Egmond aan Zee, The Netherlands. September 16-18, 2015.

Participant. European Partnership for Alternative Approaches to Animal Testing (EPAA) Workshop: Harmonization of 3Rs in Biologicals. Egmond aan Zee, The Netherlands. September 15-16, 2015.

Organizer. NICEATM, National Centre for Replacement, Refinement, and Reduction of Animals in Research (NC3Rs) and European Directorate for the Quality of Medicines and HealthCare (EDQM). In Search of Acceptable Alternatives to the Murine Histamine Sensitization Test (HIST): What is Possible and Practical. London, United Kingdom. March 4-5, 2015.

Chairman and Speaker. Workshop on Alternatives to the HIST for Acellular Pertussis Vaccines: Progress and Challenges in the Replacement of HIST. Satellite Meeting to the Ninth World Congress on Alternatives and Animal Use in the Life Sciences. NICEATM, NC3Rs, and EDQM. Prague, Czech Republic, August 24, 2014.

Speaker. Alternative Safety Testing Strategies for Acellular Pertussis Vaccines. Meeting Satellite to the Eighth World Congress on Alternatives and Animal Use in the Life Sciences. Center for Vaccine Evaluation at Health Canada, NICEATM and Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). Montreal, Canada, August 21, 2011.

Participant. Animal-free Detection of Pertussis Toxin in Vaccines - Alternatives to the Histamine Sensitisation Test (HIST). Paul-Ehrlich-Institut (PEI), Netherlands Vaccin Instituut (NVI) and EDQM. Langen, Germany, June 9-10, 2011.

Invited Speaker. Potency Testing of Vaccines for Animals: The Way from *in vivo* to *in vitro*. International Workshop organized by PEI, EDQM and the International Alliance for Biological Standardization (IABS). Langen, Germany. December 1-3, 2010.

Lecturer and Organizer. International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions. ICCVAM. Bethesda, MD. September 14-16, 2010.

Invited Speaker. Biological Assay Development and Validation Conference. International Biological Assay Conference (IBC). San Francisco, CA. May 12-14, 2010.

Invited Participant. European Centre for Validation of Alternative Methods (ECVAM)/ EPAA joint workshop on the consistency approach and its potential to reduce the number of animal tests used in the quality control of human and veterinary vaccines. Brussels, Belgium January 11-12, 2010.

Speaker. Biomedical Advanced Research and Development Authority (BARDA) Industry Day. Washington, DC. December 4, 2009.

Temporary Advisor. Informal Consultation on Acellular pertussis vaccine and DTP-based combined Vaccines, WHO. Geneva, Switzerland November 9-13, 2009.

Instructor. Core Team Biologics Training. CBER/FDA. Rockville, MD. October 26-30, 2009.

Member. ICCVAM Biologics Working Group. 2009-10.

Participant. ECVAM workshop: Consistency of Production Approach and its Potential to Reduce Animal Tests in the Quality Control of Vaccines. Ispra, Italy, May 17-19, 2006.

Temporary Advisor. WHO Malaria Vaccines Laboratory Assays Evaluation Group Meeting: Optimizing and Standardizing Assays for Vaccine Evaluation - the Road to a Validated Malaria Assay. Washington, DC, September 12-14, 2005.

Temporary Advisor. Discussion of progress on testing and standardization of whole-cell and acellular pertussis vaccines, review, and planning of collaborative studies in these subjects, and draft regulatory guidelines and other documents for the consideration of the WHO Expert Committee on Biological Standardization. Geneva, Switzerland, March 17-18, 2005.

Discussant. EDQM/ECVAM's Meeting on Alternatives to whole cell pertussis vaccine potency assay. Geneva, Switzerland, March 16, 2005.

Temporary Advisor. PAHO/THS/EV. Meeting of the Regional Network of Quality Control Laboratories. Caracas, Venezuela, March 1-3, 2005.

Discussant. EDQM's International Conference on Serological potency tests for diphtheria and other vaccines. Budapest, Hungary, October 6-7, 2004

Temporary Advisor. PAHO/DVI/HVP. Workshop on Harmonization of Potency Tests for Diphtheria and Tetanus. Organizer. Rio de Janeiro, Brazil, February 4 – 6, 2004.

Temporary Advisor. Discussion of proposed amendments to the current WHO Requirements for DTw (whole cell) P vaccine. Geneva, Switzerland, June 30-July 2, 2003

Temporary Advisor. WHO Working Group on the standardization and control of pertussis vaccines. Ferney-Voltaire, France, May 6-7, 2003.

