Name: Dr. Charu Mehra Kamal

Deputy Director (Quality Control), National Institute of Biologicals, Noida

Qualification: Ph.D. in Biotechnology (ACBR, DU); Masters in Biotechnology (AIIMS, Delhi)

Specialization: Immunology, Quality Evaluation of Biologicals

Training: Have undergone various trainings on Quality Attributes viz. Statistical Methods in Evaluation of Immunodiagnostic kits, Laboratory Quality System Management and Internal Audit and ISO 17025;2005 and 2017, Laboratory Quality Planning and Risk Management, Assuring Quality of Results in Test & Calibration, Regulatory Requirements for Members of Institutional Ethics Committee and 12th OECD Training Course for GLP Inspectors.

Experience: 22 years in Quality Evaluation of Biologicals

- Immunodiagnostic Kits for HIV, Hepatitis B, Hepatitis C and Syphilis *(June 2004-December 2014)*
- Molecular Diagnostic Kits for HIV, Hepatitis B, Hepatitis C *(December 2014-October 2015)*
- Enzymes and Hormones *(October 2015- May 2016, April 2020- December 2023)*
- Vaccines and Sterility *(May 2016 till September 2016)*
- Monoclonal Antibodies *(April 2020 till March 2021)*
- Recombinant Products (Insulin, Insulin Analogs, Growth Factors) *(October 2016-till date)*

Government Analyst: Notified as Government Analyst vide Government of India, Gazette No: S.O. 203 (E) dated 27th March 2025 for Recombinant Products

GMP Inspection: Participates in Joint inspection as a subject expert with CDSCO as and when nominated

Participation in Collaborative Studies with International Organizations

Monographs: Contributed to various monographs for Biotechnology Derived Therapeutic Products in Indian Pharmacopoeia

Publications: 17

Conference proceedings (National/ International): 4

Research Group: Works in the **development and validation of physicochemical and cell-based analytical methods** for recombinant biotherapeutics. Expertise includes **characterization and evaluation techniques** to ensure safety and efficacy of biotherapeutics. Skilled in **harmonization, verification, and new method development** for quality assessment of biotherapeutics. Successfully led and contributed to multiple **intramural and collaborative research projects**, advancing innovation in biopharmaceutical analysis and regulatory compliance.
03 Ph.D scholars and 01 Postdoctoral Fellow currently working. 50 plus M.Sc dissertations guided till date.

Recent Peer-reviewed papers

1. Garg N, Gupta P, Kamal CM*. Development and Validation of an Efficient In vitro Bioassay for Potency Estimation of Recombinant Human Erythropoietin Formulations. *Pharm Res.* **2026** Mar 6. doi: 10.1007/s11095-026-04051-1.
2. Haiyan Jia et al. World Health Organization, Expert Committee on Biological Standardization, Report on a Collaborative Study for Proposed 1st WHO International Standard for Ranibizumab. WHO **2025**. WHO/BS/2026.2486 (Participant of a Collaborative study)
3. Garg N, Kumar B, Kamal CM* et al. Analytical assessment of safety and efficacy of filgrastim and pegfilgrastim formulations for treatment of chemotherapy-induced neutropenia*. 3 Biotech* **2025**, 15, 283. https://doi.org/10.1007/s13205-025-04457-5
4. Garg N, Mendiratta S, Bindra G, Gehlot S, Goswami K, Kamal CM*, Estimation of protein aggregates in Darbepoetin alfa formulations by developing a single validated analytical method, *J. Chromatogr. B* **2025**, 1254, 124518. https://doi.org/10.1016/j.jchromb.2025.124518.
5. Garg, N, Kamal, C.M. Advancements on Substitution of In Vivo Method(s) with In Vitro Method(s) for Recombinant Human Erythropoietin Potency Assays. Int J Pept Res Ther **2025**, 31, 28. https://doi.org/10.1007/s10989-025-10688-0
6. Mendiratta S, Bindra G, Kamal CM* et al. Less is more: Validating a single method for comprehensive rh-insulin analysis, *J. Pharm. Biomed. Anal.* **2024**, 244, 116122. https://doi.org/10.1016/j.jpba.2024.116122
7. Shrivastava R, Tewari S, Kamal CM, Trivedi N, Varshney M, Yadav A, Anvikar AR. National Control Laboratories in quality healthcare-a roadblock for substandard biopharmaceuticals. Biologicals. **2022** Apr;76:42-45. doi: 10.1016/j.biologicals.2022.02.002.