Chander Kanta Gupta, M.Sc.

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Profile

Research Scientist with experience in analytical methods development, qualification and validation, particularly in bioassays (toxin and virus titrations, plaque assays, neutralization assays), immunochemical methods (ELISA, Precipitation reactions, SRID, immuno-blot), molecular biology (SDS-PAGE, PCR, QPCR), bio-analytical methods (Chromatography methods of bio molecules), tests in animals (mice, guinea pigs, rabbits, monkeys); and expertise in virology & cell culture (development of vaccines, preparation of virus stocks, cell banks, etc.); worked in research, quality control, analytical development, GLP & GMP environments

Education

M. Phil. (Microbiology) Himachal Pradesh University, India

M. Sc. (Microbiology) Himachal Pradesh University, India

B.Sc. (Chemistry, Botany, Zoology) Government College, Himachal Pradesh University, India

Professional Experience

2013 – Current, **President and Consultant** (2013 – 2018) and **Advisor**, Biologics Quality & Regulatory Consultants, LLC

- Audits, gap analysis and due diligence for GLP, GMP in laboratory operations.
- GMP oversight on the operation of QC Labs
- Consultation on the Methods development, qualification and validations
- Preparation of IND, BLAs, and other regulatory documents
- Development of quality systems, master validation plans, training programs, documentation systems
- Consultation on the science and compliance of development, laboratory operations and licensure of biological products

2006- 2011 Scientist I, Intercell/Iomai Vaccines, Gaithersburg, MD

- Development, qualification and validation of biological methods (bioassays) for characterization and release testing of vaccines.
- Preparation, maintenance and characterization of cell banks used in testing
- Generation of SOPs, protocols, reports and batch records
- Supported formulation and manufacturing groups in developing methods and performing testing

1998-2003 **Senior Research Scientist I**, Wyeth Research, Pearl River, NY

- Team Leader- RSV GMP Vaccine Development Team (**Wyeth Team Award 2002**)
- Purification of RSV virus vaccine candidates by Terminal Dilution Procedure
- Maintenance and Propagation of Cell Cultures
- Testing of Purified Viral Clones for Virus titer, Identity, Attenuation, etc.
- Aseptic Techniques in viral operations and manual filling of standards & controls

1997-1998 **Research Scientist**, Wyeth-Lederle Vaccines & Pediatrics, Pearl River, NY

- Purification of *B. pertussis* antigens (Fimbriae and 69K protein)
- Analytical and Immunochemical methods to characterize pertussis antigens
- Identification of lactate dehydrogenase by SDS-PAGE and isoenzyme staining

1991-1996 **Research Scientist**, Massachusetts Public Health Biologic Labs, Boston, MA

- Development of micro neutralization test for poliovirus antibodies based on metabolic-inhibition so that the end points can be read on an ELISA reader.
- Development of ELISA-based micro neutralization test for quantitation of antibodies to cytomegalovirus (CMV) and measles virus.
- Development of an ELISA for quantitation of IgG subclass antibodies.
- Study on the role of IgG subclass antibodies to CMV in neutralization of virus.
- Correlation between IgG antibodies to CMV and neutralizing antibodies.
- Feasibility study on the preparation of measles immune globulin.
- Purification of respiratory syncytial virus from defective interfering particles and stabilization of the virus for more than 3 years.
- Purification of RSV by chromatography for development of vaccine and evaluation of RSV vaccine in animals for humoral and cellular immune responses.
- Potency testing of immune globulins for polio and measles virus antibodies.
- Viral removal/inactivation validation studies for immune globulins using polio virus as a model virus.
- Aseptic Techniques in viral operations and manual filling of standards & controls
- GMP/GLP regulations by doing validations and writing SOPs, protocols & reports

8/90 to 11/90 **Guest Worker**, Laboratory of Developmental and Molecular Immunity, National
4/91 to 8/91 Institute of Child Health and Human Development, NIH, Bethesda, MD

- Purification of lipopolysaccharide (LPS) & preparation of conjugate vaccine.
- Serologic analysis of human sera for antibodies to LPS by ELISA

1989-1991 **Technical Officer**, Immunogenetics Lab, National Institute of Immunology, New Delhi, India

- Development of monoclonal antibodies to blood groups A and B
- Development of Immunoassays – Precipitation reactions, ELISA
- Maintenance & storage of cell lines (continuous cell lines, B and T-cell lines)

1977-1989 **Technical Supervisor and Assistant Technical Officer**, Polio Vaccine Testing Laboratory and Quality Control, Central Research Institute, Kasauli, (H.P.) India

- Quality control of bulk and final polio vaccine as per WHO Regulations
- Regulatory work and review of production and testing protocols
- Preparation of monovalent and trivalent polio virus preparations and monospecific sera for quality control of oral polio vaccine
- Clinical Serological methods, Immunochemical and Functional assays – Development and Correlation between Immunochemical and Functional assays
- Development of assays for quality control of polio vaccine
- Development of allogenic hybridomas and monoclonal antibodies to polio viruses and Japanese encephalitis virus
- Standardization and Quality Control of Vaccines and antisera for human use as per Pharmacopeial and WHO Regulations, including sterility test

