**Gauri**



**Pre-clinical Research Scientist**

Email: gauri.339525@2freemail.com

**PROFILE SUMMARY**

* Professional with 4.0 years of chronicle of success driving benchmark-setting in Preparing SOP & Protocols, various non- performance study case, Team Management, R & D initial pipe line submission Quality assurance, Process Improvement.
* Experience in spearheading on laboratory compliance with GLP (Good Laboratory Practice) and regulatory guidelines and assess their impact on Studies
* Expert in Pre-clinical Invitro and Invivo genotoxicity Tests.
* Expert in Molecular biology, bioinformatics and microbiology tests
* Expert in cell line preparation, cell culture and characterization of cells.

**Personal Attributes**

**ADAPTIVE AND WILLING TO LEARN**



**TEAM WORK** **ABILITY TO WORK**

**UNDER PRESSURE**

**COMMUNICATION** **CUSTOMER**

**SKILL** **ORIENTATION**

**SKILL**

**MEET DEADLINES**

**PROFESSIONAL EXPERIENCE**

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| **Total Experience** | 4years |
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| **Last Employer** | INTOX, Pvt.,Ltd. (Aug 2010 To May 2014) |
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| **Category** | Toxicological Contract Research Organization |
|  | (OECD GLP Certified by National GLP Compliance Monitoring Authority, Department of |
|  | Science and Technology, Government of India, by The Netherland GLP Compliance |
|  | Monitoring Program, Food and Consumer Product Safety Authority (VWA), The |
|  | Netherlands) |
| **Role** | Research Scientist |
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| **Industry Experience** | CRO |
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| **Designation** | Study Director |
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**PROFESSIONAL CERTIFICATES**

1. Autonomous course in Pharmaceutical Application and handling & use of reconstructed 3D tissue Model-EPISKIN for conduct of skin irritation test following OECD Guideline No 439
2. 5 Day Hands on workshop of Molecular Biotechnology & Bioinformatics.

**PROFESSIONAL SKILLS**

**Technical & Scientific Proficiency**



Can prepare SOP’s independently



Can prepare Report independently and

Can Monitor the assay as per the guidelines and protocols

Can perform independently the following tests:

**GenotoxicTests:**

O AMES test using *Salmonella* strains (OECD Guideline No.471and ICH S2 (R1))

O *Invitro* Chromosome aberration test using human lymphocytes (OECD Guideline No.473)

O *Invivo* Chromosome aberration test in mice (OECD Guideline No.475)

O *Invivo* Micronucleus test in mice (OECD Guideline No.474)

O Cell-gene mutagen test on Chinese Hamster cell lines (OECD Guideline No.476)

O Sister Chromatid Exchange using human lymphocytes

O S9 preparation from liver of Rat and maintenance of CHOK1cell lines O Local lymph node assay (OECD Guideline No.442B)

O Biocompatibility studies on Medical Devices as per ISO 10993 Guidelines.

O Can handle 3D skin models for conduct of Skin Irritation Test following OECD Guideline No.439

**Microbiology:**

* Gram’s Staining, Endospore Staining
* Various biochemical tests employed in identification of micro-organisms
* Water quality–microbial analysis (MPN test).
* Checking purity and characterization of cultures
* Antibiotic sensitive test of cultures
* Testing antimicrobial and antibacterial action
* Determination of Minimum Inhibitory Concentration
* Total viable count of cells
* Isolation and characterization of anaerobic organism
* Preliminary pathogenic test of Rat and Rabbit food and bedding material, water bottles, cages and cage tops.
* Experience in handling viruses

**Molecular Biology:**

* Isolation, purification and estimation of chromosomal DNA
* Isolation, purification and estimation of RNA
* Agarose gel electrophoresis
* Chromosomal DNA Extraction using culturable approach
* Plasmid DNA isolation followed by gel electrophoresis
* Restriction digestion followed by gel electrophoresis
* Ligation followed by gel electrophoresis
* Preparation of competent cells
* Transformation and plating on LBA
* DNA gel electrophoresis
* Gel extraction
* PCR followed by gel electrophoresis

**Immunological Techniques:**

* Separation of lymphocytes from peripheral blood by Ficoll Hipaque Method

**Biochemistry Techniques:**

1. Estimation of sugars by Nelson-Somogyi and Dinitrosalicylic Acid Method o Estimation of total carbohydrates by Phenol Sulphuric Acid Method

o ELISA-method to detect BrdU labeled lymph nodes.

**Bioinformatics:**



Bioinformatics of DNA databases



Pair wise sequence alignment and multiple sequence alignment



Searching for homologous and paralogous sequences



Can use CLC software



Can use FASTA and BLAST tools

**Others:**

* Cultivation of heart cells of chick embryo in Modified Eagle’s Medium
* Saponification value of fat ,iodine number of fats
* Performing Thin Layer Chromatography
* Cultivation and maintenance of cells and cell lines: Human lymphocytes and Chinese Hamster ovary cell lines.

**Drug Regulatory Affairs:**

* Preparation of Common Technical Documents (CTD), ASEAN CTD and DMF’s
* Preparation of CMC (Module 3- API) in CTD Section, ACTD and DMF’s
* Preparation of Module 3- Formulation in CTD Section, ACTD and DMF’s
* Knowledge of Regulatory Bodies US FDA, EDQM, EMA, MHRA, DCGI (CDSCO)

**ACADEMICS**

2015 Post Graduate Diploma in Regulatory Affairs from Global Institute of Regulatory Affairs, Pune India

2009 M.Sc. (Microbiology), Modern College, Pune University, India

**IT SKILLS**

1. MS Office (Word, Excel, Access, Power point, Outlook)

**ACCOMPLISHMENTS**

* Published an Abstract namely “Self-renewal and Identification of Hematopoietic Stem cells” in International

Conference on Stem cells and Cancer-2011 journal.

* Presented paper in the International Conference of Stem Cells and Cancer-2011.
* Validated Local lymph node assay (OECD Guideline No.442B) using first time Albino Mouse and got excellent results compared with genetically modified mouse.

**PERSONAL DETAILS**

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| • | Date of Birth | : 14th May 1986 |
| • | Marital status | : Married |
| • | Visa Type | : UAE Resident |
| • | Nationality | : Indian |
| • | Language Known | : English, Hindi, Marathi |