CURRICULUM VITAE

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LinkedIn

EDUCATION: Ph.D. Microbiology, H.P. University, India, 1988
M.Sc. Microbiology, H.P. University, India, 1982
B.Sc. Microbiology, H.P. University, India, 1980
B.Sc. Chemistry, Botany, Zoology, Panjab University, India, 1977

PROFESSIONAL HISTORY:

2013 – Current, Co-Owner and Principal Consultant, **Biologics Quality & Regulatory Consultants, LLC**

- Consultation on the Science and Compliance of development, manufacture & regulation of biological products in a dynamic 21st century risk based regulatory environment
- Consultation on total sustainable compliance in manufacturing operation of biologics and drugs based on science & law for the international market, using modern concepts of quality by design and risk management approaches to exceed minimum requirements
- Consultation on Combining scientific & regulatory expertise with strong mentoring, motivating & decision making skills, using modern technologies, strategic planning leading to achieving vision & mission of the organization
- Consultation on the Methods development, qualification and validations
- Preparation of IND, BLAs, and other regulatory documents
- Audits, gap analysis and due diligence for GLP, GMP in laboratory operations.
- Development of quality systems, master validation plans, training programs, documentation systems

2016 – Current, Member – Scientific Committee, **VaxYnethic** (Joint Venture between Menarini NewTech and BiosYnth)

2015 – Current, Scientific Advisor, **Metaclipse Therapeutics**

2006 – 2013, *Deputy Director and Lab Chief*, Division of Biological Standards and Quality Control**, Center for Biologics Evaluation and Research, FDA**, Rockville, MD

- Management of Lot Release Testing for biologics under ISO 17025 Compliant Labs
- Management of Standards and Reagents for Biological Products
- Management of Quality Systems, including Testing Plans, SOP, etc
- Review of regulatory filing documents, including BLA, BLA supplements, IND, etc.
- Represent CBER for analytical methods, lot release testing, standards and reagents at

the FDA/Industry Meetings and discussions with sponsors of BLAs.
- Management of research Labs working on Development of Rapid Methods for Sterility and Mycoplasma testing and Alternate Potency Methods for Influenza Vaccines
- Led Division in 1SO 17025 accreditation of analytical methods used in lot release testing
- Conducting training to CBER's CMC reviewers, Team Biologics Inspectors, Foreign Regulators on Analytical Methods, Rapid Microbiological Methods, Lot Release Process, Standards and Reagents

2004 – 2006 *Senior Consultant*, **Biologics Consulting Group**, Alexandria, VA
- Consultation on the science and compliance of development, manufacturing operations and licensure of biological products
- Consultation on the Methods development, qualification and validations
- Preparation of IND, BLAs, responses to FDA 483 and warning letters
- Consultation on meetings with FDA
- Audits, gap analysis and due diligence for GLP, GMP and manufacturing operations.
- Development of quality systems, master validation plans, training programs, documentation systems

2001 – 2004 *Associate Director*, **Wyeth Research**, Pearl River, NY
- Head, Analytical Development Group, Set-up a new group to operate under cGMP
- Analytical methods, Immunochemical methods, Molecular biology assays, Bio-assays, Functional assays – Development, Qualification and Validation
- Test and Release of Clinical Trial materials, cell banks and seeds for lot release & stability
- Equipment Qualification, routine and research type, examples, Research Laboratory Instruments, such as SDS-PAGE/Western Blot, ELISA Reader, PCR, Near IR
- Consult with other Analytical Development, Formulation Development and Process Development groups on issues related to equipment qualification, methods and process validation and formulation studies.

1997 – 2001 **Wyeth-Lederle Vaccines and Pediatrics**, Quality Control (1998-2001 *Associate Director*, 1997-98 Senior Manager; QC).
- Head, Assay Development & In-vitro Testing Department
- Management of Budget (> $ 3 millions) and Resources for Department
- Implement cGMP by setting Quality Systems
- Initiate and Implement Methods Validation as per ICH and USP by writing Policies and Procedures; Leader, Methods Validation Team, Prepare Master Validation Plan and validate all QC methods.
- Initiate Equipment Validation at QC Labs, and Analytical Development Lab, by writing Standard Operating Procedures and Master Validation Plan.
- Write and review Corporate Policies and Guidelines and SOPs to develop systems for implementation of cGMP, safety and environmental regulations.
- Implement Investigation (OOS) and Change Control Procedures.

