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OBJECTIVE

Seeking a challenging role that requires knowledge, skills, and experience in the following areas:

1. Biological safety evaluation associated with medical devices and component materials, and process changes in accordance with ISO 10993 and other national and international standards.
2. Toxicological risk assessment on extractable and leachable profile of the medical devices.
3. Biocompatibility testing strategy for new products and sustaining products that include studies using in vitro culture and in vivo animal models.
4. Compliance with internal standards and regulatory requirements to ensure the efficacy and safety of medical devices.

PROFESSIONAL SUMMARY

Biocompatibility and Toxicology Specialist with 13+ years of experience in biological safety evaluation and toxicological risk assessment of medical devices as per ISO 10993 standards. Proven history as a successful biocompatibility scientist from a combination of industry experience working in the medical device industry for new product development and life cycle management of sustaining products and hands-on experience working in a CRO as a study director for different classes of medical devices. Having an in-depth technical knowledge of the ISO 10993 standards and regulatory requirements in the US and EU. Expert in developing biocompatibility testing strategy, biological evaluation plan, executing the biocompatibility testing, and authoring biological evaluation report for successful regulatory submissions. Member of BIS ISO 10993 committee, India. Having an excellent record as an international speaker/trainer in ISO 10993 standards to leading manufacturers and regulatory bodies like Saudi FDA (SFDA), HOYA Optics-Thailand, and LG Chem-Korea and as a speaker in national conferences like “Medical Device Regulatory and Quality Summit”, in 2017 and 2022, India and organized multiple 10993 Biocompatibility workshops in India.

PROFESSIONAL EXPERIENCE

Organization	Designation	Duration
Baxter Healthcare	Research Scientist II	Dec 2023-Present
Baxter Healthcare	Research Scientist I	Aug 2018-Nov 2023
UL India Private Limited	Biocompatibility Engineer	May 2017-Jul 2018
GLR Laboratories Pvt Ltd	Senior Scientist	May 2010-Apr 2017

EDUCATION

Advanced Comprehensive Course in Toxicology, American College of Toxicology, 2020
Master of Science (Biotechnology) - Vinayaka Mission University, India, 2013
Bachelor of Technology (Biotechnology), Anna University, India, 2008

RESPONSIBILITIES

Current Employer: Baxter Innovations and Business Solutions Private Limited

Position: Research Scientist - Biocompatibility Lead, Infusion Therapies and Technologies, Medical Products & Therapies

1. Perform gap analysis and execute biocompatibility testing to remediate the gaps to meet the state-of-the-art requirements.
2. Perform biocompatibility/toxicology impact assessments for the process changes in the existing products based on the biological risk management process.
3. Collaborate with cross-functional team members (engineering, extractable and leachable, materials, sterility, etc.) to determine a comprehensive testing strategy.
4. Monitoring biocompatibility studies in external CROs, technical review of study protocols, and test reports.
5. Authoring BEP and BER for regulatory submissions.
6. Effectively coach and mentor junior team members.
7. Develop biocompatibility testing strategies to qualify new products and materials per global standards. Ensure compliance with regulatory guidelines such as ISO, ASTM, and USP 87 and 88.
8. Develop preclinical regulatory summaries for DHF files, USA FDA 510 K submissions, and CE Mark.

9. Utilize Siemens Team Center Unified global material management system (GMMS) for biocompatibility testing, product development, and registration support.
10. Develop project schedules; provide estimates and timelines to meet project milestones.
11. Attend Project Review and Core team meetings.
12. Implement the use of ISO10993-1, regional pharmacopeia, 21 CFR Part 58 Good Laboratory Practices for Non-Clinical Laboratory Studies, and/or other regulatory guidance documents to qualify Baxter products.
13. Performing toxicology risk assessment of extractable and leachable in line with ISO 10993-17.

Previous Employer: Underwriters Laboratories Private Limited, Bangalore, India

Position: Biocompatibility Engineer

1. Conduct international and national biocompatibility training, workshops, seminars, and webinars.
2. Design and recommend testing strategies to global customers.
3. Biological safety assessment of medical devices to issue "Declaration of Compliance" (DoC) to ISO 10993.
4. Genotoxicology assessment of leachable from medical devices using the TTC concept based on ICH M7 guidelines.
5. Recommend toxicology testing requirements for medical devices as per ISO 10993 standards.
6. Design study protocol for toxicology testing as per regulatory needs.
7. Monitor toxicology studies and review reports.
8. Recommend toxicology testing requirements of medical device packaging materials as per ASTM standards.
9. Recommend toxicology testing requirements of raw materials like plastics and elastomers as per USP 87 and 88.
10. Conduct a literature search to support toxicology risk assessment of implant devices.
11. Perform toxicology risk assessment of medical devices, pharmaceutical containers, bioreactors, etc., based on extractable and leachable testing.
12. Establishment of allowable limits of leachable substances from medical devices based on ISO 10993-Part 17.
13. Design chemical characterization test methods for medical devices in consultation with a chemist and material scientist followed by a risk assessment of toxicology.
14. Risk management of medical devices as per ISO 14971.

