**GAURAV SONI**

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Seeking challenging assignments in Quality Assurance - Regulatory Affairs Department

with a growth oriented organisation of high repute

**Professional Snapshot**

* A dynamic individual withcumulative **5.5 years** of pharmaceutical work experience.
* Possess highly motivated and positive attitude towards life along with focussed approach.
* **Currently working with Astron-Research Limited, Ahmadabad as a Senior Research Associate in QA-Regulatory Department.**
* Extinguishly able to work individually or as a team member with equal ease and sincerity.
* **Last worked with Lupin Limited, Indore as a Quality Assurance Executive.**
* Possess exceptional team spirit thereby helping in easy achievement of organisational and personal goals.
* A proactive learner with a flair for adopting emerging trends and addressing industrial requirements to achieve organisational objectives and profitability norms.
* Exceptionally organised with a track record to demonstrate creativity and having ability take self initiative to achieve smart objectives and goals.
* An effective communicator with an excellent relationship building and interpersonal skills.

**Academic Credentials**

**M. Pharm.** Nargund College of Pharmacy, R.G.U.H.S. Bangalore, Karnataka in June 2009

**(P. Chem.)** Andsecured **77.2%** Marks, stood **2nd** in the college.

**B. Pharm.** G.R.K.I.S.T. Jabalpur, R.G.P.V. Bhopal, M.P. in June 2006, Secured **66%** marks.

**XII** Saraswati H. S. School, Jabalpur, M. P. Board in March 2002, Secured **73%** marks.

**X** Saraswati H. S. School, Jabalpur, M. P. Board in March 2000, Secured **70%** marks.

**Current Job Responsibilities**

* Review of documents especially to assist QP (Qualified Person) for batch release in UK.
* Ensuring that batches of medicinal product have been manufactured and assembled in compliance with the EU legislative requirements.
* Preparation and review of APQR (Annual Product Quality Review Report) for UK site including plant COA comparative trending.
* Ensuring Manufacturing Authorisation requirements for medicinal products have been met for the batch concerned.
* Principles and guidelines of GMP as interpreted in the EU Guide to GMP have been followed.
* Necessary quality assurance checks and tests have been performed, and account taken of the assembly and packaging conditions, including a review of records.
* Changes or non-conformances in assembly, packaging or quality control are dealt with correctly.
* Query handling related with batch records, variation, mock-ups and art work along with Coordination for Batch release activities.
* Ensuring regular audits, self-inspections and spot checks are being carried out by experienced and qualified staff as per intended job responsibilities.
* Review of data Loggers readings for received shipment in UK.
* Reviewing Batch Record documents with reference to RTD for the market specific requirement for batch release.
* All associated documentation has been completed and endorsed by suitably authorised staff.
* Review of batch document, in-process and finished product COA with RTD.
* Cross verification of plant change controls with the current Market authorization variation and ensuring their implementation within time limit.
* Resolving QP Issues from the batch document related to market complaint, deviation, stability data and Qualification status.
* Responsible for documents review of new product introduction for product launch to new country for existing product.

**Previous Job Accountabilities**

**From 15/03/10 to 13/05/13 (3.2 years) with Lupin Limited, Indore as an Executive QA-RA.**

* Module 3 Dossier Preparation & Ensuring adherence and compliance with applicable guidelines ICH, cGMP.
* Supporting regulatory CMC filing for meeting the regulatory requirement of USFDA, MHRA and TGA.
* Successfully faced USFDA, MHRA, TGA and SANDOZ Audits at Lupin Limited, Indore, M.P**.**
* Review of BMR and BPR after manufacturing and packing to ensure compliance to DRA submission.
* Preparation and review of SOPs, Hold Time Protocols and Reports including Process Validation Reports.
* Monitoring and review of Quality system documents i.e. OOS, OOT, Deviation, Change Control etc.
* Review of Qualification & Validation documents i.e. IQ, OQ, PQ, TBPQP, TBPQR etc. and Stability data grids.
* Investigated the recall batch of finished product of steroids in minute quantity with an excellent documentation practice to ensure consistent premium quality of the product and their safety and stability studies are carried out for secured and optimized therapeutic efficacy.

**1 year with GlaxoSmithKline Pharmaceuticals Ltd. at Ahmedabad as a Medical Representative.**

* Promoting premium quality antibiotics including world’s No.1 antibiotic Augmentin on ethical and scientific basis by visiting super speciality Doctors to achieve the targets successfully.

**Academic Projects & Dissertation Handled**

**M. Pharm. (Pharmaceutical Chemistry) Project**

**Title :** Synthesis of Substituted Fluoro-Pyrazole Compounds for their Biological Activity.

**Description :** The project involves synthesis of derivatives of Fluoro-Pyrazole compounds

And their characterisation by UV, IR and NMR.

**Duration :** 6th Jul’08 - 30th Jun’09.

**Personal Portfolio**

**Date of Birth :** 26th September, 1984

**Current Address :** C-36, Shivdhara Apartment, Near Heritage Homes, Thaltej, Ahmedabad-380054.

**Permanent Add. :** 1550, Navnivesh Colony, Ganga Nagar, Garha, Jabalpur-482003, (M.P.)

**Linguistic Abilities :** English and Hindi.