- Implement Training Program for the Staff (Training curricula) & Documentation Systems (note books, worksheets, log books) to comply with cGMP regulations
- Quality control operations, including, on time testing and release of samples for lot release and stability, investigations, development and validation of assays.
- Represent Dept in audit from Corporate, FDA and other Regulatory Agencies.
- Assay Transfer from R & D to QC and Consultation to other Departments, including R & D, and Manufacturing on issues related to development, manufacture, control and regulation of vaccines.
- Develop IND applications, CMC section of BLA (NDA).

1996 – 1997 *Consultant***, Chiron Vaccines**, Emeryville, CA.

- Project Leader for Meningococcus C clinical serology.
- Leader, Validation Team for validation of assays for clinical serology
- Develop combination vaccines.

1991 – 1996 **Massachusetts Public Health Biologic Labs**, Boston, MA (1994-96 *Assistant Director*, 1993-94 *Chief of the Lab*; 1991-1993 *Senior Research Scientist*)

- Head, Bacterial Vaccine Research and Clinical Serology Laboratory
- Manage following projects by developing agreements and collaborations.
  - Controlled Release of Vaccines (funded by NIH and WHO), collaboration with MIT
  - Production of Safe Diphtheria Toxin Mutant (funded by NIH), collaboration with Harvard University
  - Polysaccharide-protein conjugate vaccines, collaboration with Uniformed Services University
  - Liposomes as delivery vehicles for vaccines with Novavax
- Set-up Research Lab and GLP Lab for development of controlled release vaccines and combination vaccines
- Evaluate Adjuvants and Delivery Systems for Vaccines
- Research on Formulations – combination vaccines, carrier specific epitope suppression, antigenic competition, interference between components, controlled release, lyophilization
- Develop alternative methods for control of vaccines for reducing the use of animals
- Clinical Serological methods, Immunochemical and Functional assays – Development and Validation; Correlation between Immunochemical and Functional assays
- Scientific support and guidance to Bacterial Vaccine Production Dept

1989 – 1991 *Visiting Fellow*, Laboratory of Developmental and Molecular Immunity, NICHD, **National Institutes of Health**, Bethesda, MD.

- Develop polysaccharide-protein based cholera vaccine & complete Phase I clinical trial
- Develop novel method for detoxifying lipopolysaccharide (LPS) for preparing its conjugate vaccines for human use.
- Develop and characterize conjugates of detoxified LPS from *E. coli* J5 and O111
- Purification of proteins, polysaccharides, antibodies and other microbial components

- Conjugation of polysaccharide and proteins – Development of high yield methods

1984 – 1989 Japanese Encephalitis Vaccine Division, **Central Research Institute**, Kasauli, India (1986-89 *Assistant Technical Officer*; 1984-86 *Technical Supervisor*)

- Production and in-process quality control of Japanese encephalitis vaccine
- Research on development of cell-culture based Japanese encephalitis vaccine by adapting the virus on Vero cells
- Research on the development of assays for in-process quality control of JE vaccine
- Research on the production of monoclonal antibodies against Japanese encephalitis virus and polio viruses

1977 – 1984 *Technical Supervisor*, Biological Standardization & Quality Control Div. (National Control Authority), **Central Research Institute**, Kasauli, India.