Previous Employer: GLR Laboratories Pvt Ltd, India

Position: Senior Scientist

1. To scientifically conduct the non-clinical toxicity studies in compliance with the Principles of GLP, regulatory guidelines and animal welfare guidelines.
2. To plan, conduct and monitor the studies required to be conducted in the toxicology department.
3. To take part and monitor the study related activities like study designing, study plan writing, experimental procedures, data recording and analysis, report writing and archiving.
4. To prepare and review SOPs required for day to day working in the areas of direct concern and to review and provide inputs in the SOPs of the other related groups.
5. To conduct, participate, supervise, and ensure the validation studies are conducted wherever/whenever required in the group.
6. To ensure, in case of multisite studies, as Study Director, that the delegated Phase of the study is being performed in compliance with the Principles of GLP.

Study Director

1. Conducted more than 300 biocompatibility studies in a GLP Set up as a Study director.
2. Supported different class of devices like implants, catheters, disposables, dialyzers, stents, IOLS, respiratory and cardiovascular devices.
3. Hands on experience in cytotoxicity, irritation, sensitization, acute/sub chronic systemic toxicity, implantation, genotoxicity, hemocompatibility and pyrogen testing of medical devices.
4. To act as the single point of study control and take the responsibility for the overall conduct of the study and for its final report.
5. To approve the study plan and any amendments to the study plan by dated signatures.
6. To ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study.
7. To ensure that study plans and amendments and Standard Operating Procedures are available to study personnel.
8. To ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study.
9. To ensure that the procedures specified in the study plan are followed and assess and document the impact of any deviations from the study plan on the quality and integrity of the study and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study.

10. To ensure that all raw data generated is fully documented and recorded.
11. To sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the Principles of Good Laboratory Practice.
12. To ensure that after the study's completion (including termination), the study plan, the final report, raw data, and supporting material are archived.

CERTIFICATIONS, CONFERENCES, AND TRAINING

1. Conference Speaker "Regulatory Compliance in Biocompatibility Testing" - Medical Device Evolution: Advancements and Innovations Webinar, 5 Sep 2024, Virtual.
2. Attended 42nd Annual Conference of the Society of Toxicology, India (STOX 2023), Calicut, Kerela, Nov 23-25, 2023.
3. Attended EUROTOX 2023 Conference - 57th Congress of the European Societies of Toxicology, Ljubljana, Slovenia. 10th -13th Sep 2023.
4. Conference Speaker- "Current Challenges in Biocompatibility Testing of Medical Devices"-6th Annual Medical Device Regulatory and Quality Summit, 2022, India
5. Course-Certificate of completion in "Dose-Response Assessment Boot Camp" by TERA-Toxicology Excellence for Risk Assessment, 2022, India
6. Conference Participant-MedTech Summit Virtual Event - Biocompatibility of Medical Devices, 2020, Virtual event, UK.
7. Course-Advanced Comprehensive Virtual Course in Toxicology, American College of Toxicology, 2020
8. International training - Biocompatibility testing requirements for medical devices, HOYA Optics-Thailand, 2019
9. Conference Participant-Asian Federation of Laboratory Animal Science (AFLAS) Conference, 2018, Bangalore, India.
10. Training-Quality Management System Training: ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, 2018, UL India.
11. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, New Delhi, India.
12. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, Ahmedabad, India.
13. Course-Certificate of completion in "Train the Trainer" course, 2017, India
14. Conference Speaker-Strategy for biocompatibility evaluation of medical devices, 2nd Annual Medical Device Regulatory and Quality Summit, 2017, India
15. International training - "Overview about 10993 standards and requirements" to Saudi FDA (SFDA), 2017, Saudi Arabia.

16. International training - Implementation of Biocompatibility requirements based on ISO 10993, LG Chem - UL joint seminar, 2017, South Korea

PUBLICATION

B.Brabu, S.Haribabu, M.Revathy, S.Anitha, M.Thangapandiyan, K.R.Navanethakrishnan, C.Gopalakrishnan, S.S.Murugan, T.S.Kumaravel. Biocompatibility studies on lanthanum oxide nanoparticles. Toxicology Research. 2015; 15, 43-30.