Temporary Advisor. PAHO/DVI/HVP. Manufacturing and testing of whole-cell pertussis vaccines. National Institute of Hygiene and National Public Health Laboratory Mexico, D.F., Mexico. November 27-29, 2002.

Temporary Advisor. WHO Working Group on the standardization and control of pertussis vaccines. National Institute of Biological Standards and Control, Potters Bar, UK, September 16-17, 2002.

Temporary Advisor. WHO Consultation on DT potency assay and consistency measurement. Bilthoven, The Netherlands, December 16-17, 2002.

Lecturer. IBC Life Sciences' 4th Conference on Biological Assay Development and Validation. San Francisco, CA, May 6-8, 2002.

Lecturer. National Institute of Hygiene "Rafael Rangel." First International Course on Sanitary Surveillance of Biologics. Caracas, Venezuela. May 14-17, 2001.

Organizer. CBER/WHO Workshop on the Standardization and Control of Pertussis Vaccines, Bethesda, Maryland, U.S.A., November 15 - 16, 2000.

Temporary Advisor. PAHO/DVI/HVP "Programa de Acreditación" Mexico, D.F., Mexico. October 25-27, 1999.

Lecturer. Inspector's training program, Mexican Secretariat of Health: Inspection of quality control testing of vaccines and Inspection of whooping cough vaccines manufacturing. Mexico, D.F., Mexico. October 26, 1999.

Invited Contributor. Third World Congress on Alternatives and Animal Use in the Life Sciences. Bologna, Italy, August 29-September 2, 1999.

Temporary Advisor. Working Group on the standardization and control of pertussis vaccines. WHO/BLG. May 19-20, 1998.

Temporary Advisor. Department of Vaccines and Other Biologicals. WHO/CVI. Informal consultation on the control of pertussis with whole cell and acellular vaccines. Geneva, Switzerland, May 18-19, 1998.

Invited Lecturer. I International Symposium: Vaccine Strategies. "Universidad de la Frontera." Temuco, Chile 6-8 May 1998.

Session Co-chairperson. WHO/IABS/NIBSC International Meeting: Control and Standardization of Acellular Pertussis Vaccines. Potters Bar, UK, September 26-27, 1996. Invited presentation: FDA Experience in Toxicity Testing of Acellular Pertussis Vaccines. Session 7 - Requirements for Reference Materials.

Lecturer. Biologics Control and Regulation. "Benemérita Universidad Autónoma de Puebla." Puebla, Mexico, 1996.

Consultant. Informal Consultation on Requirements for Acellular Pertussis Vaccines. WHO. Rome, Italy, 1995.

Lecturer. Quality Control Techniques for Modern Vaccines. Meeting of the Regional Network of National Vaccine Control Laboratories. PAHO. Santiago, Chile, 1994.

Presenter. Workshop on the Quality Control of Component Pertussis Vaccines. Invited Presentation: Approaches to the Toxicity Testing of Acellular Pertussis Vaccines. Willowdale, Canada, 1992.

Lecturer. Symposium. "Dr. Miguel Enrique Bustamante." SSA/DGE/INDRE. Mexico City, Mexico, 1991.

Expert in Pharmacopeia. Permanent Commission of the Mexican United States Pharmacopeia. Bioassay and Statistics Committee and Biological Products Committee. 1984-1988.

LANGUAGES

Fluent in English and Spanish; knowledge of French, Italian, and Portuguese.

HONORS AND AWARDS

CBER Scientific Achievement Honor Award - Regulatory Scientist: International Working Group for Alternatives to HIST. 2016.

FDA Group Recognition, as a member of the Pentacel® Vaccine Licensure Group. "For outstanding teamwork enabling the development and licensure of DTaP-IPV/Hib vaccine." 2009.

FDA Individual Award (Reward and Recognition Program; Quality Performance). Cash Award. 2007.

FDA Award of Merit, as a member of the Pertussis Vaccine Licensure Group. "For exceptional review of clinical and manufacturing data supporting licensure of ADACEL™, BOOSTRIX® and DAPTACEL®, pertussis containing vaccines for use in children, adolescents and adults." June 16, 2006.

FDA Leveraging/Collaboration Award (CDRH), as a member of the Anthrax Diagnostics Premarket Review Team. "For outstanding collaborations and review of two new anthrax diagnostic tests for use in bioterrorism preparedness and response." June 2005.