- Standardization and Quality Control of Vaccines and antisera.
- Regulatory work and review of production and testing protocols.
- Preparation of National Standards against the International Standards.
- Quality Control of raw materials
- Research and Development on assays for quality control of vaccines

PROFESSIONAL SOCIETIES:

1990 – Present	American Society for Microbiology
1981 – 2006	International Association of Biological Standardization/International Association of Biologicals
1986 – Present	Indian Association of Medical Microbiologists

EXPERT MEMBERSHIP

- Member of World Health Organization Expert Committees and Other Teams formed by regulatory agencies, including FDA & EMEA to develop regulations for vaccines
- HHS H5N1 Vaccine Working Group
- FDA Liaison – USP Committee on General Chapters, Microbiology, 2010 – 2013
- FDA Liaison – USP Committee on General Chapters, Biological Analysis, 2010 – 2013
- CDC's International Vaccine Stability Working Group
- Co-Chair, CBER's Rapid Microbiological Methods Group
- Member – USP Committee on General Chapters, Microbiology, 2015 – 2020
- Member – USP Panel on Modern Microbiological Methods, 2016

HONORS AND AWARDS

1980	Gold Medal, standing 1st in University for B.Sc. Degree
1982	Gold Medal, standing 1st in University for M.Sc. Degree
2008	CBER, FDA, Managerial Excellence Award – For clear vision, strong leadership and excellence in team building and staff motivation during the planning and

development phases of DPQ

2008 CBER Group Award – Alfuria® Influenza Virus Vaccine Review Team – For exceptional and expedited review of clinical and manufacturing data licensure of the Influenza Virus Vaccine, Afluria®, via an accelerated approval pathway

2008 FDA Scientific Achievement Award - Excellence in Analytical Science

2009 FDA Group Recognition Award on Laboratory Quality Systems Group – For building de novo a division of laboratories to be the first to operate under the CBER Laboratory Quality System

2009 CBER Group Award on Influenza Vaccines Potency Reagents Development – For efficient and timely development, manufacture and supply of potency reagents for inactivated influenza vaccine during a season when all 3 strains were changed

2009 Certificate of Appreciation – Core Team Biologics Training, FDA Office of Regulatory Affairs/ORAU - For Outstanding Contributions to Core Team Biologics Training

2009 Certificate of Appreciation – Team Biologics Update, FDA Office of Regulatory Affairs/ORAU - For Outstanding Contributions to Team Biologics Update

2009 Certificate of Appreciation – Core CBER Foreign regulators Seminar, CBER - For Presenting at the CBER Foreign Regulators Seminar

2010 FDA Commissioner's Special Citation on the FDA Response to 2009 H1N1 – For extraordinary achievements ensuring the public health of our nation in response to the 2009-2010 H1N1 influenza pandemic

2010 CBER Group Award – Seasonal Influenza Vaccine Licensing Review Group – For outstanding performance in review activities resulting in sustained and expanded seasonal influenza vaccine supply across age groups

2010 FDA Public Health Achievement Award – Hiberix and Ixiaro Licensing Review Team – For outstanding accomplishment in approving new vaccines to address critical shortages

2011 FDA Outstanding Service Award – For exceptional vision and persistence in implementation of new DPQ operational business model that has resulted in ISO accreditation of Lot Release testing activities

2011 FDA Commissioner's Special Citation for CBER Laboratory Quality System – For re-engineering CBER's product testing program to meet internationally recognized standard ISO 17025 on laboratory competence and for achieving third party accreditation to the standard

2011 CBER Group Award – Menveo Licensing Review Group – For outstanding achievement in approving a complex new vaccine for the prevention of invasive meningococcal disease in adolescents and adults

2011 CBER Public Health Achievement Award – Prevnar 13 Licensure Review Group – For outstanding achievement in approving a significant new vaccine with expanded protection against serious pneumococcal disease in young children

2011 FDA Excellence in Analytical Science - For significant contributions to the agency in evaluating and implementing rapid microbiological methods for sterility testing of biological products

2011 Reward of Recognition - Leadership in the preparation of additional assays in order to allow expansion of scope of CBER accreditation of testing

2012 CBER Group Award – Adenovirus Vaccine Licensure Team – For outstanding accomplishment in the review and approval of clinical prophylactic vaccine for US military use fulfilling an unmet medical need
2013 FDA Outstanding Service Award
2014 CBER Group Award – Flublok-Influenza Vaccine BLA Review Team – For Outstanding achievement in the review and approval of the first seasonal, recombinant, egg-free influenza vaccine licensed in the United States.

