Shreekant V. Karmarkar, Ph.D.
30 Andrew Lane, Hawthorn Woods, IL 60047, Phone: (224) 383-4493, Email: karmarkars@att.net
Linkedin.com/in/shreekant-karmarkar

Consulting role in pharmaceutical or biopharmaceutical

AREAS OF EXCELLENCE

- **Analytical**: Strategies and innovative approaches to solving R&D, manufacturing, QC, and stability (OOS and OOT) challenges. Analytical Quality by Design approaches. Rugged and robust methods for drug products. Impurity isolation and identification. CMC section authoring and FDA and EMA submission and query responses. Reference standards' strategies.
- **Strategic engagement of Western companies with CROs (in drug and devices) from emerging economies:** due diligence, strategies, engagement and governance cadences, and metrics
- **Innovative solutions**: Focused innovative stage-gate approaches to solving current challenges. Selection of latest and greatest analytical technologies.
- **Remediation**: Evaluation and remediation of existing specifications, reference standards, or analytical methods against current regulatory expectations
- **Continuous improvement:** Expert in tools such as LEAN (to eliminate waste) and green belt (to minimize defects) approaches
- **Technical project management:** Simplify the complex, outside the box thinking, success enablers, and metrics driven approaches

PROFESSIONAL EXPERIENCE

Baxter Healthcare Corporation, Round Lake, IL: 2002 through 2018

Hired as Senior Research Associate in 2002. Promoted to Research Scientist in 2004, Senior Research Scientist in 2007, and Director, Project Management in 2014.

Director, Project Management, 2014-2018: Tapped to turn around a non-productive international CRO relationship with over 200 FTEs. Instituted an accelerated cadence and significantly improved relationship with CRO team including analytical innovations. Disciplined efforts transformed the relationship into becoming one of the best CRO relationships within Baxter with an annual saving of $5 M. Role expanded to manage CRO in medical devices.

- Selection and management of CRO's in India with responsibility for over 200 staff members
- Identified and established vision and strategy for collaborative success
- Removed barriers and established metrics and processes to deliver consistent success
- Established pace, engagement models, and key performance indicators. Set precedents for partnership that were then recognized for success and redeployed in other projects
- Resolved OOS and OOT investigations
- Managed medical devices' CRO with about 400 FTEs.
- Serves as subject matter expert for supplier quality audits in Europe, China, and India
- Built a professional network both internally within business unit, across units, and outside of Baxter

Associate Research Scientist, Research Scientist, and Sr. Research Scientist, 2002-2014: Served as analytical lead for Baxter's new and line extension products. Unique skills allowed for Analytical Quality by Design (AQbD) techniques to be applied to over 15 methods. Collective result of technical skills and operational acumen delivered increased

operational efficiencies, robust method development, and helped move products to market faster while delivering over $20M/year of revenue.

- Led analytical development from feasibility studies through stability batches and commercial launch for several drug products (clients and in-house programs)
- Authored analytical CTD sections and defended them at the regulatory reviews by FDA and EMA
- Developed analytical methods using HPLC, IC, SEC, and UPLC to solve analytical challenges in R&D, mfg. plant, and stability labs.
- Directed innovative solutions such as calibration of SEC method for Dextrans, AccQ-Tag UPLC for amino acids, and analytical QbD
- Conducted gap assessments of existing analytical methods against the current regulatory expectations
- Evaluated compendial methods and implemented them with necessary modifications
- Organized workshops on ion chromatography, compendial and regulatory guidances, and AQbD at PITTCON and AAPS.

Cedarburg Pharmaceuticals, LLC, Grafton, WI
Senior Analytical Chemist, Quality Control Department — 2001 – 2002

- Worked closely with formulation chemists in developing test methods for new drug substances and intermediates
- Validation of GC and HPLC methods

Lachat Instruments, Milwaukee, WI
Hired as Applications Chemist in 1992. Promoted to Separations Manager in 1994, to Product Manager in 1995, and Director, Chromatography Development in 1999. — 1992 - 2001

- Developed ion chromatography product line, in commerce since 1994.
- Developed Flow Injection Analysis methods and products, also in commerce since 1995.

