

Ms.Shivani V Bhapkar

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A highly accomplished and result-oriented Pharmaceutical/Healthcare professional knowledge of Formulation Research and Development, (Drug/Medical Devices) Regulatory Affairs, Quality Assurance, ICH Guidelines, GMP, GLP, PV, Data integrity, and pharma compliance.

Key Technical Skills :

- (Drug/Medical Devices) Regulatory Affairs
- Knowledge of CTD, eCTD, DMF, NDA, ANDA, SNDA, INDA GLP.
- Scientific/Medical Writing engaging content on various healthcare topics.
- Relevant knowledge about medical terminology, anatomy and physiology and SOP adherence
- Basic information about signal detection methods PBRERs, PSURs and RMP .
- Knowledge of ICH guidelines
- Data Integrity and Pharma-Compliance,
- Problem-solving and motivational skills
- Good verbal and written communication

Educational Details :

- Pursing Master of Pharmacy Pharmacology and Toxicology. (2023-2024)
- Bachelor of Pharmacy (2019-2020)

Languages :

- English(Full Professional Proficiency)
- Hindi,Marathi.

Career Summary :

- Well-versed with the concepts of (Drug/Medical Devices) Regulatory Affairs, Quality Assurance, ICH Guidelines, CTD, eCTD, ICH guidelines,PIL & Labelling, NDA, ANDA, SNDA, INDA, Para IV Application, First to file (FTF) of drug product, Post-approval activities, Dossier, Biowaiver, DMF, AMV, PDR, FDR, MedDRA coding, Argus database, QbD, GMP, GLP, Data integrity, and pharma compliance.
- Handling of the experimental animals.
- Handling of various analytical instruments like UV,IR, Celvenger extraction.
- Ability to work collaboratively and effectively with multidisciplinary teams in a fast-paced high-energy environment under tight deadlines while adapting to changing priorities.
- An effective communicator with honed interpersonal, analytical, problem-solving, and motivational skills.
- Superior computer operating and internet surfing skills including experience in handling tools and software such as Microsoft Word, Excel, and PowerPoint, using various data retrieval such as Google Scholar,Science direct, Research gate for literature survey, operating systems like Graph pad prism, SwissADME,PyRx, Autodock Vina2.0 ,Ex-pharma,RASAR,Venny.

Notable Accomplishments :

- **Patents:**
1. Formulation and evaluation of herbal gel from Piper betle leaf extract for treatment of Rheumatoid arthritis.
- **Publications**
1.An Review on Nanopraticles for herbal extracts in Web of Science listed IJPSR.ISSN:2455-4685

Academic Project :

- 1.Formulation and evaluation of herbal gel from Piper betle leaf extract for treatment of Rheumatoid arthritis.

Certifications and License :

- Done Maharashtra State Pharmacy Councils Drug Information Centre:Pharmacist Refresher Course.
- Received a Certificate Course in Drug Regulatory Affairs from Undemy.
- Maharashtra State Pharmacy Council –Registered Pharmacist 2023.