Publications

1. **Gupta, C.K.** Comparative studies on antisera against polio viruses raised indifferent animals. M.Sc. dissertation, Himachal Pradesh University, Shimla, 1981.
2. **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. 1983;26:127-132.
3. **Gupta, C.K**., Gupta, R.K., Sharma, B., and Singh, H. A rapid method for raising monospecific antisera against polio viruses in monkeys. J. Com. Dis. 1985;17:243-245.
4. Sokhey, J., **Gupta, C.K**., Sharma, B. and Singh, H. Production and standardization of polio antisera in different animals. Proceedings of National Seminar on Quality Control of Vaccines, Central Research Institute, Kasauli, 1985:27-32.
5. Singh, H., **Gupta, C.K.**, Sharma, B. and Sokhey, J. Stability study of oral polio vaccine. Proceedings of National Seminar on Quality Control of Vaccines, Central Research Institute, Kasauli, 1985:40-45.
6. Sokhey, J., Sharma, B., **Gupta, C.K.** and Singh, H. pH studies on oral polio vaccine. Proceedings of National Seminar on Quality Control of Vaccines, Central Research Institute, Kasauli, 1985:46-51.
7. Singh, H., **Gupta, C.K.**, Sharma, B., Rao, G.L.N.P. and Sokhey, J. Sero-immunity of normal Rhesus monkeys to polio viruses. Indian Vet. Med. J. 1986;10:37-38.
8. Sharma, B., **Gupta, C.K.**, Rao, G.L.N.P., Maheshwari, S.C., Gupta, R.,K. and Singh, H. Sero-immunity to poliomyelitis in Himachal Pradesh. Indian J. Pathol. Microbiol. 1986;29:101-107.
9. Sokhey, J., **Gupta, C.K.**, Sharma, B., and Singh, H. Stability of oral polio vaccine at different temperatures. Vaccine 1988; 6: 12-13.
10. **Gupta, C.K.** Standardization of the procedure for production of monoclonal antibodies against polio viruses. M.Phil. dissertation, Himachal Pradesh University, Shimla, 1990.
11. Sokhey, J., **Gupta, C.K.**, Sharma, B. and Gupta, R.K. Statistical analysis of virus titres obtained in repeated assays of working standard of trivalent oral polio vaccine. Vaccine 1991;9:69-70.
12. Gupta, R.K., Misra, C.N., **Gupta, C.K.** and Saxena, S.N. Growth of allogenic hybridoma cells in non-histocompatible mice with the help of Ehrlich-Lettre ascite tumor cells. Biologicals 1991;19:243-245.
13. **Gupta, C.K.**, Sokhey, J., Gupta, R.K. and Singh, H. Development of allogenic hybridomas for production of monoclonal antibodies against oral polio vaccine strains. Vaccine 1991;9:853-854.
14. Sokhey, J., **Gupta, C.K.**, Sharma, B. and Gupta, R.K. Statistical evaluation of virus titres of working standard of oral polio vaccine. Vaccine 1992;10:423.
15. Gupta, R.K., Relyveld, E.H., Lindblad, E.K., Bizzini, B., Ben-Efraim, S., **Gupta, C.K.** Adjuvants - a balance between toxicity and adjuvanticity. Vaccine 1993;11:293-306.
16. Leszczynski, J., **Gupta, C.K.** and Siber, G.R. The use of intravenous gamma globulin for CMV prophylaxis. Transplantation 1993,56,765.
17. Gupta, R.K., Higham, S., **Gupta, C.K.**, Rost, B. and Siber, G.R. Suitability of the Vero cell method for titration of diphtheria antitoxin in the United States potency test for diphtheria toxoid. Biologicals 1994;22:65-72.
18. **Gupta, C.K.**, Leszczynski, J., Gupta, R.K. and Siber, G.R. An enzyme immunoassay based micro-neutralization test for titration of antibodies to human cytomegalovirus (CMV) and its correlation with direct ELISA measuring CMV antibodies. Biologicals

1996;24:41-49.

19. **Gupta, C.K.**, Leszczynski, J., Gupta, R.K. and Siber, G.R. IgG subclass antibodies to human cytomegalovirus (CMV) in normal human plasma samples and immune globulins and their neutralizing activities. Biologicals 1996;24:117-124.
20. **Gupta, C.K.**, Leszczynski, J., Gupta, R.K. and Siber, G.R. Stabilization of respiratory syncytial virus (RSV) against thermal inactivation and freeze-thaw cycles for development and control of RSV vaccines and immune globulin. Vaccine 1996;14:1417-1420.
21. Randolph, V., **Gupta, C**., Kane, A., Lopez, V. and Shutyak, L. Phenotypic correlates of mutations engineering into recombinant RSV vaccine strains. Discovery Research Meeting 1999 Poster, Lake George, NY.
22. Kane, A., Chen, W., **Gupta, C**., Shutyak, L. and Randolph, V. Genetic stability studies of recombinant derivatives of the cpts-248/404 live attenuated RSV vaccine strain. Discovery Research Meeting 2000 Poster, Lake George, NY.
23. Goodwin TJ, Deatly AM, Suderman MT, Lin YH, Chen W, **Gupta CK**, Randolph VB, Udem SA. Three-dimensional engineered high fidelity normal human lung tissue-like assemblies (TLA) as targets for human respiratory virus infections. 22nd Annual Meeting of the American Society for Virology - Workshop 20. University of California. Davis, CA. July 12-16, 2003.
24. Deatly, A M., Lin, Y-H, Goodwin, T. J., Suderman, M. T., Chen, W., **Gupta, C. K.**, Randolph, V. B. and Udem, S. A. A Novel 3D Engineered Normal Human Lung Cell Culture Model to Evaluate Attenuation of RSV Strains. *12th International Conference Negative Strand Viruses 2003, Palazzo dei Congressi, Pisa, Italy*
25. Gupta, R.K., Gupta, C.K. and Mallet, L. Lot Release of Vaccines by Regulatory Authorities and Harmonization of Testing Requirements. In: Nunnally, B., Turula, V and Sitrin, R. Eds. Vaccine Analysis: Strategies, Principles and Control, Springer, 573 – 596, 2015.