# ASHWINI KUMAR SRIVASTAVA

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Key Skills

Corporate Quality Assurance Site Quality Assurance/ Control Audit & Compliance

Regulatory Affairs

Training & Development Documentation

Quality Metrics

ITes – LIMS, LMS, Trackwise, DMS, SAP

Process Improvement Technology Transfer

Team Building & Leadership

# Profile Summary

### Nearly 25 years of rich experience in Corporate Quality Assurance, Site Quality Assurance (including Quality Control) and Quality Compliance and Regulatory Affairs

Steered organization through complex Quality & Regulatory challenges, transitions and building an empowered, talented work force. Leading compliance initiatives

Successful management of Regulatory Agency inspection and Audits by USFDA, MHRA/EU, TGA, DCGI (CDSCO), WHO Geneva, ANVISA, GCC , ISO

9001 and ISO 13485 etc. [USFDA : 9 times; MHRA/TGA : 12 times] Development of regulatory strategies and providing guidance and consultation for regulations

Hands- on experience in carrying customer audits, GMP audits, Internal ISO audits and ensuring audit compliance & timely closure

Played a key role in technical collaborations of my previous organizations with Baxter US, Pliva -Crotia, Novavax US, United Drugs –Ireland

Managed three projects from their conceptual stage to operational stage namely, a dedicated Cephalosporin facility and two Biopharmaceutical bulk manufacturing facilities including that of VLP based vaccines

Awarded by Hon. Governor – Rajasthan, Chief Minister, Rajasthan, SP –

Udaipur Range, Chairman – Atomic Energy Commission

Liaised/Interaction with regulatory authorities, consultants, collaborators, business associates, FDA authorities, financiers and other govt. officials Highly professional, organized, energetic, committed & motivated with excellent analytical, communication and problem-solving skills

Good technical writing and communication skills

# J&J Key accomplishments



Working as Plant Quality Manager, India, Baddi Site

Regulatory Affairs, Quality Engineering, Supplier Quality and Training function at Site has a matrix reporting to me.

Member of India PSLT

Steered SDCAP to successful closure at Site -**Leadership Award (Lead & Deliver)**

**Project lead – Medical Devices Rules 2017 (Ethicon Manufacturing Sites)**.

Successful transition to ISO 13485 : 2016 and ISO 9001 : 2015 Quality Metrices well in Control

Renewed WHO-GMP certification at Site

Completed LDL curriculum and Faster Forward Immersion Certified Quality Engineer from ASQ

Certified Internal Auditor for ISO 9001 : 2015, ISO 14001:2015

Completed Transition Auditor Training for ISO 13485: 2016, EU Medical Device Regulation (2017/745) and MEDDEV 2.7/1 rev.4

# Career Timeline

General Manager – Quality Control **Ranbaxy Ltd.**

Vice President - Technical **Bilcare – Global**

## Clinical Supplies

Associate Vice President- Corporate Quality Operations **Wockhardt Ltd.**

1994\* 2006 2008 2010 2012 2013 2017

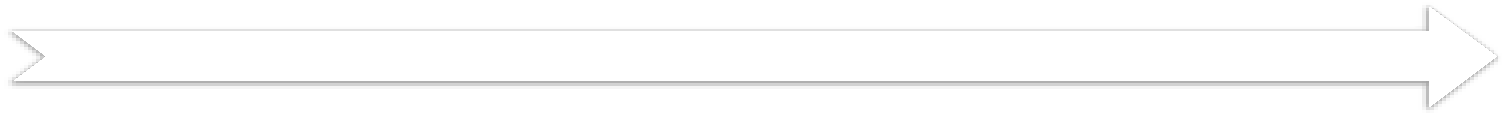
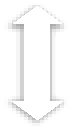
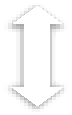
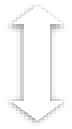
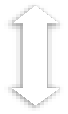
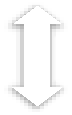
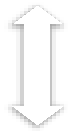
General Manager – Corporate QA **Cadila**

## Pharmaceuticals Ltd.

CEO

## APJ Laboratories

Plant Quality Manager **Johnson & Johnson**



\* *From 1994 to 2006 refer below*

# Education

**MS (Pharmacy Operations)** from Birla Institute of Technology and Sciences ( BITS), Pilani, India in 1997

**B. Pharm** from University of Rajasthan, Jaipur, India in 1994

# Certifications

### Certified Internal Auditor for ISO 9001: 2015, ISO 14001:2015

**Completed Transition Auditor Training for ISO 13485: 2016, EU Medical Device Regulation (2017/745) and MEDDEV 2.7/1 rev.4**

