



**SHRI
DHARMASTHALA
MANJUNATHESHWARA
UNIVERSITY**

**Applications are invited from suitable candidates for the following Post(s) in
SDM Research Institute for Biomedical Sciences**

S. No.	Post	No. of Vacancies	Essential Qualification & Experience
1.	Regulatory Affairs Officer/Manager	01	<p>B.Sc/M.Sc/B.Pharma/M.Pharma/Ph.D in a relevant scientific subject or Post graduation in Clinical Research/Management & IPR Management would be an advantage.</p> <ul style="list-style-type: none">• Experience in a regulatory capacity within regenerative medicine-cell & cell products-based therapies, stem cells, cosmetic & medical device industry.• Must have experience of working regenerative medicine products.• Sound knowledge of International (harmonized) standards in particular: ICH-GCP, ISO 13485, ISO 14971, ISO14644-1/2 and related standard, SOPs, GMP, GLP, FDA, CTRI, DCGI, Drugs and Cosmetics Act, Schedule Y and ICMR-DBT norms.• Experience in compiling and preparing technical documents for submission and assessment by Regulatory bodies at national and international level.• Experience in preparing SOPs and technical documents related to clean room activities, regenerative medicine, clinical grade human cells/stem cells production and clinical trials.• Develop regulatory strategies to ensure effective registration of Cleanroom facility/eGMP certification, marketing of products, etc.• Lead re-certification/licensing processes for facility and products.• Assist in the building and maintenance of effective working relationships with internal functions to facilitate the implementation of effective Quality processes, agreed performance improvements and corrective actions.• Assist in the documentation and progressing of Quality related corrective actions raised by internal and external audits.• Assist QA/QC personnel in periodic preventive maintenance of clean rooms.• Strong organizational skills• Good communication skills (written & verbal)

Those interested may apply by sending their CV by e-mail to HR Department of the University.

E-mail: hrd@sdmuniversity.edu.in

Phone: 0836-2477028/2477027

Salary : Commensurating with qualification and experience

Last Date for receiving the Applications is **31/07/2020**

Short listed candidates will be called for the interview, notifying the dates.