INVITED PRESENTATIONS (Scientific/Regulatory Meetings, Conferences & Workshops)

1984 Invited speaker for the "Round Table Discussions" during VII International Conference on Tetanus in Italy.
1987 Invited participant at the VIII International Conference on Tetanus in USSR.
1987 Invited as Consultant for 3 days to Bacterial Vaccines Unit of Institut Pasteur, Marnes-La-Coquette, France.
1988 Invited to present a paper at the "FEMS-Symposium" on pertussis in GDR.
1989 Invited to present a paper at the WHO sponsored workshop on Diphtheria-Tetanus-Pertussis vaccine held at the Central Research Institute, Kasauli, India.
1990 Invited to deliver a Guest Lecture at the Central Research Institute, Kasauli, India on polysaccharide-protein conjugate vaccines.
1990 Invited as Consultant for 3 days to Bacterial Vaccines Unit of Institut Pasteur, Marnes-La-Coquette, France.
1991 Invited to deliver a Guest lecture at the Central Research Institute, Kasauli, India on New Advances in Vaccinology.
1993 Chairman of "Modern Vaccines" session at the 28th Annual meeting of North-East Branch of American Society for Microbiology.
1994 Chairman of "Vaccine Production" session at the Second International meeting on Vaccines - New Technologies & Applications held at Alexandria, VA, USA.
1994 Organizer and Invited Speaker at the Inaugural Symposium of the International Society for Vaccines at Las Vegas, NV, USA.
1994 Invited to deliver a Guest Lecture on Adjuvants/delivery systems for human vaccines at the Fourth annual meeting of the Indian Academy of Vaccinology and Immunobiology at Hyderabad, India.
1994 Invited to deliver a Guest Lecture on Adjuvants/delivery systems for human vaccines at the Paul Ehrlich Institute, Langen, Germany.
1994 Chairman, Workshop on Serological Methods and Cell Cultures held during International Symposium on "Replacement, Reduction and Refinement of Animal Experiments in the Development and Control of Biological Products" at the Paul Ehrlich Institute, Langen, Germany.
1995 Invited to present a paper on "Liposomes and Biodegradable microspheres as vaccine adjuvants/delivery systems" at the IBC's 2nd Annual Conference on New Advances in Vaccine Technologies and Applications at Bethesda, MD.
1995 Chairman of "Adjuvants" session and invited speaker on "Polyester Microspheres for Controlled Release of Vaccines" at the Third Annual Meeting on Vaccines - New Technologies & Applications at Alexandria, VA, USA.

1995 Chairman of "Adjuvants & Delivery Systems" session and invited speaker on "The Role of Adjuvants and Delivery Systems in Modulation of Immune Response to Vaccines" at the 39th OHOLO Conference on Vaccines: Novel Strategies in Design and Production at Eilat, Israel.

1995 Invited to participate in the International Association of Biological Standardization/ World Health Organization's International Symposium on Progress on the Stability of Vaccines, Geneva, Switzerland.

1996 Invited Speaker at the annual meeting of the Brazilian Society of Biochemistry and Molecular Biology at Caxambu, Brazil.

1996 Co-Chairman of a session "New Adjuvants and Vaccine Formulations" and invited Speaker at the IABS/WHO meeting on "Progress on Modulation of the Immune Response to Vaccine Antigens" in Bergen, Norway.

1996 Invited Speaker at the "WHO/IABS/NIBSC International Meeting on the Control and Standardization of Acellular Pertussis Vaccines" at Potters Bar, UK.

1997 Temporary Advisor and Invited to Present a review on Animal Models for conjugate vaccines at the World Health Organization Informal Meeting on the Requirements for the *Haemophilus influenzae* type b conjugate vaccines in Belgium.

1998 Invited Participant at the "CVI/WHO Informal Consultation on Control of Pertussis with Whole Cell and Acellular Vaccines" at WHO, Geneva, Switzerland.

1998 Invited Participant at the "WHO/NIBSC Informal Workshop on Physico-chemical Procedures Appropriate to the Characterization of *H. influenzae* type b Conjugate Vaccine" at Potters Bar, UK.