**Certified Quality Engineer,** American society for Quality

**Laboratory Lead Assessor ISO 17025: 2005**, National Accreditation Board for Testing & Calibration Laboratories, New Delhi

**Lead Auditor ISO 9001: 2008**, Exemplar Global TNV Certification Pvt. Ltd.

### Certified Performance Coach and Mentor

Work Experience

**Mar’17 – till date: Johnson and Johnson (J&J) Pvt. Limited, Baddi Plant Quality Manager**

**Key Result Areas:**

Providing Leadership for effective implementation of Quality System strategy defined by relevant Regulations, WW Quality System, and Standards ISO 13485: 2016 and ISO 9001: 2015.

As Plant Quality Head, directly responsible for both Quality Assurance and Quality Control functions.

Regulatory Affairs, Quality Engineering, Supplier Quality and Training function at Site also has a matrix reporting to me.

Lead the Quality System execution at the Site, with primary function as Achieving product quality systems goals for Site and assuring execution of the quality system at the Site and utilize process excellence tools/ methodology for continuous improvement and predictability.



Overall responsible for regulatory deliverables from Baddi Site.

Ensuring coordination with Medical Affairs and other stakeholders in managing field action/ adverse event reporting to meet local country regulatory requirements.

Takes appropriate actions to create and maintain a working environment aligned with CREDO. Serve as a role model for making Credo-based decisions

Create a trusting, collaborative, and ethical work environment

Maintain the highest standards of quality, compliance and accountability Champion programs and initiatives that support our environment and communities

Support Quality Improvement Processes, Affirmative Action objectives and all activities to achieve World Class Manufacturing Plant and attain Quality Objectives

Participate or support major Plant projects, such as transfer of new product or process.

Establish, and operate within, an effective budget and manpower plan for the Quality organization. Recruit, select and develop adequate human resources.

Enforces, promotes and observes all safety, industrial hygiene rules and regulations established by the Company.

### Oct’13 – Mar’17: Wockhardt Limited, Aurangabad Associate Vice President-Corporate Quality Operations

**Key Result Areas:**

**Compliance Quality Audits**

To establish, implement and monitor compliance audit program as per commitment to regulatory agencies. This included all Manufacturing (Formulations, API, API – Biotech) and R&D (CPB) sites in India

To ensure timely closure of audit observations, ensuring appropriate CAPA so as to avoid any repeat observations. To appraise senior management with respect to progress related to closure of audit observations.

To conduct “For-cause” audit for vendors, third party testing lab- etc. as warranted.

### Corporate CAPA

To establish, implement and monitor Corporate CAPA (lateral learning) program as per commitment to regulatory agencies-to all sites of Wockhardt in India and abroad.

To identify and percolate the Corporate CAPA from the audit observations given by regulatory agencies in timely manner

Provide execution support in the implementation of Corporate CAPA systems, including training and effectiveness monitoring

To ensure that, there is timely closure of Corporate CAPA thereby eliminating potential non-conformity from the system To appraise senior management with respect to progress related to closure of Corporate CAPA.

### Corporate Remediation and Regulatory Communications

Second in-line of remediation team (Corporate and Site)- for five sites in India.

Co-ordination with Third party consultant to develop, implement and monitor M-CAP (Master Compliance Action Plan). Review of Actions Taken / Identified versus Regulatory commitments and expectations.

Feedback to/from third party consultants on overall status of assessment of GMP compliance and progress made. Updates to Regulatory agency on progress of remediation.

### Miscellaneous

Corporate manuals/Corporate procedures- Review, approval and Harmonization. Organizing Management Review- Corporate Quality Committee (MR-CQC) meetings Quality MIS – Compiling and analyzing Monthly Quality Metrics of all Sites in India.

Regulatory audit support – audit preparedness, back room support, response/ exhibits - preparations and review. Training and development – Organizing Workshops, case study, faculty for Quality related topics.

Assist SVP-Quality in recruitment and grooming of Quality team.

