DARSHIL UPADHYAY
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PROFESSIONAL SUMMARY

An ambitious toxicologist with non-clinical an insight to details, Currently working with one of the Fortune 500 CRO of the world as a HOD for life science department Biocompatibility Medical Device, with total experience with a pharmaceutical and Agrochemical company since 8 years, performing regulatory and discovery toxicology studies. Skilled in handling, rodents and non-rodent well versed with regulatory guidelines and dose calculations. Multi-task oriented with experience of working in a GLP, AAALAC,USFDA, SCCS and GCP approved testing facility. Experience with PDE reports preparation and audit management.

HOD
December 2021 to till Date LabCorp (Laboratory Corporation of America Holding)

Working as Head to just manage Non-clinical regulatory to entire Global for the submission. Participates in quality improvement efforts to increase overall operational efficiency.

- Develops reputation for the Company as industry leader in Regulatory by attending and speaking at industry events such as seminars, association meetings, authoring articles for trade journals, and participation in industry association through memberships and oncommittees.
- Develops solutions to complex problems.
- Provides internal training in appropriate areas of expertise to other departments.

-To manage the entire team of 23 people for non-clinical department.

Technical Lead
November 2020 to November 2021
HCL Technologies Ltd.

Toxicology:
Worked as a representative of the regulatory department with other departments. Supports business development, including generation of repeat business from existing clients and proposal development.
Monitors project budgets; reviews client invoicing.
Monitors personal utilization and utilization of direct reports.
Acts as a key point of contact for clients and regulatory authorities. Acts as a resource for technical knowledge, SME Biocompatibility and Toxicology Risk Assessment
GAP Assessment and Remediation for EU-MDR 2017/745 for International Medtech ClientsTechnical Writing/Report writing and documentation for Eu MDR assessment Technical Documentation Review (Biocomp Report)
Review of Deliverables and conducting regular DPA(Defect preventive analysis) Biological Evaluation and Biological risk assessment for Medical Device as per ISO-10993 Part.ISO-10993-10
ISO-10993-11 ISO-10993-23

Toxicology:
Prepare, maintain and update toxicology summaries for the products marketed globally, in accordance with company policies and guidelines
PDE calculations for various generic compounds
Toxicology risk assessment as per SCCS guidelines for cosmetics products.

Research Officer
September, 25 2017 to March 16, 2020
Jai Research Foundation – GLOBAL (GLP)

Worked as Executive (Research Officer) in Toxicology department as a Study Director
In Acute Section.
Study plan preparation and report preparation as per OECD and EPA guidelines, dose selection for oral, dermal and sensitivity studies for the acute section for the submission at regulatory through various sponsors.
Involved in In-vitro studies like Bovine Cornea Opacity/Permeability test (BCOP) OECD 437 Also involved in repeated dose toxicity studies for range and main studies.
Also preparing IAEC form for the approval of animals for conducting toxicity in acute section.
Preparation of Dose formulation. Expertise in dosing by various routes in laboratory animals viz., oral, intravenous, subcutaneous, intradermal, intraperitoneal etc.
To face the internal and external audits.
Preparing/Reviewing the protocols, SOP, reports and Calibration records
To communicate with Sponsor with their ongoing projects and solve their queries. To train the technical staff.
Maintain skills, training records of all personnel working in the technical areas Giving training to the personnel and evaluating the skills
Giving guidance to colleagues for quality systems. To assist deviations related activities.
Documentation of log books, calibration records, temperature and humidity records etc.

Senior Scientific Assistant
September, 2014 – 2017 (Three Year Bond)
Zydus Research Centre
Cadila Healthcare Ltd., Ahmedabad, India

Experienced as a Study Personnel in designing, conducting, reporting and archiving GLP and Non- GLP toxicology and toxicokinetic studies.
Repeated and Carcinogenicity toxicity studies in rodents.
In addition to general toxicology, also been a part of studies of discovery toxicology, reproduction toxicology, dermal toxicology and carcinogenicity studies.
Necropsy for various animal's rats and mice and collecting the organs

Research Contractor
2013-2014
Piramal Healthcare Ltd. (Pay Role by Sciformix Pvt. LTD)
Mumbai, India

Preparation of pharmacokinetic and efficacy studies under GLP compliance. Involved in designing, conducting and analyzing preclinical TK and PK. PK studies to support development of molecules.
Conducting and performing QC check of PK output from WinNonlin analysis. Conducting tissue distribution studies
Homogenization Process for Various Animal Tissues
Recording of toxicity sign and symptoms of experimental animals
Involved in the Toxicokinetic activity such as bleeding and separation of plasma as per mention in the study plan
Withdrawal of blood samples retro orbital route in rats and mice, Marginal ear veins of rabbit.

EDUCATION

QUALIFICATION	BOARD/ UNIVERSITY	Year
Ph.D.	OPJS	2019
M.Pharm (Pharmacology and Toxicology)	CMJ University	2013
B.Pharm	Pune University	2010

INDUSTRAIL TRAINING AND CONFERENCES ATTENDED

One Month Industrial Training in RANBAXY LABORATORIES LIMITED in Research and Development 2009.GURGAON.
One Month Industrial Training in JAI RESERCH FOUNDATION in Analytical Development Laboratory.2008. GUJARAT.
One Month Industrial Training in ASHCO ANALYTICAL SERVICE in Analytical Development Laboratory 2008. MUMBAI.
The Ramanbhai Foundation 8th International Symposium on Current Trends in Pharmaceutical Sciences, "Advances in New Drug Discovery Technologies and Translational Research"; Ahmedabad; 2nd to 4th February, 2017.
"Organizational Procedures in Good Laboratory Practices", held at Zydus Research Centre, Ahmedabad.
"Organizational Procedures in Good Laboratory Practices", held at Jai Research Foundation held at Vapi.