

CURRICULUM-VITAE

NAME: DR. SUMANT SHARACHCHANDRA KARNIK

EDUCATIONAL QUALIFICATIONS :

1. Scientific Qualifications:

Degree	Year	University	College
Ph.D. (Biochemistry)	1996	Mumbai University	G.S. Medical College
Ph.D Thesis Title: "Studies on Quality Assurance in Lipid Analysis" (Extracted Lipids From Plasma Fractionation)			
M.Sc. (BioChem) I st Class	1980	Mumbai University	T.N. Medical College
B.Sc. (Chem.) I st Class	1978	Mumbai University	Parle College

2. Management Qualification:

Degree	Year	University	College
Masters in Human Resources Development Management	1998	Mumbai University	N. M. Institute of Management Studies.

EXPERIENCE:

Designation & Institute	Period	Experience
Adviser, Haffkine Institute for Testing, Research & Training	From August 2021	Consultant
Head Quality Assurance & Projects Haffkine Bio-Pharmaceutical Corporation Ltd	From July 2015 to July 2021	Managerial
Director, <i>National Plasma Fractionation Centre</i>	From 25 th Sept'2009 To 30 th April 2015	Executive
Manager, Quality Assurance, <i>Haffkine Bio-Pharmaceutical Corporation Ltd.</i> (A Govt. of Maharashtra Undertaking), Mumbai	From Feb'99 to Sept'09	Managerial
Scientist I/c. Production, <i>National Plasma Fractionation Centre</i>	From Aug' 88 to July' 98	Managerial
Jr. Sc. Officer (Bio-chem.), <i>Dr. R.N. Cooper / Bhagwati Hospital, MCGM</i>	From Mar' 84 to Aug' 88 From July'98 to Jan'99	Supervisory
Jr. Research Assistant, <i>Nair Hosp., Mun. Corp. of Greater Mumbai</i>	From June' 82 to Mar' 84	Supervisory
Lab Tech., <i>Nair Hosp., Mun. Corp. of Greater Mumbai</i>	From Nov. 80 to May' 82	Technical

RESIDENTIAL/OFFICE ADDRESS:

105, Jaykamal, Shrikrishna Nagar, Rd No.7, Borivali (East), City: Mumbai,
State: Maharashtra, Pin Code- 400 066, INDIA, Tel:® 91(022) 28974152

DATE OF BIRTH : 7th April' 1957, NATIONALITY : Indian
FAMILY : Wife & Two Daughters (one married)

Invited as Speaker for 7th Annual Bio-Plasma World Asia Conference in Singapore by IMAPAC held on 12 & 13th Sept 2018. Lecture Delivered on Plasma Fractionation.

Currently:

- 1. Member of expert committee of Indian Pharmacopeia (IP) commission for vaccines, Govt. of India.*
- 2. Member of expert committee of Blood Products of National Institute of Biologicals (NIB), Govt. of India.*
- 3. Member of Expert committee of Plasma Fractionation project SBTC, Govt. of Maharashtra*
- 4. Member of Ethical Committee of Haffkine Institute & Research Training (HITRT), Govt. of Maharashtra.*

3. Achievement:

Year 2016- till date: Recalled at Haffkine Bio-Pharmaceutical Corporation, A Govt. of Maharashtra Undertaking as Head Quality Assurance and sustaining WHO Prequalification of OPV vaccine and other sites of Mfg. Antisera Pune for GXP and ongoing projects. Responsible for WHO Geneva & NRA audits. Undergone external audits & training by international WHO consultants (Dr Sandra from Argentina & Mr Alain Kupferman from France). NABL internal Auditor for HBPCCL QC.

Year 2009-2015: Director & Head of “National Plasma Fractionation Centre” & “Research Foundation For National Blood Transfusion Services” (A Trust of MCGM), a not for profit organization.

Instrumental to set up New National Plasma Fractionation centre in different location with increased capacity of approx 20,000 lits per annum by improvement in the plant design to meet WHO GMP & Sch M requirement and approval of layout plan from DCGI.

The plant facility is now almost ready for installation of Plant & Machinery with the capacity of Processing 20,000 lits of Human Plasma for fractionation by Total large scale Chromatography Technology to produce Human Albumin, IV/IM Immunoglobulin (IgG) & Coagulation Product (Prothrombin Complex) to meet the requirement of poor & needy patients in Govt Hospitals at affordable cost.