1998 Member of the Scientific Committee and invited Key-note speaker at the "IABS Symposium on Alternatives to Animals in Development and Control of Biological Products for Human & Veterinary Use", London, UK

1998 Invited Participant at the Workshop on "The Harmonization of Technical Requirements for Vaccine Production, Quality, Licensing and Registration held during Meeting on the Children's Vaccine Initiative, Consultative Group, Geneva, Switzerland.

1998 Invited Participant at the "WHO/NIBSC Informal Consultation on Mouse Protection Models for Acellular Pertussis Containing Vaccines", Potters Bar, UK.

1999 Invited Participant at the "WHO/RIVM Working Group on Harmonization of Antigen Content and Potency Measurement of DT Vaccines", Bilthoven, The Netherlands.

1999 Co-chairman of a Workshop on "The Development of New Vaccines Without Using Animals" held during 3rd World Congress on Alternatives and Animal Use in Life Sciences, Bologna, Italy.

1999 Invited Participant at the European Department for the Quality of Medicines meeting on "Vero Cells Assays as Alternative to Animal Testing", Strasbourg, France.

2000 Invited Speaker at the National Vaccine Program's Workshop on "Aluminum in Vaccines", San Juan, Puerto Rico

2000 Invited Speaker at European Department for the Quality of Medicines meeting on "Tetanus Vaccines for Human Use", Strasbourg, France.

2000 Invited Participant at the CBER/WHO Workshop on the Standardization and Control of Pertussis Vaccines, Bethesda, MD

2002 Invited Participant at the WHO Meeting on Diphtheria and Tetanus Vaccines, RIVM,

Bilthoven, The Netherlands.

2005 Invited Speaker at the IBC's International Conference on "Analytical Method Validation", Boston, MA

2005 Invited Speaker at the "GMP Update 2005" Conference, Toronto, Canada.

2005 Invited Speaker at the "2nd Annual Toxicology Study Director & Monitors Conference – Examining GLP Compliance Issues & Gaining Insight from Practical Case Studies", Princeton, NJ

2007 Invited Speaker representing CBER at the WHO/Health Canada Consultations on Vaccine Lot Release (February/March 2007 and September 2007), Ottawa, Canada

2007 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD

2008 Invited Participant representing CBER at the WHO/East Mediterranean Regional Office Drafting Group Meeting on Lot Release of Vaccines Consultations, Egypt, Cairo

2008 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD

2008 Organizer and Key Participant in a Public Meeting on "Rapid Methods for Detecting Mycoplasma Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines and Other Biological Products" Gaithersburg, MD

2009 Co-chair of a Workshop on "Design Space for Analytical Methods" at the WCBP 2009: 13th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products, San Francisco, CA

2009 Represented CBER at the Vaccines and Related Biological Products Advisory Committee on "Candidate Vaccine Strains and Potency Reagents, 2009-2010 Season"

2009 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD

2010 Represented CBER at the Vaccines and Related Biological Products Advisory Committee on "Candidate Vaccine Strains and Potency Reagents, 2010-2011 Season"

2010 Co-chair of Workshops on "Trading Spaces: Risks and Mitigations for Assay Transfer" and "QbD for Analytics" at the WCBP 2010: 14th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products, Washington, DC

2010 Invited Speaker representing CBER at the PhRMA – FDA CBER Vaccines Dialogue on "Lessons Learned from H1N1 swine influenza vaccine development" Rockville, MD

2010 Invited Participant at the WHO, FDA and Health Canada Workshop on lessons learned from potency testing of pandemic (H1N1) 2009 influenza vaccines and considerations for future potency tests, Ottawa, Canada.

2010 Invited Speaker at the International Pharmaceutical Academy's CMC Regulatory Compliance Conference, Montreal, Canada

2010 Invited Speaker at the "Third International Conference on Modern Vaccines/ Adjuvants Formulation 2010 – Impact on Future Development", Cannes, France

2010 Invited Speaker at a Plenary Session and Participant at the PDA's 5th Annual Global Conference on Pharmaceutical Microbiology, Advances in Microbial Control and Product Quality, Washington, DC

