

## **Educational Qualifications**

Graduation (B.Sc)	Seksaria Science College, Belgaum Chemistry and Zoology, Karnataka University, 1969
Post Graduation (M.Sc)	Karnataka Medical College, Hubli Pharmacology, Karnataka University, 1972
Doctorate	Haffkine Institute, (Ph.D. Medicine) University of Bombay 1983,
Member	Institute of Clinical Research, UK 2006
	Approved Trainer in GCP Association of Clinical Research Professionals, US, 2008
	Certification (CCRA) Association of Clinical Research Professionals US, 2008

## **Work Experience**

(Only the major functions done at each place of work are given)

### **Present Position**

Director, Scientia Clinical Services

Consultant: Venture Centre, National Chemical Laboratories, Pune.

Consultant: Kalinga Institute for Industrial Technology, Bhubaneshwar,

Consultant, BIRAC, Dept of Biotechnology, Govt of India.

Chairman: Institutional Ethics Committee, Jehangir Hospital, Pune.

Chairman: Institutional Ethics Committee, Sahyadri Hospitals, Pune.

Chairman: Ethics Committee, Chellaram Diabetes Institute, Pune

Member, Task Force on Repurposing Drugs for Covid, Govt of India

Member Symbiosis International University, Ethics Committee, Pune.

Member, Cipla Palliative Care Centre, Ethics Committee.

Member, Editorial Board, Perspectives in Clinical Research.

Ph. D Guide, Symbiosis International University, Pune.

## Past Positions Held

1. Professor, Drug Discovery and Development, Symbiosis School of Biomedical Sciences, Symbiosis International University, Pune (2011-2013)  
Teaching and guiding research at Post graduate and doctoral levels.
2. Dean, **Bilcare Research Academy**, Pune (March 2007-to July 2011).  
Teaching clinical research to students at a postgraduate level.  
Administration of the campus at Pune. Liaison between the academy and universities, government and regulatory authorities, etc.
3. Principal, **Institute of Clinical Research (India)**, New Delhi (2006- 2007)  
Teaching at Post Graduate level M. Sc in Clinical Research (Cranfield University, UK), and Post Graduate Diploma in Clinical Research and Clinical Data Management  
Conducting Corporate Training Programmes  
Administration of the Campus,  
Overall incharge of all academic activities on the campus.
4. Vice President, **CliniRx Research Pvt. Ltd.** Gurgaon (2000- 2006)  
Setting up the CRO for JK Organization.  
Identifying office sites, requirements, personnel, for the CRO. Setting up the systems, software, equipment for the CRO, establishing network of investigators, laboratories for clinical research. Hiring and training of personnel, and managing an NIH sponsored trial.
5. 5. Medical Advisor, **JK Drugs and Pharmaceuticals**, New Delhi (1994-2000)  
Training of Medical Sales Representatives  
Liaison with Drug Controller, India  
Phase III clinical trials of Company's products  
Out sourced Bioequivalence studies of formulations developed in the company.
6. Medical Advisor, **Unichem Laboratories**, Bombay (1988-1994)  
Training of Medical Sales Representatives  
Liaison with Drug Controller, India  
Phase III & IV clinical trials of Company's products  
In House Bioequivalence studies of formulations developed in the company.  
Quality control (Biological)

7. Manager Medical Services, **FDC LTD**, Bombay (1983-88)  
Training of Medical Sales Representatives  
Liaison with Drug Controller, India  
Phase IV clinical trials of Company's products  
In House Bioequivalence studies of formulations developed in the company.
8. Scientist **Haffkine Institute, Mumbai 1978-1983**  
Scientific Administration of the Institute with respect to budgets, Government controls etc.  
Headed a DST project on "Investigation of the anti cancer activity of *Semecarpus anacardium*."
9. Overseas fellow **Max Planck Institut für Experimentelle Medizin, Göttingen 1976-1978**  
Effect of drugs on Prostaglandin synthesis  
Studies on the biochemistry of lipases  
Investigations on Prostaglandins as modulators of autonomic functions.