Year 1999-2009 :- Head Quality Assurance of “Haffkine Bio-Pharmaceutical Corporation Ltd” (A Govt of Maharashtra Undertaking) Mumbai, manufacturing Vaccines, Sera , Tablets & Oral liquids at three location Mumbai, Pune & Jalgaon in Maharashtra.

One of the Responsible Team Head for Accreditation of Oral Polio Vaccines pre-qualified by WHO, Geneva for supply of OPV vaccine to UNICEF, a first Public Sector Company in India, to achieve this kind of certification in Year 2006/2008 with WHO appreciation certificate.

Year 1988-1998:- Head Production team of National Plasma Fractionation Centre at KEM Hospital, Mumbai

Successful commissioning of the first unit in South East Asia for processing of Blood & Blood Products by large scale chromatography Technology, funded to Govt. of India by Swedish International Development Authority (SIDA), Sweden & National Aids Control Organization (NACO), India.

4. International Training / Conference / Visits:

1. Participated in international scientific seminar on “The recent global trends in vaccine technology” at Jakarta/Bandung, Indonesia organized by M/s BioFarma P.T. held on 4-5 August 2006 & site visit to manufacturing facility of Biologics Manufacturer, M/s P.T. BioFarma, Indonesia.
2. Participated in North-Zone Workshop on “Good Manufacturing Practices (GMPs) Inspection for Vaccines” held by WHO, Immunization & Vaccine Development, WHO, Geneva & Regional office for South East Asia, conducted from 4-12 August 2003, Chandigarh, India
3. Participated in the Global Training Network Course on "Good Manufacturing Practice" at International Children's Vaccine Training Programme, Massachusetts Biologic Laboratories from 11th September to 29th September 2000 by World Health Organization (WHO), Department of Vaccines & Biologicals in USA.
4. Participated in a six week Advanced course in “Human Plasma Fractionation techniques” (Plasma Fractionation, Process Equipment, Microbiological Control) held in Sweden at Pharmacia A.B., Kabi Vitrum AB, The National Bacteriological Laboratory & the Department of Blood banking Uppsala University Hospital from 22nd August to 16th September, 1988 in Sweden.

5. FDA Approval: The Food & Drug Administration of Govt. of Maharashtra

- i. Approval in Manufacturing of Blood & Blood Products.
- ii. Approval in Chemical and Instrumental Analysis.
- iii. Approval in Microbiology and Sterility testing.
- iv. Approval in Bioassay, Pyrogen & Toxicity testing

6. ISO 9001-2008 Auditor: Completed IRCA approved training course for Lead Auditor & Audited various organizations for ISO certification for Quality Management and Authorized for ISO audits as a specialist & auditor.

7. a) Nominated as an "Expert" for Inspection of Vaccine/Biological Manufacturing units by **Directorate General of Health Services (Drugs Section)**.
- b) Expert/Special Invitee for Steering Committee of Plasma Fractionation Centre (PFC) Project by **National Aids Control Organization (NACO)**, Ministry of Health and Family Welfare, Govt. of India since August 2011 onwards.
- c) Identified as a Resource Person for Indian Pharmacopeia Commission, Scientific Body’s Expert Committee on Biologicals & Immunologicals since August 2011 onwards. Attended various meeting of IPC on Vaccines.

- d) Invited to attend the meeting regarding Harmonization of Blood Products monographs & its testing Policy organized by National Institute of Biologicals (NIB), Ministry of Family Welfare & Govt. of India on March 2012 onwards & nominated on the Committee of Testing Policy of finished Blood Products & Indian Pharmacopeia monographs of Blood Products.
- e) Invited as Project Consultant of Plasma Fractionation Centre of State Blood Transfusion Council (SBTC), Govt. of Maharashtra since 24th April 2013 onwards.
Submitted Draft Project Report on 19th June 2013 for PFC in Maharashtra for processing of 50,000 to 1,00000 liters of Plasma Annually.

8. Computer Training: Windows and MS Word in Civic Training Institute & Research Center, Municipal Corporation of Greater Mumbai.

9. Recognized Teacher: M.Sc (by Research) in Mumbai University,
P. G. Teacher in Biochemistry, Mumbai University.

10. Teaching Experience:

- Honorary faculty member to conduct lectures & practicals **at Medical Electronics Department**, S.B.M. Polytechnic, Vile Parle, Mumbai from 1986 to 1992.
- Invited P.G. Teacher in **Bio-Chemistry**, University of Mumbai from 2004 till date.
- Members of the **Board of Studies** of the **Life Science & Biochemistry Dept.** of St. Xavier's College, Mumbai (Autonomous) for the academic year 2012-13.
- Invited for Lecture series for **Transfusion Medicine** by College of Physicians & Surgeons of Mumbai on the subject Plasma Fractionation & Viral Inactivation of Blood Products on 12th & 15th July 2013 respectively.