Department of Chemistry, University of Wisconsin, Milwaukee, WI — Spring 2002 and 1998
Invited Lecturer to teach graduate level course "Advanced topics in Analytical Chemistry, Chromatography"

Iowa State University, Ames, IA. Post-doctoral research associate — 1989 – 1992

EDUCATION

Ph.D., Utah State University, Logan, Utah. — 1989

Selected list of publications and patent: Please Review Full Portfolio of Scientific Contribution via LinkedIn

1. M. Argentine, K. Barnett, M. Chatfield, E. Hewitt, P. Jackson, S. Karmarkar, A. Marolewski, A. Pless, A. Ringnall, D. Semin, M. Trone, Q. WQang, Z. Williams, and Y. Zhao. Evaluating progress in Analytical Quality by Design, Pharmaceutical Technology, April, 52 (2017).
2. S. Karmarkar, X. Yang, R. Garber, A. Szajkovics, and M. Koberda, Quality by Design (QbD) based development and validation of an HPLC method for amiodarone hydrochloride and its impurities in the drug substance, J. Pharmaceutical and Biomedical Analysis, 100C:167-174 (2014).
3. S. Karmarkar, Analysis for impurities by ion chromatography. In "Ion Chromatography for Pharmaceutical Applications", John Wiley & Sons, edited by L. Bhattacharya and J. Rohrer; pp 159-174 (2012).
4. S. Karmarkar, Validation of ion chromatographic methods. In "Ion Chromatography for Pharmaceutical Applications", John Wiley & Sons, edited by L. Bhattacharya and J. Rohrer; pp 285-308 (2012).

5. S. Karmarkar, R. Garber, Y. Genchanok, S. George, X. Yang, and R. Hammond, Quality by Design (QbD) based Development of a Stability Indicating HPLC method for Drug and Impurities, J. Chrom. Sci., 49, 439-446 (2011).
6. S. Karmarkar, R. Garber, J. Kluza, and M. Koberda, Gel Permeation Chromatography of Dexrans in Parenteral Solutions: Calibration Procedure Development and Method Validation, J. Pharma. Biomed. Anal., 41, 1260 (2006).
7. S. Karmarkar, M. Koberda, J. Momani, D. Kotecki, and R. Garber, Validated Ion Exclusion Chromatographic Method for Citrate and Acetate in Medical Fluids, J. Chromatogr., 1039, 147-153 (2004).
8. S. Karmarkar and D. Jenke, Applications of Ion Chromatography in Pharmaceutical and Drug Analysis, USP Pharmacopeial Forum, 29(6), 2082 (2003).
9. S. Karmarkar, Anion Exchange Chromatography of Metal-cyanide Complexes with Gradient Separation and Direct UV Detection, J. Chromatogr. A, 956, 229 (2002).
10. S. Karmarkar, Analysis of Wastewater for Anionic and Cationic Nutrients in a Single Run using Ion Chromatography with Sequential Flow Injection Analysis, J. Chromatogr. A, 850, 303 (1999).
11. S. Karmarkar, System and a Method for Using a Small Suppressor Column in Performing Liquid Chromatography, US Patent 5,567,307 (1996).

Invited seminars

1. S. Karmarkar, Findings from an IQ Consortium survey: How far have we progressed in Analytical Quality by Design (AQbD)?, Intl. Forum Process Analytical Chemistry, 2016.
2. S. Karmarkar, A review of applying QbD concepts for analytical development for pharmaceutical drug products, PITTCON 2015
3. S. Karmarkar, Lessons learned from QbD based analytical method development, PITTCON 2014.
4. S. Karmarkar, Role of Ion Chromatography in Pharmaceuticals – Assay and Impurities, PITTCON 2014.
5. S. Karmarkar, Ion Chromatographic Methods for Heparin, PITTCON, March 18 2013.
6. S. Karmarkar, Analytical Controls for Impurities, University of Illinois, Urbana Champaign, Course on Organic Chemistry in Context, October 24, 2012.
7. S. Karmarkar, Develop, Implement, and Maintain Effective Method Validation in Your Organization, IVT's 8th Annual Method Validation, Philadelphia, August 24, 2011.
8. S. Karmarkar, Design of Forced Degradation Experiments to Demonstrate Specificity of Stability Indicating Methods for Pharmaceutical Injection Products, Presented at the PharmSep's LC/GC Symposium, Philadelphia, September 2009.
9. S. Karmarkar, Forced Degradation Strategies for Validation Specificity of Methods for Pharmaceutical Injection Products" at the 4th Forced Degradation Conference, Las Vegas, January 2007.
10. S. Karmarkar, Co-chair of Ion Chromatography Workshop to be held on October 28th, in conjunction with AAPS 2006 meetings. Presentation on "Applications of IC in Pharmaceuticals" at the IC workshop, October 2006.

AFFILIATIONS

American Association of Pharmaceutical Scientists
American Chemical Society
IQ Consortium

PROFESSIONAL DEVELOPMENT

Lean Six Sigma and Green Belt • Situational Leadership • Feedback and Coaching through Management Essentials • Building Business Acumen through Management Essentials

REFERENCES: Available upon further request.