FDA Award of Merit, as a member of the Pediarix™ Licensure Group. "For exceptional review of manufacturing and clinical data supporting licensure of Pediarix™, the first combination vaccine for prevention of five diseases in infants and children." May 9, 2003.

FDA Group Recognition Award. Anthrax Vaccine Availability Group. "For significant and exceptional performance in responding to a national emergency through efforts enabling current and future availability of anthrax vaccines, including use under IND." June 21, 2002.

Reward and Recognition Award Certificate for "Assuming increased laboratory management and review responsibilities at a time when substantial laboratory resources were being directed to anthrax vaccine regulation." April 9, 2002.

Reward and Recognition Award Certificate for "his leadership in organizing, hosting and conducting a WHO Workshop on the standardization and control of pertussis vaccines." April 6, 2001.

FDA Group Recognition Award. Team Biologics. "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 9, 2000.

Reward and Recognition Award Certificate for "Effective oversight of pertussis vaccine lot release; in particular, for maintaining timely and high-quality protocol review when laboratory was short-handed." June 19, 1999.

FDA Award of Merit. Certiva Licensing Group. “For critical and careful review of the acellular pertussis vaccine Certiva for immunization of infants and young children, an important public health measure.” June 11, 1999.

Reward and Recognition Award Certificate for “His contributions to the quality control of vaccines through his effective oversight of pertussis vaccine lot release activities.” June 26, 1998.

FDA Award of Merit. Infanrix Licensing Group “For timely and thorough review of Infanrix, an important new vaccine for American infants and children.” May 8, 1998.

PHS/FDA On-the-Spot Award Certificate. August 21, 1997.

FDA Commendable Service Award. Acellular Pertussis Vaccine Review Group “For timely and precedent-setting review of acellular pertussis vaccines for immunization of infants, an important health measure and significant improvement in the vaccine regimen." May 9, 1997.

PHS/FDA On-the-Spot Award Certificate for "Expediting the licensure of two acellular pertussis vaccines." May 22, 1997.

PHS/FDA On the Spot Award Certificate for "Special work done in expediting the licensure of the first acellular pertussis vaccine for infant use." October 9, 1996.

FDA/CBER Public Health Achievement Award: Laboratory of Pertussis for "Demonstrating exceptional and collaborative efforts which brought honor to CBER, the Public Health Service, and the Department of Health and Human Services." October 1995.

Fogarty Fellowship. Pertussis Laboratory. CBER/FDA. Dr Charles R. Manclark/Dr. Drusilla L. Burns. 1989-1992.

National School of Biological Sciences. National Polytechnic Institute. Distinguished Graduate Award for "Relevant academic or professional activity in regards of his contributions to science, technological development or social issues." Mexico City, D.F., Mexico. 1989.

Honorable mention for "Exceptional oral dissertation, uninterrupted studies, 9.0 or above (out of 10) overall ranking grade and overall consent to award the distinction by the jure." Doctoral dissertation. 1987.

WHO/PAHO Fellowship. Pertussis Laboratory. CBER/FDA. Dr Charles R. Manclark/Dr. Drusilla L. Burns. April-June 1986.

Honorable mention. "Exceptional oral dissertation, uninterrupted studies, 9.0 or above (out of 10) overall ranking grade and overall consent to award the distinction by the jure." Pre-doctoral (Master of Science) exam. 1985.

CONGRESSES

Corvette LJ, Dominguez-Castillo RI, Sirota L, Arciniega J. Differences in the Immunogenic Response to Pertactin (PRN) in Two Pertussis Combination Vaccines in Mice. Ninth International Bordetella Symposium. September 30 - October 3, 2010. Baltimore, Maryland, USA.

McNichol BA, Verma A, Burns DL, Dominguez R, Arciniega J. Stibitz S.
Towards a More Stable rPA Vaccine: The Effects of Substitution of Deamidation-Susceptible Asparagine Residues on Biological Activity and Stability. 2010 ASM Annual Meeting. Abstract B-555.

Castelán-Vega JA, Sirota L, Parreiras P., Arciniega JL. Comparison of ELISA and toxin neutralization to detect changes in immunogenicity of anthrax vaccines in mice. 2008. 2nd Global Vaccine Congress. Boston, MA, USA. Abstract P-21.

Parreiras P, Sirota L, Wagner L, Menzies S, Arciniega J. Agreement between Estimates of Antibodies Induced by Anthrax Vaccines Containing Protective Antigen, Using ELISA and Toxin Neutralization. 2006. ASM Biodefense Research Meeting. Washington, DC, USA. Abstract 201 E.