11. Experience:

Designation / Dept.	Institute	Period	Experience
Head Quality Assurance	HBPCL	From July 2015 till date	Responsible for Quality Management & QA, Projects
Director	National Plasma Fractionation Centre/Research Foundation for National Blood Transfusion Services	From Sept. 2009 to April'2015	Responsible for the Management of Centre Administrative/Manufacturing, Testing, Training & New Project Activities, etc.
Manager, <i>Quality Assurance</i>	Haffkine Bio-Pharmaceutical Corporation Ltd. (HBPCL), Mum.	From Feb' 99 to Sept'09	Quality Planning Monitoring issues of GMP, Validation, Projects, Regulatory Affairs, Release etc.
<i>a)Research & Development (Addl. Charge)</i>	„	From Jan'2006 to Sept' 2009.	R&D Pharma & Bio-Pharma (Biologicals)Projects
<i>b)Quality Control (Bio) (Addl. Charge)</i>	„	From May'01 to July'01 & April'06 to	Responsible for Quality Control & Testing

c) General Manager	„	May'2006 One month	
Scientist In charge, Production	National Plasma Fractionation Center, KEM Hospital, Mum.	Aug' 88 to July' 98	Manufacturing of Blood products from Human Plasma using chromatography
Jr. Scientific Officer, Biochemistry	1) Dr. R.N.Cooper & 2) H. B. Hospital, Mun. Gen. Hosp. Mumbai	Mar' 84 to Aug.' 88 July' 98 to Jan.' 99	Supervising, Standardizing and Quality Control of Laboratory Tests. Developing new methods and reagents.
Jr. Research Assistant, Gastroenterology	B.Y.L. Nair Hospital, Mumbai	June' 82 to Mar' 84	R&D projects & Special Tests: HBsAg, Electrophoresis, Schillings test, absorption etc
Laboratory Technician, Chemical Pathology	T.N. Medical College, Mumbai	Nov.' 80 to May' 82	Testing of Biochemical Parameters.

Previous Experience: - Manufacturing & Testing & Administration & Regulatory Affairs and R & D.

I) Manager, Quality Assurance: (From Feb'1999 to Sept' 2009)
Haffkine Bio-Pharmaceutical Corporation Ltd.,
(A Govt. of Maharashtra Undertaking), Mumbai

Job Description and Responsibility:

- **Monitoring of GMP, New Projects, Regulatory Affairs, R&D**
- To Approve, Review and Control Standard Operating Procedures of Company..
- To Prepare, Approve & Implement Validation plan.
- To approve new product launch, to convene Technical Committee Meeting.
- To Co-ordinate Self-audit Team and Prepare self-inspection report.
- To initiate actions to resolve non-conformance & Market Complaints.
- Review Batch Record Certification & Release.
- Liaison with FDA/DCI, Vendor Evaluation, Training etc

II) Scientist In-charge (Production): (From Aug'88 to July'98)
National Plasma Fractionation Centre (NPFC), K.E.M. Hospital, Mumbai.
(First unit in South East Asia using large scale Column Chromatography Technology)

Job Description and Responsibility

- Manufacturing of Human Blood Products by Large Scale Chromatography.
- In process Quality Control, formulation and filling & W.F.I. Production.
- Review manufacturing protocols of Plasma Proteins i.e. Human Albumin, Immunoglobulin, Factor-IX complex.
- Documentation, maintaining & implementing G.M.P, Training & Supervision.
- In house R & D., General administration, proposals and budgeting.
- Liaison with FDA for manufacturing license, approvals etc

12. Papers Published/Presented

Paper Published:

- “Manufacturing of Safe Blood Products using biotechnology”
Article in Bio-Medical update 14(2), 1996.
- “Preparation of Lyophilized Lipid Rich Quality Control Serum by Isolating Lipids using Large Scale Chromatography technology” in Indian Journal of Clinical Biochemistry, 1997 July; 12(2): 134-8.

Poster:

- “Study of Radial Flow & Axial Flow Process Columns, for Protein Fractionation by Large Scale Chromatography” Poster presented in Plasma Product Biotechnology meeting’ 99 on 27th March’ 99 in Australia.