2010 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD
2011 Invited Speaker at the Plenary Session on "Assay Modernization – Good for Industry, Regulators and Public Health" and Co-chair of Workshop on "Modernizing Analytical Methods for Legacy Products" at the WCBP 2011: 14th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products, Washington, DC
2011 Invited Speaker at the USP Expert Committee meeting on Biologics and Biotechnology 2 on "CBER Perspectives on Use of Rapud Microbiological Methods for Sterility Testing of Biological Products"
2011 Invited Speaker at the European Compliance Academy Meeting on "Validation of Molecular Biological Methods, Vienna, Austria
2011 Invited Speaker and Participant at the PDA 2011 Analytical Methods Development & Validation Workshop, Bethesda, MD
2011 Invited Speaker and Participant in the FDA/IABS Workshop on "Reference Standards for Therapeutic Proteins: Their Relevance, Development, Qualification and Replacement", Bethesda, MD.
2011 Invited Speaker at the IBC's 15th Annual Well Characterized Biological Conference, Washington, DC.
2011 Invited Speaker at a Plenary Session and Participant at the 2011 USP Science & Standards Symposium on Biologics & Biotechnology: Advancing Quality Standards through Analytics and Assays, Seattle, WA
2011 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD
2012 Co-chair of a Workshop on "Spotlight on Reference Standards – what is required to become "The Standard" at the WCBP 2012: 13th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products, San Francisco, CA
2012 Represented CBER at the Vaccines and Related Biological Products Advisory Committee on "Candidate Vaccine Strains and Potency Reagents, 2012-2013 Season"
2012 Invited Speaker representing CBER at the Annual PhRMA Flu Meeting, Rockville, MD and made 3 presentations on 'Updates from CBER", "Updates on Rapid Microbiological Methods for testing influenza vaccines" and "Understanding Single Radial Immunodiffusion method for potency testing of inactivated influenza vaccines"
2012 Panel Member and Invited Speaker at the PDA/FDA Vaccines Conference – Challenges and Opportunities for Providing Vaccines to the World, Bethesda, MD
2012 Co-Chair and Invited Speaker at the USP's 5th Bioassay Workshop, Rockville, MD
2012 Invited Speaker at the European Compliance Academy's "Rapid Microbiological Methods Conference", Munich, Germany (Presented by telephone)
2013 Co-chair of a Workshop at the WCBP 2013: 16th Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products, Washington, DC
2013 Invited Speaker at the exl Pharma's Bioanalytical Methods & Modeling Integration Summit, Baltimore, September 16 – 18, 2013. Chaired the Critical Reagent Think

Tank and made 3 presentations "Generation, Calibration, Qualification, and Use of Critical Reagents and Standards", "KEYNOTE: Make the Necessary Extrapolations between Regulatory Guidelines for Vaccines and Therapeutic Proteins" and "Streamline Development of Novel Scaffolds by Transitioning Assays from Research to Commercial Manufacture"

2013 Invited Speaker and Panel Discussion member on Regulatory Update at the 2013 PDA Analytical Methods Development & Validation Workshop, Baltimore, October 7 – 8, 2013 and made a presentation on "Method Life Cycle Overview – The Validation Phase"

2013 Invited Speaker at the International Society for Bioprocess Technology's 1st Fall meeting on Cell Line Development & Banking + Rapid Scale-up & Testing, Rosslyn, VA October 14 – 16, 2013 and made a presentation on "Scientific and Regulatory Aspects of Methods for Cell Culture-Based Biological Products in Ensuring Safety and Building Quality"

2013 Invited Speaker at the European Compliance Academy's PharmaLab 2013 Analytics, Bioanalytics and Microbiology Congress, Dusseldorf, November 13 – 14, 2013 and made 2 presentations on "Rapid Sterility Methods Versus Compendium Methods" in ECA – Current Developments and Trends in Sterility Testing Symposium and "Scientific & Regulatory Aspects of Microbial Safety of Starting Materials used in Manufacture of Biological Products" in ECA – Microbial Safety of Raw Materials and Excipients.

