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| Name | | Gopal Srivastava | | | | |  |
| Position Applied | | India Head- Quality | | | | |
| Current Company | | Cadila Healthcare Ltd | | | | | |
| Since | | Aug’17 till date | Reason to change if less than 6 months | | | Better Potential Utilization | |
| Designation | | General Manager – CQA – QUEST | | | Experience | 24 years | |
| Previous | | * Mankind Pharma Limited, New Delhi (Mar’11 – Aug’17) * Sun Pharmaceutical Industries Limited, (Mar’04 – Mar’11) * Hindustan Syringes & Medical Device Limited, (Nov’96 – Mar’04) | | | | | |
| Total CTC | 60 Lacs | Fixed | 55 Lacs | Variable | 5 Lacs | In hand |  |
| Expectation | | Negotiable | | Last Bonus received | |  | |
| Last appraisal % | |  | | Appraisal Received date | |  | |
| Promotion Due(If any) | |  | | Appraisal due date | | April 19 | |
| Graduation | | Bachelor of Science - 1985 | | | | Full Time( Y/N ) | |
| PG (If any) | | * Post Graduate Diploma in Quality Assurance and ISO9000 from AIIMS, Chennai in 1996 * Master of Philosophy (M.Phil.) from Jawaharlal Nehru University (JNU), New Delhi in 1994 * Master of Science (Microbiology) from G.B. Pant University, Pantnagar in 1988 | | | | Full Time( Y/N ) | |
| Notice Period | | 3 Months | | | Buyable (Y/N) | - | |
| Current Location | | Ahmedabad | | Hometown | | = | |
| Details of Spouse | | Profession | Wife And Son | | | | |
| Note | | * No. of plants managing: 21 * Audit faced : USFDA -12 Times , MHRA 3 Times, PICS 4 Times, ROW - MANY, WHO-GMP- 20 Times * Reporting to: SR. VP * Reportees: 7 DR | | | | | |

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| **General Manager – CQA –Indian Multinational Pharma Major**  Visionary professional offering over 24 years of experience in driving the **Corporate Quality Function**  **Industry Preference:** Pharmaceutical & Medical Devices  **Gopal Srivastava** | |
| **Career Summary**   * Insightful knowledge of **GxP (cGMP)& guidelines** of pharmaceutical industry; proven track record of clearing internal, customer and regulatory audits * Proven record of developing a robust and sustainable corporate quality and compliance structure and system across organization * Displayed credentials in obtaining approvals & certifications from global statutory & regulatory bodies such as; US-FDA, MHRA, MCC, ANVISA, INVIMA, government agencies of several countries across Europe, Africa, CIS and Asia in Formulation, API and R&D environments at Sun Pharma and Mankind Pharma * Expertise in **applying quality standards** to various processes within the business unit and maintaining quality assurance objectives complementary to corporate policies and regulatory requirements * Ensuring all laboratory activities are conducted in compliance with existing SOPs/ QCP/ STP/ SCP/ Safety guidelines * Incisive acumen in ensuring **complete in-process quality control** and continuous improvement in process capabilities; **investigating the unusual/ unacceptable results**, process validation & cleaning validation * Ensured **compliance:** USFDA | MHRA | MCC | ANVISA | INVIMA |Emerging Markets, Medical Device Directives ISO 9001, ISO 14001 & OHSAS 18001, ISO 13485, CE Marking * Familiar with various international and domestic statutory, regulatory, and quality compliances; conducted as well as successfully faced large audits * Co-authored various papers and abstract writings for international and domestic publications; contributed to 5 publications on varied topics * A keen communicator with strong **research, analytical, problem-solving** and interpersonal communication skills   **Training/ Workshops/ Publications**   * Short-term Course in Genetic Engineering from Pantnagar in 1987 * Familiarization Course in Oceanography at National Institute of Oceanography, Goa in 1993 * Attended multiple conferences, symposiums, and workshops on Biochemistry, Microbiology, Molecular Biology, Biotechnology and Environmental Sciences * Attended and participated in various industrial conferences and workshops**- DCGI, ISO, FDA, PDA, IPA, ISPE** | Contact  gopals412@gmail.com  gopsrikan@gmail.com  +91-9711223196  +91-7948907608  Core Competencies   |  | | --- | | Quality Management Systems | |  | | Manufacturing Quality Assurance | |  | | Packaging Material Quality Assurance | |  | | New Product Quality Assurance | |  | | Supplier/ Research Quality Assurance | |  | | Statutory Compliance | |  | | Strategy Formulation/ AOP Preparation | |  | | Technology Transfers | |  | | Quality Culture Development | |  | |
| **Career Path**    Hindustan Syringes & Medical Device Limited, Faridabad as **Deputy Manager - QA**  Max Pharma (Max India Limited), New Delhi as **Senior Supervisor - QA**  Mankind Pharma Limited, New Delhi as **General Manager - CQA**    **Cadila Healthcare, Ahmedabad as General Manager – CQA**  1996 - 1996  J.K. Pharmaceuticals, Gajraula as **QA Officer**  1995 - 1996  1996 - 2004  Sun Pharmaceutical Industries Limited, Vadodara as **Manager – Corporate Quality**  **Since2017**  2011 - 2017  2004 - 2011  **Professional Experience**  **Aug’17 till date**  **Cadila Healthcare, Ahmedabad as General Manager – CQA – QUEST**  **Key Result Areas:**   * Heading a direct team of 30 members, and spearhead the corporate quality function globally on building quality cultureacross the organization * Steering the QUEST (Quality Excellence by Sustainable Transformation) activities and interventions using analytics in manufacturing and quality domains * Ensuring vertical and horizontal integration and oversight of quality culture development initiatives and interventions * Evaluating QMS data & trends to identify