Papers Presented:

1. “Large Scale purification of Human Albumin by using Chromatography” in 17th Annual Conference of ACBI’ 1991 in Shimla.
2. “Preparation of Cholesterol or Lipid Quality Control” (Plasma Chromatography Fraction) in the 5th Annual Conference of ISAR’ 1992 in Tirupati.
- 3a. “Good Manufacturing Practices in Blood Products: Our Experience in Plasma Fractionation “in Hospital Pharmacy Session.
- b. "Blood Plasma Protein Fractionation by large scale Chromatography" in Biotechnology Session in 45th Indian Pharmaceutical Congress 1993 in Delhi.
4. “Manufacturing of Virus Inactivated I.V.IgG by Chromatography Fractionation” in Biotechnology Session in IPC’ 1994, Chandigarh.

12. i) WORKSHOP/SEMINARS PARTICIPATED

- Workshop on “Implementation of Global Action Plan III(GAP III) and certification of poliovirus essential facilities” conducted by WHO country office, INDIA, held from 7th February to 10th February, 2016.
- Regional GMP Strengthening Workshop for Indian Pharmaceutical Manufacturers & State Regulators By Dept. of Pharmaceuticals , Ministry of Chemical & Fertilisers, Govt of India in collaboration with WHO & FICCI, held on 17th Feb’ 2015 in Mumbai.
- Training Seminar on “Complying with WHO-GMP” from Raytheon Engineers & Constructors, UK funded by WHO held on 20th & 21st January, 2000 held in HBPCCL
- Workshop on “Drug Policy Issues for Developing Countries” conducted by WHO, Boston University School of Public Health care for International Health in collaboration with GS Medical College and KEM Hospital, Mumbai held from 29th November to 10th December, 1999.
- Course on “The introduction to Pharmaceutical Process Filtration” by Bio-process Division, Millipore (India) from 9-11th June’ 99 in Bangalore.
- Colloquium on “Labels and Good Labelling Practice” by Klenzaid’s GMP Academy on 21st June’ 1997.
- Post conference workshop on “Coagulation technique” by SASAT, 1st International Symposium on “Atherosclerosis, Thrombosis, Homeostasis and Transfusion Medicine, December’ 1994 in Indian Institute of Immuno-Haematology (I.C.M.R), Mumbai.

- Seminar on “Asia Pacific Bio-Process Seminar our Bio manufacturing – Advances in Vaccine Production” by GE Healthcare on 22nd May 2006 in Mumbai.
- Participated as Delegate in the C. M. E. on “*Safer Blood–Nucleic Acid Amplification Technology*” on 12th Sept. 2012 organized by **Federation of Bombay Blood Banks**.
- Participated in the four day workshop on “*Implementation of Quality Management System in Blood Banks*” from 23rd to 26th April 2012 organized the **National Aids Control Organization (NACO)**, Ministry of Health and Family Welfare, Govt. of India.
- Participated as Delegates in the Training of “*Good Clinical Practice*” organized by **Infectious Diseases Department (IDD)**, Maharashtra University of Health Sciences (MUHS), Nashik on 25th Feb. 2012.

ii) **OTHER SEMINARS**

1. Electrophoresis and Chromatography Techniques” by Association of Clinical Biochemists of India, Nashik Chapter, March’ 1993.
2. Recent trends in Freeze Drying Technology, Validation and Current Good Manufacturing requirements” by Vertis comp., Mumbai
3. The selection and Control of Elastomeric closures for Parental Products” by The West Pack Company, Mumbai.
4. Pyrogen Testing using LAL test” by R.P. Products, Mumbai
5. Membrane Filtration” by Millipore, Mumbai.
6. Aseptic processing areas using Seamless Hygiene Control Systems” from Liquid Plastics, Klenzaid, Mumbai.
7. Preparative Chromatography” by E-Merck, Mumbai

14. Additional Activities:-

National Plasma Fractionation Centre :

Short term Training, Projects & Dissertation by Students in Colleges & Universities:

1. 2011-2012: A dissertation submitted to the University of Mumbai for the Partial fulfillment of the Degree of Master of Science in Biotechnology by Remya Nair, S.I.E.S College of Arts, Science & Commerce, Mumbai
Title : Study of the Blood Bank & Blood component separation
2. 2012-2013: A dissertation submitted to the University of Mumbai for the Degree of Master of Science (By Papers) in Biochemistry by Ms. Tanaya Pande , Seth G S Medical College, KEM Hospital, Mumbai
Title : Screening of Serum Samples obtained from the Blood of Voluntary Donors for the Presence of ANTI-HIV 1 & 2 Antibodies by Enzyme Linked Immunosorbent Assay (ELISA)
3. 2012-2013: A dissertation submitted to the University of Mumbai for the Degree of Master of Science (By Papers) in Biochemistry by Ms. Bonny Satish Pasad, Seth G S Medical College, KEM Hospital, Mumbai.
Title: Assessment of Clotting Pattern & Fibrinogen Content in the Plasma of the Voluntary Donors.

