

Venkateswara Karumanchi
Research and Development Scientist

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SUMMARY

- Inventor of five patents, author of 45 peer-reviewed scientific articles, one book chapter, and presenter at 20 national and international conferences.
- Proven ability in process development, achieved in the scale-up of the drugs lovastatin, taxol, and docetaxel those were subsequently launched in India.
- Extensive experience in natural products chemistry, analytical chemistry, medicinal chemistry, and downstream processing in pharmaceutical, biotechnology, nutraceutical, and medical device industries.
- Developed and validated HPLC, LC-MS/MS, GC, and CG-MS analytical methods for the pharmacokinetics, quantification of constituents present in the plant, marine, microbial, synthetic, pharmaceuticals, and polymer extracts.
- It has been my honor and privilege to mentor and supervise a team of scientists, chemists, post-docs, graduate students, and technicians throughout my career and accomplish the goals I have been assigned.

PROFESSIONAL EXPERIENCE

Analytical Scientist, Enveda Therapeutics, Boulder, Colorado, 2023 – Present

- Analyzes raw materials, intermediates, drug substances and drugs in terms of their physical and chemical characteristics and solve their structures using 1D and 2D NMR data.
- By means of semi-preparative chromatography, we isolated bioactive compounds, their impurities, and degradation products from plant extracts and studied their chemical structures using 1D and 2D NMR, high-resolution mass spectrometry, and LC-MS/MS data.
- Establish and validate solid phase extraction, HPLC, GC-MS, and LCMS/MS methods for the isolation and quantification of targets in plant extracts.
- A method for scouting and purifying target compounds from plant extracts based on the Q-TOF Method
- Write and execute testing protocols in accordance with local procedure and regulatory requirements.
- Provide training or mentorship to other QC or cross functional team members.

Laboratory Scientist, Global Analytical Chemistry, Quality Labs, Terumo BCT, *Lakewood, Colorado*, 2012 – 2023

- Received Raising the Bar Award 2016 winners circle for saving the company in external testing costs as well as reducing the time to get results from 6 weeks to 1 week.
- Performing analysis of products using USP, ISO 17025, ICH, and SOPs and in-house testing methods utilizing HPLC, LCMS, LCMS/MS, GC, GCMS, FT-IR, UV, GPC, ICP-MS, and wet chemical techniques.

- Development of new and innovative analytical chemistry and methodology to support manufacturing and regulatory requirements. Supports and facilitates the transfer of analytical technologies within and between laboratories.
- Contributed to the identification and problem-solving of a variety of production or service-related problems.
- Performing Ethylene Oxide residual testing for validation, verification, and lot/load release by Headspace Gas Chromatography and/or GC/MS.
- Collaborated with engineers and scientists in the design, development, and execution of test protocols and procedures. Executing studies to support product and process optimization, investigation on deviation and root cause analysis; technology transfer activities, and product characterization studies, and any other activities required by the organization.
- Developed and validated LC-MS and GC-MS methods for the quantification of leachable and extractable medical devices.
Develops and maintains Standard Operating Procedures (SOPs) related to instrument operation/maintenance, method development, method validation and staff training and competency.
- Conducts productive literature searches for troubleshooting existing methodologies, developing new methodology and identifying new technology.

Process Development Scientist, Cedarburg Hauser Pharmaceuticals, *Denver, CO* 2010 – 2011

- Successfully designed and implemented the isolation and purification procedure using multi-kilo preparative scale (Biotage) Flash chromatography for thapsigargin and QS-21, and scaled up to 150 kilograms, according to cGMP guidelines.
- Isolated, purified, and elucidated the structures of drug intermediates, degraded products, impurities, and APIs using UPLC, HPLC, NMR, and MS.
- Generated and executed ideas and solutions that contributed to improvements in processes used to synthesize APIs such as GRN1005 and zirconium silicate, and scaled up from gram scale to kilogram scale per cGMP requirements for manufacturing
- Developed and validated analytical methods to support various research and development programs, manufacturing divisions, and technical service requests.

Process Development Scientist, ChromaDex Analytics, *Boulder, Colorado*, 2007- 2009

- Increased productivity from 65% to 82% by developing cost-effective methods and managing assigned projects to meet objectives.
- Reduced in-process analytical costs for projects by identifying and deploying in-house instrumentation.
- Isolated the drug impurities and elucidated their structures using NMR and MS.
- Purified proteins from tobacco leaves and resolve technical issues as well as performed results and data analysis.
- Isolated and synthesized dietary supplements to meet our catalog and customers' needs.
- Successfully accomplished isolation and purification of extremely sensitive compounds such as Lutein and Zeaxanthin, Procyanidins, and Betanins.

Research Scientist, *University of Mississippi, University, Mississippi, 2001 - 2007*

- Discovered several novel peptides and alkaloids from marine sources, prepared analogs, and carried out SAR studies. Some of the analogs exhibited the immense potential to be used for controlling cancer, malaria, and viral diseases.
- Discovered a new microbial source that produces Kahalalide F, currently undergoing phase III clinical trials in solid tumors.
- Discovered a new microbial source that produces Manzamine A, which is active against malaria with significant improvement over chloroquine and artemisinin.
- Directed both internal and external research projects; coordinated group research activities; supervised M.S. and Ph.D. Thesis and lab projects.

EDUCATION

Ph.D. Natural Products Chemistry, Sri Venkateswara University, Tirupati, India