RADHIKA RAJAGOPALAN, PH.D.
P.O. Box #1264, McLean, VA 22101
(E) Rrajagopalan@Pharmamodusllc.com

Objective: To provide consultation and guidance for innovator and generic drug companies on regulatory matters, and FDA submissions; assist with CMC technical skills to work with R & D, production, and regulatory professionals to plan, and author submissions, respond to FDA review deficiencies/comments for Drug substances (Type II DMFs), and Products, review site-inspection reports and respond to deficiencies on 483 comments.

Skills: Extensive experience with FDA regulatory submission preparation/discussion, Stability data interpretation, Pharma R&D product development, and submissions to the FDA in pre and post approval scenarios

EXPERIENCE

September 2019 – Present: CMC Consultant – Pharma Modus LLC

Works as an independent Consult for 505 (b, b2) and 505 (j) applications after signing confidentiality agreements for new and generic drug development strategies with companies; discuss submission strategies and CMC application contents; assist in FDA deficiencies response preparation, and review device related packages and labeling; trained to conduct mock inspections for drug manufacturing/testing sites on QMS, Laboratory Controls, Reference standard and Equipment Qualification. Experienced in small molecules formulation development, and Pre-submission meeting package preparations. Assisted in filing several supplemental applications for NDAs, and ANDAs, and one institutional IND submissions; Consulted for two Alcohol manufacturers to supply the Hand Sanitizer formulations since the FDA guidance was issued in the Spring of 2020 during Covid-19 emergency. Prepared to assist as an expert witness in Court cases involving drug product stability related issues.

Food and Drug Administration - CDER

Over 23 years of experience with several dosage forms' CMC sections for both 505(j) and 505 (b2) applications along with supervisory skills. Review expertise is in the CMC package which includes NDAs, DMFs (Type 2 and 4), INDs, Bio-INDs, supplemental new drug applications, novel technology approval, drugs in device as well as devices co-packaged with drugs at GS 15 level, and stability sections of submissions. Received several awards at the FDA, CDER and Office levels over the years for contributions. Graduate of the Government Leadership Program.

Quality Assessment Lead, & Expert Reviewer in ANDA Stability Testing <January 2010- March 2019

- Chaired Stability working group and delivered two FDA guidances on stability for ANDAS
- Experienced with complex innovator and generic drug products review and approvals under User Fee Programs for solid oral doses, nanotechnology products, peptides, parenteral, drugs in device, and liposomal drug products
- Handled policy development activities through the review of *controlled correspondences* from Industry within the Center for Drug Evaluation and Research as a designated stability expert with in the Office of Pharmaceutical Policy; recruited, and trained several reviewers with in CDER
- Published five guidances, representing FDA policy positions on chemistry review topics, authored a chapter in a book, and presented in several national and international conferences on several CMC related topics. These include AAM, and AAPS-FDA conferences

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- Delivered Cross-Center Projects with the Commissioner's Office for the approval of novel therapies and managed six Ph.D. level Chemists as a team leader
- Obtained *ASQ Certification* for Quality Assessment, and Quality Systems Management; trained in Risk Management (ICH Q9)

Special Assistant to CMC Director <*January 2004-December 2009*>

- Delivered about 7 peptide approvals and cleared policy documents within the Office.
- Led working groups within 3 CMC review divisions and with the New Drugs Office with working knowledge of several dosage forms to assist the Office with consistent approvals
- Created a platform to share approved applications such that data and knowledge sharing are made easy within the Office, and delivered *Question Based Review template* for reviewers
- Chaired Technical committee work group consisting of cross-center professionals and delivered guidance for publication
- Designed comprehensive review templates for the Process and Product development sections of CMC review

Senior Reviewer <*July 1995 – December 2003*>

- Chaired several working groups and delivered both supplemental and new drug approvals of injectable and modified release dosage forms

Bristol-Myers Squibb *Sr. Research Scientist* <October 1991-July 1995>

- Developed and conducted pre-formulation studies and analytical validation (GMP) for Rx, and Rx to OTC switches; provided scale up support at pilot plants and in production sites for several Rx products under FDA submission. Supported several FDA submissions.

Warner-Lambert (Parke-Davis) R & D *Research Scientist* <*January 1990- September 1991*>

- Successfully filed INDs, Phase 2 submissions, and SNDAs to the FDA. Performed under GMP conditions and managed a team of several technicians for product development, validation, and technology transfer within manufacturing sites from Morris Plains, NJ facility.