### 1994 – till date: Regulatory Affairs related experience summary



Support product registration to US, EU and ROW including India/ IB Market. Provide inputs to product dossiers for submission to Regulatory Authorities

Worked closely with Regional, Country, and Global teams to implement regulatory strategies and initiatives. Responsible for all acquired business integration and divestiture project completion as per defined strategy (Baxter US, Pliva -Crotia, Novavax US, United Drugs –Ireland).

Ensuring review of promotional materials for regulatory compliance.

Interprets and applies local regulations to business practices and provides regulatory input, advice, and guidance to the organization.

Sound knowledge MOH set up, drugs act/ medical device rules and import licence Procedure. Understanding of protocols, clinical reports, and dossier preparation (Bilcare, GCS)

# Previous Experience

### Oct’13 – Mar’17: Wockhardt Limited, Aurangabad Associate Vice President-Corporate Quality Operations

**Jul’12 – Sep’13: APJ Laboratories, Paonta Sahib**

**CEO**

**Aug’10 – Jun’12: Bilcare - Global Clinical Supplies, Pune VP –Technical, Asia Pacific**

**Sep’08 – Aug’10: Cadila Pharmaceuticals, Ahmedabad**

**GM-Corporate QA**

**May’06 – Sep’08: Ranbaxy, Paonta Sahib**

**GM-Quality Control**

**Oct’04 – May’06: SGS India, Life Science Services, Chennai Manager QA**

**Aug’03 – Oct’04: Dr. Reddy’s Laboratories, Goa**

**Manager QA**

**Sep’01 – Aug’03: Intas Pharmaceuticals, Ahmedabad**

**Manager QA**

**Sep’00 – Sep’01: Alkem Laboratories, Daman**

**Dy. Manager QA**

**May’99 – May’00: Unichem Laboratories, Baddi**

**Executive QA**

**Oct’94 – Apr’99: Ahlcon Parenterals, Bhiwadi**

**Asst. Manager QA**

Trainings



Attended following:

Agilent Laboratory Informatics Conference, September 2007, Berlin, Germany

Training on Research Quality Assurance in Good Laboratory Practices by British Association for Research Quality Assurance, October 2005, Cambridge, UK

Training on Good Laboratory Practices as per OECD Guidelines, SGS Biopharma SA, Jan 2005, Wavre (Belgium) Training on Good Clinical Practices as per ICH Guidelines, SGS Biopharma NV, Jan 2005, Antwerpen (Belgium) and Medisearch International, Mechelen (Belgium)

Training on Quality Assurance in a Bioanalytical Set Up, SGS Biopharma SA, Jan 2005, Wavre (Belgium)

In India, attended following:

Training on various topics such as:

Quality Culture Business Analytics Negotiation Skills Performance Coaching

Leadership Development Program Appreciating Cultural diversities GLP as per OECD

Train the Trainer Integrity Program

Presentation Skills, Pharmaceutical and Bio-pharmaceutical Inspections Complying with International Standards in the Pharmaceutical Industry Interpersonal effectiveness

Six Sigma Breakthrough Approach WHO/cGMP

Validation & Process Optimization

# Paper Presentation

Presented a paper at International Conference on Science & Technology sponsored by Alena Chemicals of Canada and have many National/ State Level Recognition including that from IPA; acted as a Resource Person, Speaker, Question paper setter and external examiner for M. Pharm.

# Knowledge Purview

Exposure to Formulations, API, Large Volume Parenterals (FFS Technology), Tablets, Capsules, Liquid-Oral, Dry Syrup, Dry Powder Injection , Liquid Injections, Biotechnological Products, Soft gelatin capsules, Hospital products, Ointment, Clinical Trial Supplies Material, Medical Devices

Hands-on experience of complete Quality Assurance activities per se New projects, Formulations, API, Generics, Laboratories, regulated and non-regulated business markets

Technology Transfer & Scale up from R&D to Plant for Pharma & Biotechnological Products

Management lnformation System along with implementation of statistical techniques for capacity utilization, breakdown analysis, yield monitoring, calculation of process capability index (six sigma), Quality Metrics

Insightful understanding of SAP (Quality and MM module) and hands-on experience with Caliber LIMS, Star LIMS, LabVantage LIMS, DMS, Trackwise, LMS

QSP for commercial departments like Import, Export, Marketing, Purchase, PPC Product Management

# Personal Details

**Date of Birth:** 30th September 1971

**Languages Known:** English, Hindi

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