Berthold I, Pombo M, Wagner L, Jaramillo MT, Arciniega J. Formulation Studies of New Anthrax Vaccines Containing Purified Recombinant Protective Antigen (rPA). 2003. ASM Biodefense Research Conference. Baltimore, Maryland, USA. Abstract 76.

Pombo ML, Berthold IG, Gingrich E, Jaramillo MT, Leef M, Arciniega JL. Validation of an Anti-PA ELISA for the Potency Testing of Anthrax Vaccine in Mice. 2003. ASM Biodefense Research Conference. Baltimore, Maryland, USA. Abstract 93a.

Roecklein T, Gingrich E, Razzaque N, Arciniega J. Studies to Assess Immunogenicity of Acellular Pertussis Vaccines: Use of a Murine Model of Antibody-Mediated Protection from Pertussis Toxin-Induced Leukocytosis to Evaluate Different Pertussis Toxoids. 2001. ASM Annual Meeting. Abstract E-28.

Kardas O, Lynn F, Meade B, Arciniega J. Use of antibody-mediated protection from pertussis toxin-induced leukocytosis in mice to evaluate procedures of chemical inactivation. 1999. ASM Annual Meeting. Abstract B/D 276.

Romani T, Lynn F, Meade B, Arciniega J. Restoration of virulence of a pertussis toxin minus mutant of Bordetella pertussis by systemically administered PT in the murine intracerebral infection model. 1997 ASM Annual Meeting. Abstract B416.

Arciniega JL, Lynn F, Hsu H, Meade BD. Validation of a test for residual pertussis toxin activity in acellular pertussis vaccines. FDA Forum on Regulatory Sciences, 1996. Abstract C12.

Lynn F, Meade B, Arciniega J. Quantitation in mice of antibody-mediated protection from the leukocytosis produced by pertussis toxin. 1995 ASM Annual Meeting. Abstract B417.

Lynn F, Burnette N, Romani T, Mar V, Edwards K, Meade B, Arciniega J. Human antibody response to the B oligomer of pertussis toxin. 1993 ASM Annual Meeting. Abstract B31.

Arciniega JL, Hewlett EL, Edwards KM, Meade B. Antibodies to Bordetella pertussis adenylate cyclase toxin in neonatal sera. 1992 ASM Annual Meeting. Abstract C432.

Gould-Kostka JL, Arciniega JL, Burns DL. Characterization of a monoclonal antibody which inhibits the ATPase activity of the molecular chaperone, GroEL. 1992 ASM Annual Meeting. Abstract K103.

Arciniega, JL, Burnette, WN, Mar VL, Burns, DL. Protective activity of a recombinant B oligomer of pertussis toxin. 1991 ASM Annual Meeting. Abstract B279.

Gould-Kostka J, Arciniega J, Burns DL. Biochemical and immunological characterization of a GroEL-like protein from Bordetella pertussis. 1991 ASM Annual Meeting. Abstract B283.

Arciniega JL, Johnson F, Hewlett E, Deforest A, Endoh M, Manclark C. Human serological response to Bordetella pertussis antigens. 1990 ASM Annual Meeting. Abstract B145.

Burns D, Arciniega J, Gould-Kostka J, Endoh M, Kessel M. Characterization of a protein from Bordetella pertussis which is antigenically related to a 65-kDa mycobacterial heat-shock protein. 1990 ASM Annual Meeting. Abstract B144.

Arciniega JL, Burnette WN, Bartley TD, Mar VL, Whiteley DW, Manclark CR, Burns DL. The enzymatically-active A subunit is required for the leukocytosis-promoting and histamine-sensitizing activities of pertussis toxin. Sixth International Symposium on Pertussis, 1990. Abstract 3.

Arciniega JL, Hewlett EL, Gray MC, Deforest A, Wassilak, SGF, Onorato I, Manclark CR, Burns, DL. Human serological response to adenylate cyclase toxin of Bordetella pertussis. Sixth International Symposium on Pertussis, 1990. Abstract 39.

Gould-Kostka J, Arciniega J, Kessel M, Manclark CR, Burns DL. Characterization of a 63-kDa protein from Bordetella pertussis which is antigenically related to a mycobacterial heat-shock protein. Sixth International Symposium on Pertussis, 1990. Abstract 32.

Uribe, RM, Porras, JA, Arciniega, JL. "Analysis of the homogeneity of DTP vaccine through the determination of aluminum ion." Congress of the Mexican Association of Microbiology, 1989.

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Pan American Journal of Public Health
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