Castrol USA *Chemist* <*July 1988-December 1989*>

- Managed a highly capable laboratory specializing in several chromatographic techniques with five technicians for synthesizing and quality control testing of viscosity index improving agents

Volunteer Experience

The United States Pharmacopeia:

- Published monographs with the USP Expert Committee 3 for nine years while as FDA volunteer for several drug products such as Proton pump inhibitors, Ophthalmic drugs, and peptides for the establishment of public standards; currently serving in the *2020-2025* Expert Committee also as a volunteer
- Delivered CDER several monographs in return for which public standards development is essential

Product Quality Research Institute (PQRI) for the Stability expert working group:

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- As an FDA representative and as a freelancer (now) evaluate alternate means to Internationally harmonized standards for shelf life estimation of approved drug products

Education

University of Kansas: *Post-Doctoral research*, 1985- March '88, Lawrence KS Center for Bioanalytical research: Synthesis and femtomolar quantitation of peptides, and amino acid derivatizing agents, along with HPLC quantitation techniques

Oklahoma state University*: Ph.D.*, December 1984, Stillwater, Ok Department of Chemistry

Organic chemistry with experience in chromatography separation sciences, and NMR analysis

B.Sc., Chemistry with Sciences - Annamalai University, Annamalai Nagar, India

List of Publications in United States Federal Register

- Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products – Draft published on September 26, 2012, Federal Register Publication
- Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products – Final Guidance published on June 20, 2013
- Guidance Andas: Stability Testing of Drug Substances and Products, Questions & Answers – Draft Published on August 27, 2013
- Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products – Guidance to Industry December 2012
- Analytical Procedures and Method Validation – Draft CDER level guidance published on March 1, 2000
- Container Closure Systems for Packaging Human Drugs and Biologics – Final guidance July 1999

List of Publications in Journals:

Rajagopalan, R., et al., "Analytical Procedures and Method Validation: Highlights of the FDA's Draft Guidance", LCGC, 19, 74, 2001

Layloff, T., et al., "The U.S. FDA Regulatory Methods Validation Program for New and Abbreviated New Drug Applications". Pharm-Tech, 2000

Analytical Procedures and Method Validation: Highlights of the FDA's Draft Guidance LCGC, Vol 19, 1, 2001

Ph.D. Thesis Publication
Rangarajan, R., and Eisenbraun, E.J., "Oxidation at the benzylic position using Jones and other Cr(VI) Reagents' Journal of Organic Chemistry 1985.

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Presentations as a Principal Consultant, Pharma Modus LLC

'State of CDER 2022' May 17, 2022 at the WCG Clinical and FDA News Webinar

'Good ANDA Submission Practices' March 23, 2022

'ANDAs, 505(b)(2), Patents, and Exclusivities' April 15, 2020 at the Food, Drug, and Law Institute as an Instructor

Presentations (International and in National Trade Meetings)

- 'Introduction of New Analytical Technology in Regulated Products' – FCP Conference in Barcelona Spain 1999
- 'Question Based Review' – GphA Conference Bethesda, MD 2005
- Emerging Stability Expectations – FDA-GPhA Technical Workshop, Bethesda, MD May 4-5, 2011
- ICH Q1D: Bracketing and Matrixing with Case Studies - FDA-GPhA Technical Workshop, Bethesda, MD May 22-23, 2012
- OGD Efforts to Publish a Stability Guidance – Center Director Presentation, May 18, 2012, Silver Spring, MD
- ICH Q1D, and Q1E Considerations for Drug Products – CMC Leadership Training November 6, 2012 [This is a training conducted for all Team leaders in OGD for all Chemistry review Divisions]
- Participant in three FDA-GPhA member face-to-face discussions regarding Stability Guidance development and expectations
- Participant in Q & A session – FDA-GPhA Fall Annual Meeting October 1-3, 2013 Bethesda, MD
- Stability Considerations for Drug Products, ICH Q1D and Q1E – Organizer and speaker – DIA Webinar Training for the Generic Industry November 13, 2012
- Further Stability Consideration FDA-GPhA Workshop, Bethesda, MD, June 4-5, 2013
- Webinar Training for the Generic Industry [November 4, 2013] on the draft Questions and Answers Guidance supporting the ANDAs: Stability Testing of Drug Substances and Product
- Implementation and post-implementation Follow-up Discussions FDA-GPhA Workshop 2016