### **Medical Writing**

I have over 50 articles in national and international journals, including **The Lancet**. I have written one book **Essentials of Clinical Research**, it is used in colleges and institutions involved in clinical research. I have edited a multi-author book **Principles of Clinical Research**, which was published in 2013.

I have been involved in non-scientific writing and have published over 30 short stories.

### **Academic Affiliations**

I have been a faculty member (as a visiting faculty) teaching Pharmacology or Clinical Research at a number of Institutes listed below:

**University Department of Chemical Technology, Mumbai**

**CU Shah College of Pharmacy, Mumbai**

**KMK College of Pharmacy, Mumbai**

**Bombay College of Pharmacy, Mumbai**

**Department of Biophysics, University of Pune**

**College of Pharmacy, Hamdard University, Delhi**

**School of Health Sciences, University of Poona**

**Maharashtra University of Health Sciences, Nashik.**

**Indian Dental Association**

**DY Patil Deemed University, Navi Mumbai.**

I also have been an examiner for a number of Universities. The courses are listed below with the name of the relevant University.

<b>University of Bombay</b>	<b>Bachelor of Pharmacy</b>
	<b>Master of Pharmacy</b>
	<b>Master of Science</b>
	<b>Doctor of Philosophy</b>
<b>University of Poona</b>	<b>Master of Philosophy</b>
<b>SNDT University</b>	<b>Master of Science</b>
	<b>Master of Philosophy</b>
<b>Cranfield University UK</b>	<b>Master of Science</b>
<b>Symbiosis International University</b>	<b>Master of Science</b>

Presently I am a guide for Ph. D at the Symbiosis International University.

### **Clinical Research**

In 1983, I set up a facility for BABE studies at FDC, later I set up a similar facility at Unichem Laboratories. During my career at FDC, Unichem and JK, we conducted a large number of Phase III trials, which led to the launch of **Flurbiprofen, Cetirizine, Ampicillin Sulbactam** for the first time in India. I also conducted extensive trials on Ribavirin, but the compound failed in the indications for which it was studied, hence we did not launch it.

At CliniRx I was responsible for bagging the contract for an NIH trial known as the STICH trial.

I have conducted a large number of Phase IV studies on many pharmaceutical products including **Electral, Soyol, Theophylline, Secnidazole and Metformin**.

### **Extra Curricular Activities**

**Editing** - In Haffkine Institute I was responsible for editing the Bulletin of Haffkine Institute, a multidisciplinary science journal. Editor of Sulekha – an e- magazine devoted to good writing.

**Education** - I was closely associated with Nehru Science Centre in Bombay and we organized Science awareness programmes for school children. I have been a visiting lecturer at CU Shah College of Pharmacy, KMK College of Pharmacy, Bombay College of Pharmacy, University Department of Chemical Technology, and Dept of Biophysics, University of Poona.

**Social** -I am actively involved in cancer support groups that work in the area of palliative care.

**Alumni** – Secretary and Managing Committee Member of my School's Old Boys Association, which is known as the Georgian's Association (India) Pune..

**Literary** - I write short stories and around 30 of them are published. Many of them in E magazines ( [HYPERLINK "http://www.sulekha.com"](http://www.sulekha.com) )

[www.sulekha.com](http://www.sulekha.com), HYPERLINK "http://www.adbhut.com" [www.adbhut.com](http://www.adbhut.com), HYPERLINK "http://www.zine5.com" [www.zine5.com](http://www.zine5.com) )

**Ethical Research Initiatives-** With other colleagues from Pune, we have formed this organization for the promotion of ethical research in the country. The organization trains EC members and conducts EC audits. It is a non-profit organization registered in Pune.