2014 Invited Speaker at the European Compliance Academy's European Microbiology Conference, Prague, May 7 -8, 2014 and made 2 presentations on "Validation of Microbiological Methods – Expectations for Regulatory Compliance" and "Role of Environmental Monitoring and Microbiological Testing during Manufacture of Sterile Drugs"

2014 Invited Speaker at the International Society for Bioprocess Technology's 2nd Fall meeting on Cell Banking, Contamination Control & Rapid Scale-Up & In-Process Testing, Rosslyn, VA October 27 – 29, 2014 and made a presentation on "Role of Environmental Monitoring and Microbiological Testing During Manufacture of Cell Culture Based Biologics"

2015 Invited Participant and Speaker at the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)'s Workshop on "In search of Acceptable Alternatives to the Murine Histamine Sensitization Test (HIST): What is Possible and Practical?" London, UK, 4-5 March 2015 and made a presentation on "Role of Toxoiding and Adjuvanting in Detection of Residual Pertussis Toxin by *in vitro* Methods"

2015 Invited Speaker at the International Society for Bioprocess Technology's 3rd Fall meeting on Cell Banking, Contamination Control, Process Analysis & Automation, Rosslyn, VA September 28 – 30, 2015 and made a presentation on "Analytical Methods in Monitoring and Managing Manufacturing Processes"

2015 Invited Speaker at the European Compliance Academy's PharmaLab 2015 Analytics, Bioanalytics and Microbiology Congress, Dusseldorf, November 10 – 11, 2015 and made 2 presentations on "Approaches for Validation of Rapid Sterility Testing Methods" in ECA – Rapid Microbiological Methods Symposium and "Challenges in

Testing for Adventitious Agents during Manufacture of Biological Products" in ECA – Adventitious Agents – Impurities and Contaminants.

2016 Invited Speaker at the AOAC International Sothern California Section (SCS) and USP Western Compendial Discussion Group (WCDG), Irvine, CA, April 28, 2016 for a presentation on "Analytical Methods in Assuring Quality of Biological Products"

2016 Invited Speaker at the AAPS Sothern California Pharmaceutical Discussion Group Meeting held at Irvine, CA on April 28, 2016 for a presentation on "Assay Modernization – Good for Industry, Regulators and Public Health"

2017 Invited Speaker at the Cambridge Healthtech Institute's 8th Annual Biotherapeutics Analytical Summit, Bethesda, MD, March 20 – 24, 2017, for a presentation on "New Paradigm of Building Quality during Manufacture – Challenges with Biological Products".

2017 Invited Speaker at the BIT's 9th Annual World Congress of Vaccine = 2017, Beijing, China, March 29 – 31, 2017 for a presentation on "Building Quality during Manufacture of Vaccines Quality by Design (QbD), Product Life Cycle and Modern Technologies/Methods"

OTHER RECOGNITIONS

1995 Temporary Adviser for the World Health Organization meeting on the Single Dose Tetanus Vaccine held at the Royal Veterinary College, UK.

1995 Listed in the American Men and Women of Science (A Reed Reference Publishing Company)

1996 Member, Steering Committee on "Toxin Neutralization Evaluation Project" of Rijks Instituut Voor Volksgezondheid en Milieu, The Netherlands, Statens Serum Institute, Denmark, Perum Bio Farma, Indonesia and National Institute of Vaccines and Biological Substances, Vietnam (supported by the Commission of the European Communities).

1997 Steering committee meeting on "Toxin Neutralization Evaluation Project" at the Rijks Instituut Voor Volksgezondheid en Milieu, Bilthoven, The Netherlands.

1998 Listed in the American Men and Women of Science (Reed Elsevier Reference Publishing Company)

2003 Member of the International Association of Biologicals (IABs) Human Vaccines Scientific Committee

2004 Editorial Advisory Board, BioPharm International

2016 Panel Member on Peer Reviewed Medical Research Program of Department of Defense (DOD) US Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP)

2016 Member, VaxYnethic's Scientific Committee, Florence, Italy

RESEARCH GRANTS:

1992-1996 Co-Investigator on the NIH research grant on adjuvants.

1993-1996 Co-Investigator on the WHO research grant on single dose tetanus toxoid.