4. 2014: Project Report submitted during Summer Practical Training for Indian Institute of Technology (IIT), Banaras Hindu University
Title : Project Report on Industrial Training undertaken at National Plasma Fractionation Centre
5. Plasma Product Bio-Technology Meeting -2015 :
9th International Meeting in Sardinia Italy 11-15th Ma'2015
Paper accepted for Oral presentation session 1: Manufacturing Perspective
Title: Establishment of Feasible model of Plasma Fractionation in the Developing country

Haffkine Bio-Pharmaceutical Corporation Ltd (HBPCL)

--Member of the Sub-Committee of R & D Projects and New Projects of HBPCL (R & D. Department is recognized by Ministry of Science & Technology, GOI.)

--Member of Ethical Committee of HBPCL.

-- R&D Project: *Project Title:* Developing Enzyme-Linked Immunosorbent assay method for Antivenin Antibodies Quantitation in Serum of Immunised Equine.

(Grant: Rs.: 4 Lakhs & Students from Mumbai University)

- a) Nominated as committee member for "Biotechnology Policy '2001" of GOM.
- b) Nominated as Panel Examiner by Institute of Pharmacy for P.G. course on "Quality Assurance" in Wardha University.
- c) Faculty member & Speaker for Training Programme on "Blood Bank & Blood Products" for Drugs Inspectors Training Scheme, Drugs Controller, DGHS.
- d) Achieved WHO-GMP certification from FDA as per WHO format for Vaccine (OPV), Sera (Snake Antivenin), Pharmaceutical (Tablets)

Lectures Deliverd:

1. Invited for lectures at Entrepreneurship Development Programme (EDP) in Bio-Technology by Gujarat State Biotechnology Mission (GSBTM) held on 13th & 14th June 2007 with the objective of sensitizing the potential biotech entrepreneurs about the Biotech Business environment, market scenario, challenges & other issues.
2. Invited for lectures, workshop on "Opportunities & challenges in Export of Pharmaceuticals" at NIPER, May 28-29, 2007
3. Invited for lectures at Vidya Pratisthan's School of Biotechnology (VSBT) Baramati.
4. Participated in 53rd Pharmaceutical Congress 2001, New Delhi and invited as guest speaker. Sub: "Cleaning & Cleaning Validation"
5. Practical demonstration on Fractionation of Plasma proteins in WHO-inter country workshop in National Plasma Fractionation, Center (NPFC).
6. Lectures to various faculties (FDA Blood Bank Officials) for various training programs on Blood Fractionation in NPFC.
7. Invited as a Guest lecture on "Process pH monitoring" in MTPRO users conference by Forbes & Marshall.
8. Lecture for **Staff Development Program** on "*New Paradigm in Pharmaceutical Education*" organized by Bombay College of Pharmacy, Mumbai on 14th-26th Nov.'11.
9. Lectures on "*Blood Science*" & "*Organization and Management of Blood Transfusion Services*" organized by Mumbai District Aids Control Society on 17th Sept. 2013.

MEMBERSHIPS:

1. Indian Pharmaceutical Association, India.
2. Association of Clinical Biochemists of India.

Testimonials:

Dr. Fournier-Caruana, Jacqueline, Scientist, WHO, Geneva

References:

1. **Mrs. Seema Vyas, IAS, Managing Director,
Haffkine Bio-pharmaceutical Corporation Ltd., Mumbai**
2. **Mrs Medha Gadgil, IAS, Ex Managing Director,
Haffkine Bio-pharmaceutical Corporation Ltd., Mumbai**
3. **Mrs Manisha Mahiskar-Patankar, IAS, Ex Managing Trustee, NPFC**
4. **Dr Tehalan, Director, CRI, Kasauli**
5. **Dr. Jagdish Deshpande, Ex Director,
Entrovirus Research Centre, ICMR, Mumbai**
5. **Dr. D. K. Sood, Ex. Jt. Director, CDL, Kasauli**
6. **Alain Kupferman, International & WHO Consultant, France**
7. **Dr. Fournier-Caruana, Jacqueline, Scientist, Immunization, Vaccines and
Biological, WHO, Geneva**
8. **Dr Sandra Rumiano, International & WHO Consultant, Argentina**