### **Training**

I have been involved in training personnel from industries in GCP and other aspects of clinical research. We have conducted training programs for Sanofi, IPCA and a number of other companies. I have also trained members of IECs of different hospitals including Sahyadri Hospital, Jehangir Hospital of Pune, Fortis Hospital of Noida and Mohali, Batra Hospital of Delhi, Siddhivinayak Hospital of Miraj, Kore Hospital of Belgaum, NARI Pune, Vimta Hyderabad etc.

I have trained staff from a number of organizations in Ethics and Regulations in Clinical Research. Some of the organizations whose staff I have trained are MUHS, University of Pune, Cytel, etc.

I teach Pre Ph.D course in Research Methodology and Ethics at KLE University Belgaum and Maharashtra University of Health Sciences, Pune, Symbiosis International University Pune and SP Pune University, Pune.

### **SOPS & Audits**

I have undergone training on Quality systems and I was the management representative for ISO certification. I have been trained in developing SOPs and conducting audit of facilities and have conducted a number of audits.

### **Research Publications**

1. Pharmacological Evaluation of Vasiconone Bull. Haff. Instt. Vol. 2(1), 1974, pg. 6-11
2. Pharmacological Studies on the Chloroform Extract of Tylophora indica. Bull. Haff. Instt. Vol. 2(2), 1974, pg. 82-85
3. Effect of Disodium Cromoglycate on the formation of Bradykinin, Bull. Haff. Instt. Vol. 4(3), 1976, pg. 99-104
4. Research Highlights (Studies on the role of somatic antigens in the pathogenesis of cholera) Bull. Haff. Instt. Vol. 7(3), 1979, pg. 34
5. Studies in Anaphylaxis I. A model of anaphylactoid oedema for screening antianaphylactic agents. Bull. Haff. Instt. Vol. 9(3), 1981, pg. 64-68
6. Studies on anaphylaxis II. A selective agonist of the receptor controlling mediator release. Bull. Haff. Instt. Vol. 10(1), 1982, pg. 9-16

7. Studies on Anaphylaxis III-Phospholipase A2 Induced Mouse Hind Paw Oedema. Bull. Haff. Instt. Vol. 10(2), 1982, pg. 31-37
8. Studies of Anaphylaxis IV. Comparison of 48/80 and X-537A induced mouse paw oedema. Bull. Haff. Instt. Vol. 10(3), 1982, pg. 62-66
9. Semecarpus anacardium. Separation of the Bhilawanols A and B and a comparative study of their growth inhibitory effect on Clostridium tetani and general pharmacology. Bull. Haff. Instt. Vol. 10(3), 1982, pg. 87-92
10. Binding of Monoene Bhilawanol on Clostridium tetani. Bull. Haff. Instt. Vol. 11(1), 1983, pg. 14-17
11. Phosphatidylethanolamine derivatives of Prostaglandins E1 and E2. Prostaglandins, 16: 1006-1017, 1976.
12. Pharmacological studies on Swertia decussata: Antiasthmatic potentials. Asp. Allergy Appl. Immunol., 14 : 57-50, 1978.
13. On the antianaphylactic activity of Swertia decussata. Asp. Allergy Appl. Immunol., 15 : 53-58, 1980.
14. Lactose Intolerance: Physiological, clinical and therapeutic considerations. Ind. J. Paediatr. 51: 671-681, 1984.
15. Respiratory distress and asthma in infants and children. Indian Paediatrics. 22: 683-695, 1985.
16. **Book Chapter:** Status Asthmaticus and Acute Respiratory Failure. In "Medical Emergencies in Children" Ed. Meherban Singh, A.I.I.M.S., New Delhi, 1985.
17. Keratomalacia in Soyab fed infants. Indian Pediatrics 24:955-56, 1987.
18. A new anaerobic inhibitor of herbal origin. Ind. J. Pharm. Sci. 50: 130-132, 1988.
19. Studies on the mechanism of action of Semecarpus anacardium in Rheumatoid arthritis. J. Ethnopharmacology 25: 159-64, 1989.
20. Antibioprophylaxis with Sulbactam and Ampicillin in Intra abdominal surgery. J. Gen. Med. Vol 5: 67-70, 1993.
21. Salt Restriction in Hypertension. Med. Hypotheses 41: 137-140, 1993.

