Nishikant Wase, PhD

Richmond, VA • +1 (402) 310-9931 • nishikant.wase@gmail.com • LinkedIn

Scientific Leader | LC-MS Protein Characterization | Biopharmaceutical Analytical Development | GxP/CMC

PROFESSIONAL SUMMARY

Analytical scientist with 14+ years of expertise in LC-MS-based protein characterization, biopharmaceutical analytical method development, qualification/validation, and CMC-aligned lifecycle management. Deep hands-on proficiency with Orbitrap Tribrid and Exploris platforms for intact protein, peptide mapping, and host-cell protein (HCP) analysis. Proven track record leading method transfer, cross-functional project engagement, and GxP-compliant deliverables across preclinical through clinical development stages. Skilled at translating complex analytical data into actionable scientific insight supporting biopharmaceutical process development and manufacturing.

CORE EXPERTISE

LC-MS Protein Characterization (Intact, Peptide Mapping, HCP) • Analytical Method Development, Qualification & Validation (GxP/CMC) • Biopharmaceutical Process Development & Manufacturing Support • Orbitrap Tribrid / Exploris Platforms • Method Transfer (Internal & External Partners) • MetID DMPK • Cross-functional Project Team Engagement • Proteomics (DDA / DIA/ TMT / Lip-MS / CETSA, Drug Target Engagement) • Metabolomics & Lipidomics, ^{13}C FLUX Analysis • Regulatory Compliance & Audit Readiness • Data Science (R, multi-omics)

PROFESSIONAL EXPERIENCE

Research Scientist / Principal Investigator, Bioanalysis — *Richmond, VA*

Thermo Fisher Scientific — *Nov 2022 – Present*

- Served as PI across 16 LC-MS programs for 5 global clients, leading biopharmaceutical analytical method development, qualification, and validation using Sciex and Orbitrap Exploris / Altis platforms — similar styled instrumentation used in GSK's biopharmaceutical characterization group
- Developed and validated LC-MS/MS methods for large molecule biotherapeutics (ADCs, proteins, peptides), applying GLP/GxP analytical control strategies aligned with CMC regulatory expectations
- Led analytical method transfer to client and partner laboratories; prepared and reviewed study protocols, analytical reports, and SOPs ensuring GxP compliance and audit readiness
- Engaged with cross-functional project teams and external clients as the primary scientific interface — defining analytical strategies, troubleshooting complex data, and communicating findings to non-analytical stakeholders
- Directed internal R&D on LC-MS protein characterization workflows; mentored junior scientists on method development, data analysis, and regulatory documentation
- Performed advanced R-based data analysis for multi-dimensional LC-MS datasets; implemented automated reporting workflows for high-throughput sample analysis

Senior Scientist — *Charlottesville, VA*

University of Virginia, School of Medicine — *Jan 2020 – Sep 2022*

- Established and scaled metabolomics and lipidomics analytical platforms (LC-MS) supporting 50+ multidisciplinary research programs, including development and qualification of analytical methods from the ground up
- Developed in-house analytical workflows, SOPs, and metabolite library (~500 compounds) with full analytical lifecycle documentation
- Built bioinformatics pipelines for multi-omics data integration and visualization (R); presented findings to diverse scientific stakeholders
- Led analytical contributions to the Trans-University Microbiome Initiative (TUMI), coordinating method harmonization across partner institutions

Senior Research Associate / Postdoctoral Research Associate — *Lincoln, NE*

University of Nebraska–Lincoln *May 2011 – Dec 2019*

- Led LC-MS, GC-MS, NMR, and FT-ICR-MS-based analytical studies for drug toxicology and plant metabolomics, developing and qualifying analytical methods across multiple platforms
- Screened 43,000 compounds using metabolomics-driven approaches for lipid metabolism regulators; conducted multi-omics studies for biofuel development

SELECTED IMPACT

- PI for 16 LC-MS/MS biopharmaceutical analytical programs supporting ADC and large molecule pipelines from preclinical through Phase III
- Developed, qualified, and transferred analytical methods across internal and external laboratories under GxP frameworks
- Built and scaled multi-platform analytical laboratories (LC-MS metabolomics/lipidomics) for 50+ research programs
- Developed ~500-compound in-house metabolite reference library; authored 25+ peer-reviewed publications and 1 US patent

TECHNICAL EXPERTISE

LC-MS/MS • Orbitrap Tribrid / Exploris (protein characterization, peptide mapping, intact mass) • HPLC / UHPLC • Nano-LC-MS/MS • Proteomics (DDA/DIA/TMT) • Metabolomics • Lipidomics • Host Cell Protein Analysis • ADC Bioanalysis • GxP/GLP/GCLP Method Development & Validation • Analytical Method Transfer • Skyline • MaxQuant • Proteome Discoverer • Chromeleon • R (statistical analysis, multi-omics integration) • Regulatory Documentation (protocols, reports, SOPs)

EDUCATION

PhD, Chemical and Biological Engineering • University of Sheffield, UK
MSc, Botany • Nagpur University, India

OPEN-SOURCE SCIENTIFIC TOOLS

Shiny_ADC_Peptide_Mapping | R-Shiny | https://github.com/nishi76/ADC_Peptide_Mapper
Designed and developed an interactive R-Shiny application for LC-MS/MS-based ADC peptide map visualization and data interpretation. Scientific design, analytical logic, and biopharmaceutical domain architecture are original; implementation built with AI-assisted development. Supports identification of unique ADC signature peptides, generate transitions for direct import in Thermo and Sciex instruments, scans ADC peptides against in-silico digested human proteome and identify unique peptide signatures.

PUBLICATIONS & PATENT

25+ peer-reviewed publications; 1 US patent. Full list: Google Scholar