

SUKHBIRSODHI

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Profile

- Accomplished clinical pharmacologist holding 18+years of experience in drug safety, academia and clinical practice.
- More than 4 years of Drug Safety experience as drug safety physician and as member of pharmacovigilance committees in the academia providing awareness about Drug Safety and the evolving regulatory framework.
- About 2years of experience as Drug Safety Physician having worked for global pharmacovigilance functions of a leading research based pharmaceutical company.
- Contributed to Safety and Clinical Development activities of some blockbuster Roche's molecules, which led to market approval.
- Thorough overview of end-to-end PV processes and practices; and regulatory guidelines.

Career Summary

- Drug Safety Physician, CRO, Chandigarh, India. **(2 years)**
- Member, Pharmacovigilance Committees at various academic institutes. **(3 years)**
- Clinical experience as general physician and junior resident doctor in departments of Anesthesia, Medicine, Surgery and Pediatrics at leading tertiary care hospitals at Chandigarh, India. **(5 years)**
- Academic and research experience (held positions of increasing responsibility from Assistant Professor to Professor and Head) in department of Clinical Pharmacology, in various medical teaching institutes across India. **(12 years)**

Pharmacovigilance/Drug Safety Experience

In this role, I am working in close collaboration with Drug Safety and Clinical teams.

Scientific writing/reviewing experience

- Authoring relevant Safety sections of aggregate reports including PBRERs, Annual Safety Reports, case narratives for PBRERs, Six-monthly SUSAR Reports (SSRs)
- Strategizing, writing/coordinating Drug Safety Reports (DSRs) and Medical Assessment Reports for potential Safety signals
- Analyzing data related to signal detection activities including:
 - Periodic review of line listings
 - Periodic review of literature
- Contribute drug safety input to Clinical Development activities by providing safety content review of clinical case narratives, clinical study reports (CSRs), and providing inputs to study management teams
- Writing DSRs and Medical Assessment Reports for potential signals
- Providing medical inputs in processing of ICSRs (Individual Case Safety Reports), including performing medical review, triage, assessing events for coding, MedDRA coding of adverse reactions, providing assistance for cases (spontaneous, clinical, etc.) from a medical perspective to Pharmacovigilance (PV) Scientists who are involved in data-entry of ICSRs
- Maintaining an excellent knowledge of the safety profile of assigned drugs/products, Reference Safety Information (RSI) documents, clients' procedures and international drug safety regulations
- Maintaining an awareness of global regulatory reporting obligations and organizing workload to ensure compliance with regulatory timelines.
- Experience in handling multiple products (Early Development, Life-Cycle & Established portfolio) across various therapeutic areas like oncology, Infections and Infestations, dermatology, CVS, rheumatology, immunology/autoimmune diseases, metabolic disorders, hematology, virology, psychiatric and CNS disorders
- Participated in various internal and client GCP/GVP audit(s)

Mentoring Experience

- Providing guidance, direction and supervision to the physicians, PV Scientists involved in various PV activities.

Pharmacovigilance Responsibilities in Academic Institutes

- Generating awareness about ADRs among health care professionals and students of the college.
- Identifying ADRs occurring in the in-patients and report to the National Pharmacovigilance Center.
- Carrying out causality analysis of ADRs.

- Undertaking scientific and research activities pertaining to ADRs.
- Making efforts to minimize the chances of ADR and thereby make drug therapy safer and rational.
- Taking up activities to strengthen the ongoing National Pharmacovigilance program.

Academic Responsibilities

- Was involved with development/ planning and delivery of a Medical Council of India -accredited undergraduate medical education program (MBBS), academic guidance, departmental administration and recruitments, chairing requisite meetings and pharmacovigilance related activities.

Clinical Responsibilities

- To examine, diagnose and advise investigations and treatment to pediatric, adult and geriatric inpatients and outpatients.
- To perform and assist in interventional diagnostic and operative procedures.

