

NUPUR PANDEY

Highland haven,
Building no. 2, A wing
Flat no. 1004,
Balkum pada no. 3, Saket road,
Thane, 400608
Mumbai

Email: nupur29july@gmail.com
Mobile: 9619395904

CAREER OBJECTIVE

A Quality Assurance professional with 6 years of extensive experience in handling Quality Management Systems and Quality Control activities for pharmaceutical, medical devices and food industry; seeking a challenging position with a progressive Pharmaceutical / FMCG organization that encourages innovative thinking, recognition and career development.

SKILLS

- Good planning, organising and time management skill
- Change & adaptability
- Project management
- Vendor development
- Knowledge of ISO 9001:2015, ISO 22000, ISO 13485:2003, ISO 10993, ISO 14971, ISO 11135-1, ISO 14001 (OHSAS), ISO 18001 (EMS), FSMS, Indian & US FDA, QMS, FSSAI, Drugs & Cosmetics Act, Schedule M, ICH-GCP, cGMP standards

PROFESSIONAL EXPERIENCE

A) HIMEDIA LABORATORIES PRIVATE LIMITED

(April 2016 – July 2017)

Job Title: Senior Executive – Quality Assurance & Regulatory Affairs

- Implementation of ISO 9001:2015 standard
- Audit, Regulation & Certification
- Monitoring compliance according to the regulatory requirements of (ISO, CE, FDA, NABL, HALAL, Kosher etc.)
- Certification renewal
- Handling internal & external audits
- Monitoring and streamlining the process in overall organization
- Review – SOPs, Protocols, Manuals, Audit reports, Annual Product Review reports, Market complaints, Post market surveillance reports, Qualification documents, Training
- Monitoring & review of validation activity - Process, Equipment, Transport, Cleaning, Water System
- Training to team members on management system guidelines.

Additional responsibility:

- ***Working in close co-ordination with Management Representative***, carrying out Management review meetings and preparing its requirements like:
 - MRM schedule,
 - MRM agenda,
 - Reporting of results,
 - Guiding discussion through agenda,
 - Suggesting improvement to QMS,
 - Publishing minutes of management review meet and closure of all MOM points.
- Ensuring QMS processes are established and implemented as per requirement
- Reporting to Top Management on QMS performance (its achievements & lacunas)
- Ensuring customer requirement & customer delight as prime responsibility within the organization
- Ensuring company's third party accreditations are obtained and maintained

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- Planning & carrying out internal audits and compliance of all non-conformities

B) DEVYANI INTERNATIONAL (Brand: Costa Coffee & Pizza hut)

(Sep 2013 – Feb 2016)

The company is an associated partner of RJ Corp - largest bottler for PepsiCo with interests in Beverages / Food / Beer / Milk / Ice-cream / Stem-cell / Real Estate / Education.

Job Title: Quality Assurance – Senior Executive at Costa Coffee & Pizza hut

Scope: West region city outlets and International airport (T2) outlets

- System implementation (as per ISO 22000, FSSAI, HACCP, NSF guidelines & Costa UK guidelines)
- Internal & External Audit
- Market complaint closure, Competitor analysis, Post market survey
- Developed and maintained Quality assurance, GMP, HACCP, Allergen policy manual for the operations
- Vendor development
- Product development & process standardization
- Labeling & Packaging
- Onsite training & evaluation
- Project Management
- Supplier Quality Assurance
- Validation & Calibration

Additional responsibility:

- Induction, Training, New Product and Beverage Training for smooth launch

C) GEORGE PHILIPS MEDICAL ENGINEERING PRIVATE LIMITED

(Feb 2012 - Aug 2013)

The company is a medical device manufacturing unit, incorporating the latest in Engineering & Manufacturing technologies, manufacturing & marketing a wide range of specialized medical devices & disposables.

Job Title - Quality Assurance Executive

- Designing and implementing systems, processes and procedures
- Site Master File based on MHRA guidelines & PIC's guidelines
- Active participant of cross-functional teams (including MRM, CAPA Review Team, Management Review and Design Review teams)
- Performed CAPA Investigations and root-cause analysis
- Defining & Review of Quality documents (SOPs, Site Master file, Quality Manual, Quality Policy, BMR, Quality Test plan, Sampling plan & QC reports, Qualification documents, Technical Master file, Objectives & Standards, Validation plan, Test protocols & reports)
- Internal Audits based on ISO 13485:2003
- cGMP guidelines adherence to Clean Room Protocols
- Labeling & Packaging
- Product Recall and Advisory Notice
- Product sterilization
- Stability and Biocompatibility of products
- Environmental Monitoring of Clean room

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D) S.K.LOGISTCS

(Feb 2011 – Feb 2012)

*The Company deals in Bulk drug manufacturing and Formulations, warehouses and have various CFAs & Mother Warehouse storing drugs of MNC's like **Sanofi Aventis, Aventis Pharma, Merck, Schering Plough, Bristol Mayer's Squibb**, and Indian Companies like Kaya Ltd., Royal Hygiene, East India Pvt. Ltd., Universal Ltd. etc.*

Job Title - Quality Assurance Officer

- QMS implementation and streamline processes
 - Quality documents (SOPs, Validation master plan, Validation protocol & reports, Job aids, Qualification documents, Training records) as per ISO/GWP norms
 - Audit & CAPA closure
 - Handling of Batch release, Change control, Deviations / Non conformity, Market complaint closure, Material management, Cold chain consignment, Pest control
 - Validation & Calibration
 - Development of talent through training, performance coaching and on the job learning
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OTHER ATTAINMENTS

A) Internship: Vista Processed Foods Pvt. Ltd., (the sole suppliers of Mac Donald's) (June 2010 – Aug 2010)

➤ **Projects handled:**

- Study of dehydration process in chicken products
- Study of shelf life of frozen chicken skin in the chicken chiller

B) Internship: Blue Cross Laboratories

(Sep 2010 – Nov 2010)

➤ **Trained under QA/QC**

- Company's standard & guideline
- Documentation
- Verification, Validation & Calibration activity
- Audits & Market Complaint Handling

C) Done training at different Public testing laboratories

- Geo Chem. Labs
 - S.S. Laboratory
 - Bee Pharmo Laboratory
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EDUCATION

Sophia College of Women, Mumbai University, India Dec 2010
Post Graduate Diploma in Quality Assurance (Specialization into Pharmaceutical & Food)

R. K. Talreja College of Arts, Science and Commerce, Mumbai, India Mar 2009
Bachelor's Degree (Microbiology)

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R. K. Talreja College of Arts, Science and Commerce, Mumbai, India
HSC (Science)

April 2006

Sri Vani Vidya Shala high School, Mumbai, India
(all subjects)

Mar 2004 SSC

EXTRA CURRICULAR ACTIVITIES

- Organized the Sophia college function "ANANYA" with the theme as Importance of Fibers.
- Organized a brainstorming contest 'Micro Rocks' in RKT College.
- Participated in Extempore and various Essay Writing Competitions in College.

HOBBIES

- Traveling
- Listening music
- Cooking

PERSONAL INFORMATION

Birth Date : 29 July, 1988
Gender : Female
Nationality : Indian
Marital Status : Married
Languages Known : English, Hindi and Marathi

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