22. Inhibition of cell wall synthesis - Is this the mechanism of action Penicillin? Med. Hypotheses 44: 127-131, 1995.
23. The mechanism of action of aspirin - Is there anything beyond cyclo-oxygenase? Med. Hypotheses 44: 77-80, 1995.
24. Mother in Pain, Lancet Volume 353 Page 1625, November 1998.
25. Pain relief in India, Lancet Volume 353 Page 677, February 1999
26. Pain relief in cancer: A myth or a possibility. J. Pain & Palliative Care Pharmacotherapy 17: (3/4) 1-9, 2003.
27. **Book Chapters:** Standard Operating Procedures; Clinical Trial Logs; Investigational New Drug Application, in a text book "Basic Principles of Clinical Research and Methodology" (Jaypee Publications, India).
28. The Vulnerability of children in clinical trials in India, Monitor Vol 22(2) 71:74, 2008
29. Book- **Essentials of Clinical Research**, Nirali Publications, Pune 2010. This book is widely used by students learning clinical research and is prescribed in the Syllabi of Pharmacy colleges.
30. Trials and tribulations of clinical research teaching and training. Perspect Clin. Res. 2010, Vol 1(4): 139-42
31. The Nuremberg Code – A Critique. Perspect Clin. Res. 2011 Vol 2 (2) 72-76
32. Patients' rights in India: an ethical perspective. Indian Journal of Medical Ethics, 2012;9(4)277-281
33. Cancer, Pain and Morphine in India. Ehospice Nov, 23, 2012 available at: <http://www.ehospice.com/ArticlesList/CancerPainandMorphineinIndia/tabid/3471/ArticleId/1894/language/en-GB/View.aspx#.UK8CWldwfME>
34. Book- Principles of Clinical Research. Ed. Ghooi RB, Nirali Publications Pune , Jan 2013.
35. New Rules for Clinical Trial Related Injury and Compensation. Indian Journal of Medical Ethics 2013; 10(3): 197-200.
36. Violence against women-A case for research for a solution. Indian Journal of gender studies. SSRN Available at [HYPERLINK "http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2272617"](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2272617)  
[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2272617](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2272617)

37. Injury and death in clinical trials and compensation- Rule 122 DAB. Perspect Clin Res 2013;4:199-203
38. Preference of the place of death among people of Pune. Ind.J.Palliative Care. 2014;20:101-106.
39. Stress among caregivers, while nursing their near and dear ones suffering from cancer. Ind. J. Palliative Care 2014; 20:31-39
40. Ensuring that informed consent is really informed consent- role of videography. Perspectives in Clinical Research 2014;5:3-5.
41. Integrating care with cure in cancer. JIMA, 2013;111(9): 615-17.
42. Drug Price Control - What does it mean for the society? Economic and Political Weekly (In Press)
43. Institutional Review Boards- Challenges and Opportunities. Perspect. Clin Res 2014;5:60-65
44. The big Cs of the informed consent form: compliance and comprehension. Indian Journal of Medical Ethics. 2013; 10:232-7.
45. Population based family history analysis of Brahmins in a small town in India for the prevalence of type-2 diabetes mellitus. Indian Journal of Human Genetics. 2013;19 (3): 342-45.
46. Expert Committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drug- Comments. Perspect. Clin Res. 2014; 5(3):100-107.
47. Insurance in clinical research. Perspect. Clin Res. 2014;5(4):145-150.
48. Conflict of Interest in clinical research. Perspect. Clin Res. 2015; 6(1):10-14.
49. Patients' rights in India – Do they assure empowerment. In 'Patients' Rights- Ethical Perspectives, Emerging Developments and Global Challenges. Ed. Jena Pope, Nova Publishers, New York 2015.
50. Accreditation-A solution for problems or a fresh problem? Perspect. Clin Res. 2015; 6(3):123-24.
51. "Settlement Agreement" a new controversial agreement. Perspect Clin Res 2016;7:54.



