

Sudhir Kumar Singh

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Resume Summary

Result oriented QA lead with more than 22 years of expertise in GMP compliant vaccine manufacturing facility. Proficient in monitoring QA & RA division along with additional responsibility of GMP store. Collaborative but with a distinct personal style.

Professional Experience

Bharat Immunologicals & Biologicals Corporation Ltd. – General Manager (QA & RA)

(A Govt. of India Undertaking), Chola, Bulandshahr-203203 Level 12

September 2021 – Present

- Efficiently monitor QA & RA division along with additional responsibility of GMP store.
- Assurance to quality of more than 1500 million doses of OPV produced..
- Authorized signatory for release of manufactured batches.
- Organizing regulatory inspections and compliance to its recommendations.
- Compliance to GXP requirements of vaccine, tablet and RUTF manufacturing facility
- Coordinated to facilitate more than fifty state and joint regulatory inspections.
- Delivering training lectures to Biotech trainees and staff training batches.
- Prepared facility for successful grant of Certificate of Pharmaceutical Products (COPP).
- Participation in management level decision through various committee recommendations.
- Delegated with additional responsibility of Head, Training and Central Stores Division.

Bharat Immunologicals & Biologicals Corporation Ltd. – Dy. General Manager (QA & RA)

(A Govt. of India Undertaking), Chola, Bulandshahr-203203 Level 11

July 2012 – August 2021

- Delegated responsibility of working as In charge (QA & RA division).
- Compliance to regulatory requirements and recommendations.
- Custodian of GMP master documents and retained samples of finished goods.
- Preparation of various documents required for submission to regulatory authorities for renewal of certificates and license of approved products.
- Team leader of Covaxine project as a part of Mission Make in India.

- Authorized signatory for departmental approval of GMP documents.
- Liaoning with CDL for release of report and granting permission for parallel testing.

Bharat Immunologicals & Biologicals Corporation Ltd. – Asstt. General Manager (QA)
 (A Govt. of India Undertaking), Chola, Bulandshahr-203203 Level 10
 December 2006 – July 2012

- Monitoring of compliance with GXP requirements.
- Responsibility of third party testing, calibration, validation of facility equipments and clean room facility.
- Monitoring and control of clean room environment.
- Documentation control and issue of GMP documents.

Bharat Immunologicals & Biologicals Corporation Ltd. – Manager (QA)
 (A Govt. of India Undertaking), Chola, Bulandshahr-203203 Level 09
 January 2002 – December 2006

- Coordinated activities for acquiring VSQ prequalification.
- Preparation of facility, equipments documents etc for regulatory inspections.
- Responsibility of third party testing, calibration, validation of facility equipments and clean room facility.
- Monitoring and control of clean room environment.
- Documentation control and issue of GMP documents

SAF Yeast Company Limited , Sandila – 241127 -- Assistant Production Manager
 March 1997 – January 2002

- Production of baker's yeast (Fresh yeast , Dry yeast and Instant dry yeast) along with the maintenance of its quality
- Preparation of production program and maintenance of Production logbooks.
- Dispatch of finished goods to different destination in specified cold chain maintenance.

School of Biochemical Engineering , IIT BHU Varanasi – 221005 - Senior Research Assistant
 September 1993 – February 1997

- Microbial Production of Cephalosporin C, third generation antibiotics in different bioreactors.

- Publication of research articles and paper presentation in seminars along with classes of B.Tech and M.Tech students.

Training and Skills

Venue	From	To	Training Curriculum	Remarks
WHO,SERO	07 th Feb 2016	10 th Feb 2016	Switchover from tOPV to bOPV	Learned handling and disposal of polio virus type 2 before switch over to bOPV
Clinical Development Services Agency (CDSA) New Delhi	24 th Nov 2014	28 th Nov 2014	Basics of Statistics and Fundamentals of SAS in Clinical Research	Hand on training exposure to Biostatistics and Fundamentals of SAS.
CDSCO, South Zone Chennai	07 th March 2014	8 th March 2014	Harmonization of effective recall & Good Distribution Practices at Chennai	Learned guidelines to assure the quality & identity of biological products during distribution, storage, transportation, procurement, recall etc,
UBM India Pvt. Ltd. Mumbai	29 th Aug 2012	31 st Aug 2012	Vaccine Summit at Hyderabad	Get aware about recent advances in vaccine industry
The Center for Professional Advancement (CfPA) The Netherland	30 th Jan 2008	31 st Jan 2008	Preparing and Conducting Installation, Operational & Performance Qualification at Dublin, Ireland	Exposed to preparation of Equipment Qualification documents
National Institute for Pharmaceuticals Education and Research, Mohali	12 th June 2006	23 rd June 2006	Two weeks training programme on GMP & GLP under capacity building project sponsored by MOH & FW	Practical exposure to GMP & GLP

Education

- M.Tech in Biochemical Engineering with CGPA 8.43 in 1993 Indian Institute of Technology. Banaras Hindu University , Varanasi – 221005
- Masters degree in Biotechnology in 1991
Institute of Science , Banaras Hindu University, Varanasi – 221005
- UG diploma in French language in 1996
Faculty of Arts , Banaras Hindu University , Varanasi – 221005
- Qualified CSIR UGC NET and NET ARS Examination

Publications

i)	Singh, S.K. et al (1993) "Comparative Studies of Cephalosporin-C Production in Batch & Continuous Stirred tank Bioreactor" J Microbial Biotechnol. 8(2), 76-84
ii)	"Microbial Production of 7 – Aminocephalosporanic Acid," a paper presented in the Poster session of MICON-INTERNATIONAL 1994 organized by Association of Microbiologist of India at DFRL, Mysore.
iii)	"Biosynthesis of Cephalosporin-C in continuous modes using free and immobilized Cells – A comparative study," a paper presented in the technical session of Indian Chemical Engineering Congress 1996 (CHEMON-96) held at Gujrat Narmada Valley Fertilizer Co. Ltd., Bharuch.
iv)	Kumar A, Singh S.K (2019) "Significant Impact of Successive on job trainings on performance of technical employee in biotech industry" J of training and development, Vol-4,64-73
v)	Kumar A, Singh S.K (2020) "Laboratory Investigation for safe and efficacious use of opened multidose vials of bivalent oral polio vaccine, Prac. Clin. Invest 3(1),3-13
vi)	Kumar A, Singh S.K (2020) "Real time study for uses of opened multidose vials of live attenuated bivalent oral polio vaccine" Int. J of Pharmaceutical & Biol. Archives. 11(3).1-8

I declare that the above information is correct and complete to the best of my knowledge and nothing has been concealed/distorted.



(Signature of Applicant)