1994-1996	Co-Investigator on the NIH research grant on cross reacting materials of diphtheria toxin.
1996	Co-Investigator on the WHO research grant on low dose Hib-T vaccine and Hib-T-DPT combination vaccine.
1996	Principal Investigator on the WHO research grant on use of adjuvants and controlled release technology for single dose tetanus vaccine.
1996	Co-Principal Investigator on the NIH research contract on production of clinical lots of vaccines
2010	Principal Investigator on BARDA/HHS grants on Alternate Potency Methods for Inactivated Influenza Vaccines and Rapid Sterility Methods

REFEREE/REVIEWER FOR SCIENTIFIC JOURNALS

Vaccine
Vaccine Research
Journal of Immunological Methods
Analytical Toxicology
Journal of Pharmaceutical Sciences
Infection and Immunity
Journal of Colloid Science and Interface
Journal of Controlled Release
BioPharm International
Biologicals

BIBLIOGRAPHY (Google Scholar) and (ResearchGate)

1. Singh, H., Maheshwari, S.C. and Gupta, R.K. Deterioration of tetanus antitoxin at 4-8°C. J. Biol. Stand. 10:91-94, 1982.
2. Gupta, R.K., Kaushik, O.P., Sharma, S.B., Ahuja, S. and Saxena, S.N. The stability of tetanus antitoxin at various temperatures. J. Biol. Stand. 11:365-368, 1983.
3. Singh, H., Maheshwari, S.C. and Gupta, R.K. Sero-immunity of normal Rhesus monkeys to tetanus and diphtheria. Indian J. Med. Res. 77:187-189, 1983.
4. Gupta, R.K., Maheshwari, S.C. and Singh, H. Factors affecting the biological assay of tetanus antitoxin. Indian J. Pathol. Microbiol. 26:55-58, 1983.
5. Gupta, C.K., Mahajan, B., Gupta, R.K., Rao, G.L.N.P. and Singh, H. Antibody response of guinea pigs to polio viruses. Indian J. Pathol. Microbiol. 26:127-132, 1983.
6. Singh, H., Maheshwari, S.C. and Gupta, R.K. A suitable biological assay method for adsorbed diphtheria and tetanus toxoids. Indian J. Microbiol. 23:7-11, 1983.
7. Gupta, R.K., Maheshwari, S.C. and Singh, H. The titration of tetanus antitoxin. I. Factors affecting the sensitivity of the indirect haemagglutination test. J. Biol. Stand. 12:11-17, 1984.
8. Gupta, R.K., Maheshwari, S.C. and Singh, H. The titration of tetanus antitoxin. II. A comparative evaluation of the indirect haemagglutination and toxin neutralization tests. J. Biol. Stand. 12:137-143, 1984.
9. Gupta, R.K., Maheshwari, S.C. and Singh, H. The titration of tetanus antitoxin. III. A comparative evaluation of indirect haemagglutination and toxin neutralization titers of human sera. J. Biol. Stand. 12:145-149, 1984.
10. Gupta, R.K., Maheshwari, S.C., Bhandari, S.K., Sharma, S.B., Ahuja, S. and Saxena, S.N. Effect of storage temperatures on opacity and total nitrogen content of cholera vaccine. Vaccine 2:284-286, 1984.
11. Singh, H., Gupta, P., Maheshwari, S.C., Gupta, R.K. and Stroh, G. Earthenware pots for vaccine storage: A health hazard. Indian J. Pathol. Microbiol. 27:157-160, 1984.
12. Gupta, R.K., Maheshwari, S.C., Bhandari, S.K., Sharma, S.B., Ahuja, S. and Saxena, S.N. The stability of cholera vaccine at elevated temperatures with regard to relative antigenicity. J. Biol. Stand. 13:93-95, 1985.
13. Gupta, R.K., Maheshwari, S.C. and Singh, H. The titration of tetanus antitoxin. IV. Studies on the sensitivity and reproducibility of the toxin neutralization test. J. Biol. Stand. 13:143-149, 1985.
14. Gupta, R.K., Maheshwari, S.C. and Singh, H. The titration of tetanus antitoxin. V. Effect of formalization method for the fixation of sheep erythrocytes on the indirect haemagglutination test. J. Biol. Stand. 13:151-157, 1985.
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