

# SABARESH SUNDHER

## Senior Medical Writer

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## SUMMARY

Experienced professional with a strong background in clinical pharmacy, medical writing, and research, with over three years of experience in regulatory documentation and drug management intelligence. Adept at maintaining databases for therapeutic classes and global drug information while contributing to the preparation of regulatory documents, including Clinical Evaluation Reports, Post-Market Surveillance Plans, and Periodic Safety Update Reports. Proficient in systematic literature searches using PubMed, Cochrane, and Google Scholar and skilled in clinical data analysis and competitive data evaluation through platforms like US FD A MedWatch and EUD AMED. Holds a Doctor of Pharmacy degree from Sri Ramachandra Institute of Higher Education and Research with practical experience gained during an internship as a Clinical Pharmacist. Demonstrates expertise in tools such as adverse event databases and methodologies relevant to pharmacovigilance activities. Seeks opportunities to leverage skills in medical writing or regulatory affairs while contributing to healthcare innovation within the pharmaceutical or life sciences industry.

## EXPERIENCE

### Senior Researcher

#### IPD Analytics

02/2025 - 05/2025 Chennai, Tamil Nadu

A company focused on drug intelligence data management

- Oversaw the maintenance and management of drug intelligence data across global, regional, and local databases, ensuring accuracy and timely updates for drugs and therapeutic classes
- Contributed to the upkeep of the IPD Analytics P&T customer portal, ensuring operational reliability and seamless user experience
- Conducted formulary tracking to monitor drug coverage changes across healthcare plans and ensure updated information for stakeholders
- Managed clinical criteria tracking processes, supporting the evaluation of drug usage guidelines based on regulatory compliance
- Tracked copay and patient assistance programs to facilitate cost analysis and assess patient affordability initiatives effectively
- Assisted in the maintenance of therapeutic class information while co-authoring publications, enriching industry knowledge-sharing through detailed research contributions

### Medical Writer - Senior Medical Writer

#### HCL Technologies Ltd

10/2021 - 01/2025 Chennai, IN

An IT services and consulting company specializing in healthcare

- Reviewed and developed a range of regulatory and Post-Market Surveillance (PMS) documents, including Clinical Evaluation Reports (CER), Clinical Evaluation Plans (CEP), Periodic Safety Update Reports (PSUR), Post-Market Surveillance Reports (PMSP), and Post-Market Surveillance Plans (PMSP)
- Established effective stakeholder communication through weekly client calls, ensuring alignment on document preparation processes and compliance with regulatory requirements
- Conducted clinical data extraction and analysis to prepare critical supporting regulatory documents such as Clinical Evaluation Plans and Periodic Safety Update Reports
- Performed systematic literature searches using PubMed, Cochrane, and Google Scholar to compile data for regulatory submissions
- Gathered, consolidated, and analyzed adverse event device-related data from global databases to support PMS activities

### Clinical Pharmacist (Internship)

#### Sri Ramachandra University

06/2020 - 06/2021 Chennai, IN

A prominent university in Chennai known for its healthcare programs

- Conducted drug monitoring to ensure safe and effective medication use, focusing on patient safety and therapeutic outcomes
- Evaluated the rational prescription and facilitated the selection of appropriate drug therapies
- Identified and assessed adverse drug reactions and potential drug interactions to prevent complications in patient care
- Provided discharge patient counseling, promoting proper medication adherence
- Compiled detailed medication histories by maintaining comprehensive case reports

## EDUCATION

### Doctor of Pharmacy

#### Sri Ramachandra Institute of Higher Education and Research

01/2015 - 01/2021 Chennai, Tamil Nadu

## KEY ACHIEVEMENTS

### E Extra Mile Award - HCL Technologies Ltd

Received the Extra Mile Award for outstanding contributions and efforts during my tenure at HCL Technologies Ltd

### Excellence in document review - HCL Technologies Ltd

Recognized for excellence in document review, demonstrating attention to detail and quality in regulatory documentation

### Customer appreciation - HCL Technologies Ltd

Received customer appreciation for outstanding communication and stakeholder engagement in regulatory affairs

## SKILLS

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Clinical Evaluation Plan	Clinical Evaluation Report	PubMed	US FDA	Periodic Safety Update Report
Post Market Surveillance	Communication	PMS Plan	Project Management	Problem Solving
Quality & Compliance	Regulatory Documents Preparation		Regulatory Documents Review	Team Collaboration
Critical Thinking	Time Management	Customer Service	Endnote	EU MDR

## INTERESTS

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### Music & Performance

Music Composer, Songwriter, Vocalist, and Keyboardist performing regularly with the band

### Sports & Fitness

Enthusiastic player of cricket and badminton

### Leisure & Focus

Avid reader and hobbyist long-distance driver