Indian Institute of Technology Delhi

School of Interdisciplinary Research (SIRe)

SIRe Project Number
2024-02-28

Project Proposal for Ph.D.

Project Details	
Project Title	Pharmaceutical Regulations of Biomedical Textiles
Project Summary (Minimum 500 and maximum 2000 characters)	Biomedical textiles, an expanding field at the intersection of textiles and healthcare, have gained significant attention in recent years due to their multifaceted applications in wound care, drug delivery, tissue engineering, and medical implants. The regulatory frameworks, established by government agencies and international organizations, aim to ensure the safety, efficacy, and quality of biomedical textiles, ultimately safeguarding the well-being of patients and consumers. The regulatory landscape for biomedical textiles is complex, with key agencies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the International Organization for Standardization (ISO) playing pivotal roles. Compliance with these regulations is indispensable for manufacturers, researchers, and healthcare practitioners engaged in the development and utilization of biomedical textiles. One of the primary concerns addressed by pharmaceutical regulatory requirements is the biocompatibility of biomedical textiles. Biocompatibility assessments, by ISO 10993 and FDA guidelines are imperative to ensure that these materials do not cause adverse reactions when in contact with biological systems. Such assessments involve evaluating cytotoxicity, genotoxicity, and immunological responses, among other factors, to ascertain the safety of the textile materials. Furthermore, pharmaceutical regulations demand rigorous testing of drug-loaded biomedical textiles. These textiles serve as drug delivery systems for the controlled release of pharmaceuticals within the body. Compliance with regulations ensures that the release rates, dosage accuracy, and stability of incorporated drugs meet stringent criteria. This not only assures the therapeutic effectiveness of the textile but also prevents potential harm to patients. Manufacturers of biomedical textiles must adhere to stringent quality control standards, as stipulated by ISO 13485 and other relevant standards, to guarantee the consistency and reliability of their products. These standards encompass design controls, risk management, and traceability, crucial for the production of textiles that meet the highest standards of quality and safety. The regulatory requirements extend beyond product development to encompass the labeling and marketing of biomedical textiles. Accurate and transparent labeling is vital to provide healthcare practitioners and patients with essential information regarding the textile's intended use, care instructions, and potential risks. Misleading or inadequate labeling can have serious consequences, making compliance with these regulations paramount. Moreover, post-market surveillance and vigilance, as per regulatory mandates, necessitate the continuous monitoring of biomedical textiles once they are in use. This involves collecting and assessing data on adverse events and product performance to identify potential safety issues and take corrective actions promptly. It is an integral part of ensuring the ongoing safety and efficacy of biomedical textiles. Department of Textile Science and Fiber Engineering, IIT Delhi is working in the area of the development of biomedical textiles. I will amalgamate my pharmaceutical regulatory skills for the successful completion of the topic In conclusion, the pharmaceutical regulatory requirements for biomedical textiles are key to ensuring the safety, efficacy, and quality of these innovative materials. Compliance with these regulations is not only a legal obligation but also a moral imperative, as the lives and well-being of patients depend on it. Researchers, manufacturers, and healthcare practitioners must work in sync to navigate this sophisticated regulatory landscape and bring biomedical textiles to the forefront of modern healthcare, revolutionizing patient care and treatment outcomes. The continual evolution of these regulations will play a pivotal role in shaping the future of biomedical textiles and their impact on global healthcare.

Ph.D. Supervisors			
Role	**Name of Faculty**	**Academic Unit in IITD/Institute/University**	**Email ID (Official)**
Supervisor 1	Prof Bhupendra Singh Butola	Department of Textile and Fibre Engineering	bsbutola@textile.iitd.ac.in
Supervisor 2	Prof Tej Prakash Sinha	All India Institute of Medical Sciences AIIMS · Department of Emergency Medicine	drsinha123@gmail.com

Project requirements (Student qualifications, experience required, etc)
***The candidate will be shortlisted based on common shortlisting criteria decided by ScRC (SIRe)**

- M Pharma ("Pharmaceutics, Regulatory Affairs, Industrial Pharmacy, Pharma Chemistry, M Tech (Textile Engineering, Material Eng)
- Having at least 2 peer reviewed Scopus indexed article among which one must be in the field of regulatory affairs or Textile based/backing drug delivery systems

Source of fellowship/funding
(CSIR/UGC/DBT/ICMR/ICAR/NEET-PG/DST-INSPIRE/IRD/FITT Project details, if any)

Candidate with his/her own fellowship/ Institute Fellowship

Role of Faculty Members involved:	
Supervisor-1	Will guide the candidate about the various aspects of the textile technology and the different fiber-based materials commonly used for medical purposes
Supervisor-2	Will guide the candidate about the regulatory considerations of the Surgical and Implants