52. Evidence-based medicine: A non-starter in India? *Indian J Health Sci* 2016;9:121-6.
53. Clinical Research-Developing New Drugs. *Pharma Ingredients* 2016, 16-30 June, 28-30.
54. How informed are our subjects? *Perspect Clin Res* 2016;7:109-10.
55. Assessment and classification of protocol deviations. *Perspect Clin Res* 2016;7:132-6.
56. The urgent need for advance directives in India. *Indian J Med Ethics.* 2016; 1(4) NS:242-9.
57. Epidural block and the pain cycle. *Indian J Pain.* 2016; 30:209-210
58. Should a medical ethics journal discuss the actions of the security forces? *Indian J Med Ethics.* 2017, II, 127-28.
59. The Global Ethics Corner: foundations, beliefs, and the teaching of biomedical and scientific ethics around the world. *Biochem Mol Biol Educ.* 2017 Apr 19. doi: 10.1002/bmb.21059. [Epub ahead of print]
60. A Role of ICH- GCP in Clinical Trial Conduct. *J Clin Res Bioeth* (2017) 8: 1000297. doi: 10.4172/2155-9627.1000297
61. Narrative: The fear of disfigurement in Cancer Patients. *Ind. J. Palliative Care.* 2017; 23:347-9.
62. Multidisciplinary Approach to Palliative Care. *BAOJ Pall Medicine* 2017;3(3): 38-42.
63. Profile of patients opting for palliative care in India. *Indian Journal of Palliative Care.* 2017;23:451-5.
64. Comparative Study of Nutritional Status of Preschool Children of Rural Area and Urban Slum. *Indian J. Pub Hlth Res.* 2017; 8(4): 628-35
65. An Effort Towards Achieving Watertight Compensation System for Clinical Trial Injuries in India. *Indian J. Pub Hlth Res.* 2017, 8(4): 506-13
66. Compensation for Clinical Trial-related Injuries in the United States. *J Clin Res Excellence* 2018, 95: 57-63.

67. Ethics Committee in an academic Institute. J. Dental Research and Review. 2018; 5: 70.
68. Various kinds of dental research and their requirements for ethical review. . J. Dental Research and Review. 2018; 5: 72-74.
69. New Drug and Clinical Trial Rules 2019- Two Steps Forward and One Back. Indian Journal of Pharmacy Practice, 2019; 12: 209-14
70. Impact of Working Status of Mothers on Nutritional Status of their Preschool Children from Selected Rural Areas and Urban Slums of Pune: A Preliminary Study. Indian Journal of Public Health Research & Development 2019; 10:153-159.
71. Ethics committee meetings – Online or face to face?. Perspect Clin Res 2020;11:121-3
72. The Rights of Patients with Chronic Kidney Disease in the World: Legal Perspectives and Challenges in Brazil, India, Portugal, South Africa, and Nigeria. Silva Junior GB, Ferreiro Fuentes A, Nangaku M, Remuzzi G, Ronco C (eds): Nephrology and Public Health Worldwide. Contrib Nephrol. Basel, Karger, 2021, vol 199 (DOI: 10.1159/000517722)
73. Repurposing drugs during the COVID-19 pandemic and beyond. Pharm. Pat. Anal. (Epub ahead of print)
74. Clinical trial agreements and insurance policies – role of the EC. Perspect Clin Res 2022;13:121-2
75. Need for revision: EC process, members' training, and compensation formula in the New Drugs and Clinical Trials Rules 2019. Perspect Clin Res 2022;13:129-31.
76. Importance of ethics committees in diabetes-related clinical research in India. Chron Diabetes Res Pract 2022;1:47-50.
77. Ayurveda research-are we on the right track? J Ayur Integ Med. 2022;13:1-2

I have not maintained a list of lectures I have delivered, at different fora, they are too many to list.

### **Personal and Contact Details**

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