emerging patterns and indicators and utilizing these for developing quality mindsets and behaviours * Pioneering the establishment of an engaging connect among employees and devising strategies to empower them; conducting surveys to analyse the feel of the people (employees) * Conceptualizing & developing Key Behaviour Indicators (KBI) and other matrices as measurement tool for quality culture * Training relevant SOP’s to teams as per current updates and new insights   **Mar’11 – Aug’17**  **Mankind Pharma Limited, New Delhi**  *The Indian pharmaceutical company offers products in therapeutic areas, and is the 5th largest drug maker of India*  **Growth Path:**  Mar’11 – Oct’12: Deputy General Manager – CQA  Oct’12 – Aug’17: General Manager – CQA  **Role:**   * Headed a direct team of 30+ members, and spearheaded the corporate quality function for 14 company-owned plants, and around 100 contract manufacturers * Steered the quality management process across functions such as manufacturing, Packaging, R&D, commercial test labs, formulations, and analytics * Coordinated and monitored performances of multiple vendors and suppliers across India * Supported quality processes and systems for operations worth **INR 30+ billion**, enabled quality and compliance adherence for multiple brands and formulations * Leveraged expertise in applying total quality management tools and approaches to analytical and reporting processes within the business units * Engaged in quality planning by designing desired & deliverable quality standards, and ensuring a uniform Quality Management Systems across the organization * Recognized for successfully develop leading medicines without the use of preservatives * Administered processes, managed risks, and continually improved products to bring more stability * Conducted continual internal audits as well as vendor evaluations, as well as prepare the quality systems and processes for external/statutory & regulatory audits * Partnered with: * Cross-functional teams from concept to commercial stages for new product development * Information Technology on Developments and Validation in SAP ERP and LIMS * Pioneered in successfully availing **WHO**, **Kenya, Uganda, Ethiopia, Tanzania**, **PIC’s** and gearing up for USFDA, MHRA approvals for manufacturing units and start-up of new units of different dosage forms   **Mar’04 – Mar’11**  **Sun Pharmaceutical Industries Limited, Vadodara as Manager (Corporate Quality Department)**  *The Indian MNC pharmaceutical company manufactures and sells pharmaceutical formulations and APIs, in India and US*  **Role:**   * Mentored a direct team of 6 members as well as extended teams including RQA, and managed the quality systems for API, formulation, and R&D functions * Steered the quality system development for new plants and projects * Contributed significantly in establishing quality management systems for new plants in Sikkim and Jammu * Took approvals to queries received from Drug authorities & regulatory agencies * Acted as a SPOC for entire quality system for R&D; developed quality systems at various departments of R&D centre including analytical, preclinical & BA- BE centre * Streamlined systems and processes to successfully face internal and external inspections and audits * Led regulatory audits at various manufacturing locations and R&D centres spanning: * **US-FDA, MHRA, MCC, ANVISA, Colombia, Ministry of Health** of different countries such as **Tanzania, Nigeria, Ukraine, Indonesia, & Ethiopia** as well as WHO * Piloted all post marketing surveillance and allied activities for the company including continuous reporting, multiple audits, and recalls   **Nov’96 – Mar’04**  **Hindustan Syringes & Medical Device Limited,Faridabad**  *The syringes and medical devices company produces and markets its products in India, USA, Europe, Middle East, Africa and South East Asian countries*  **Growth Path:**  Nov’96 – Apr’98: QA Officer  Apr’98 – Oct’00: Assistant Manager - QA  Nov’00 – Oct’02: Senior Assistant Manager - QA  **Nov’02 – Mar’04: Deputy Manager - QA**  **Role:**  **~ As Deputy Manager – QA (Nov’02 – Mar’04)**   * Managed compliances to ISO 9001:2000 & ISO 9001:1994 quality systems and requirements of WHOGMP & Indian Drugs Act for 6 plants * Contributed significantly in fulfilling requirements of EN 46001, ISO 13485 and European Medical Devices Directive (MDD) for CE Marking * Adhered to international compliances such as USFDA: 821 CFR Part 820 * Administered the Central Lab of the group for receiving, in-process control and finished goods   **Sep’96 – Nov’96**  **J.K. Pharmaceuticals, Gajraula as QA Officer**  **Apr’95 – Sep’96**  **Max Pharma** (Max India Limited),**New Delhi as Senior Supervisor - QA**  **Education & Credentials**     * Post Graduate Diploma in Quality Assurance and ISO 9000 from AIIMS, Chennai in 1996 * Master of Philosophy (M.Phil.) from Jawaharlal Nehru University (JNU), New Delhi in 1994 * Won Senior & Junior Research Fellowships from UGC in 1995 and 1994 respectively * Project: Environmental Sciences (Molecular Biology) * Project Related Research (J.R.F.) in Life Sciences (Microbiology) * Master of Science (Microbiology) from G.B. Pant University, Pantnagar in 1988 * Bachelor of Science (Chemistry, Zoology, and Botany) from Gorakhpur University, Gorakhpur in 1985       **Personal Details**  **Date of Birth:**19thAugust 1965 **Languages Known:**English, Hindi & Gujarati **Address:**B-804, Ratnakar Atelier, Opp. Chandan Party Plot, Jodhpur, Ahmedabad – 380015, Gujarat  **Permanent Address:** 402-Palatial, Prateek’s The Royal Cliff, Crossings Republik, Ghaziabad, U.P. 201016, India | |