Educational Qualifications

1999-2001 MD (Pharmacology), Christian Medical College, Ludhiana, Punjab, India

1989-1995 MBBS, Kasturba Medical College, Mangalore, India

Additional Certifications

2000 Diploma in Medical Transcription, Ludhiana, India).

1996 Mc.Paed (Membership certificate in pediatrics from Society for Advanced Studies in Medical Sciences, New Delhi, India).

Computer Skills

- Good knowledge and experience in using
 - Microsoft Word (add ins and templates)
 - Microsoft Excel (Using filters, pivot tables and formulas)
 - Power point
 - Boolean search, PubMed, NCBL and other internet browsing for literature search.
 - Drug Safety tools like ARISg and TIBCO spotfire
 - Expertise in handling the Enterprise Resource and Planning (ERP) and Learning Management System (LMS).

Languages

- English (IELTS Score 8 band), Hindi, Punjabi

Dissertation

“A Study of Drug Use Patterns in a Tertiary Care Hospital Using WHO Recommended Core Indicators”

Memberships

- Member Indian Association of Medical Journal Editors
- Life Member of Indian Medical Association.
- Member of Indian Pharmacological Society.
- Ex-Student member of Canadian Pharmaceutical Society.

Extra-Curricular Activities

- President's Scout Award from President of India on 6-11-1985, No.-NHQ/7-12/80/85, Bharat Scouts and Guides.
- Secretary Students Council, D.A.V. School Shahabad Markanda.
- Member of school Cricket, Badminton and Table Tennis teams.
- Social service by educating, uneducated adults and under privileged children.

Publications

- **Singh S**, Dadhich AP and Agarwal AK. A Study of Prescribing Practices in a Tertiary Care Hospital Using WHO Core Indicators. Asia Pacific Journal of Pharmacology, Vol 16 (No 1) March 2003: 9-14.

- **Singh S.** Irrational use of Antimicrobial Agents. International Journal of Medical and Dental Sciences 2013;2(1):1-2.
- Kumar R, Sharma V, **Singh S**, Hardeep. Tetracycline induced mucosal ulceration: A rare drug reaction. Int J Pharmacol and ClinSci 2012;1:82-4
- Kaur R, **Singh S**, Chand S, Kumar R. Effect of Antihypertensive Drugs on Quality of Life in Elderly Patients. Int J Med and Dent Sci 2012; 1:9-13.
- Kaur H, **Singh S**, Patnaik VVG, Kaushal S, Agnihotri G. Mesocephaly to Brachycephaly Shift as seen in Punjabi Children. International Journal of Medical and Dental Sciences 2012;1(2):1-5.
- Kaur H, **Singh S**, Patnaik VVG, Kaushal S. A Comparative Study of Head Circumference of Infants in Two Ethnic Groups. International Journal of Medical and Dental Sciences 2012;1:33-37.
- Kumar R, Bajaj JK, **Singh S**, Sood M. Rationality of Prophylactic Antibiotic use in Genitourinary Surgery in a Tertiary care Hospital. Int J Pharmacol and ClinSci 2012;1:106-10.

Reviewer-ship

- On reviewers panel of Indian Journal of Pharmacology.
- On reviewers panel of British Medical Journal.

Conferences Participated

- On 28-8-2001, delivered a guest lecture on drug therapy of Benign Prostatic Hyperplasia at D.M.C. Ludhiana.
- On 24-4-2001, participated in seminar on Diabetes Mellitus, organized by college of veterinary science, Punjab Agriculture University, Ludhiana.
- On 27-2-2001, participated in symposium on Angina Pectoris, held in D.M.C. & Hospital, Ludhiana.
- (22-27 January 2001), Workshop on Clinical Pharmacology at Post Graduate Institute of Medical Education and Research (Chandigarh), India.
- (13-14 November 2000), Organizing Member of Symposium on Rational Drug Use. Sponsored by WHO as an Organizing Member, at C.M.C. Ludhiana, India.
- (26-29 February 2004), Workshop on Drug Discovery & Development in New Millennium at National Institute of Pharmaceutical Education and Research (Mohali), Punjab, India.

Personal Details

- Date of Birth 1 January 1971
- Civil Status Married

Sukhbir Sodhi
MD