

Saloni Gupta

Executive- Regulatory Affairs

Results-driven QA/RA professional with 2+ years of experience in regulatory compliance, quality systems, and audit management within the medical device industry. Proven ability to manage CAPA, deviations, and regulatory documentation while ensuring adherence to global standards such as GMP and ISO. Adept at driving continuous improvement and supporting successful regulatory inspections.

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BANGALORE, India

SKILLS

- Analytical Skills
- Time Management Skills
- Problem Solving Skills
- Presentation Skills
- Negotiation Skils

LANGUAGES

English
Full Professional Proficiency

Hindi
Native or Bilingual Proficiency

Kannada
Elementary Proficiency

INTERESTS

Learning about quality standards and compliance

Continuous learning through online courses

Regulatory Compliance

WORK EXPERIENCE

Executive- RA

Biorad Medisys Pvt Ltd

06/2023 - Present, *Bangaluru*

Achievements/Tasks

- Write, analyze, and edit technical documents to support country- specific regulatory submissions and compile submissions in a format consistent with applicable guidance documents, including investigational device submissions in USA, Canada and Europe. Work with other departments and communicate the submission requirements when documents are needed for regulatory submission. .
- Maintain regulatory files. Maintain and update regulatory authorizations, such as IDEs, 510(k)s, Canadian medical device licenses, and CE dossiers for EU,other certifications etc. Assure that appropriate maintenance of registrations occurs including renewals, device listings, site registrations, supplements for changes and annual reports. Support approval in other regions as required.
- Assist in preparing response to regulatory authorities questions within assigned timelines.
- Handled deviations, CAPA, and change control processes
- Assess device related incidents/complaints for medical device reporting requirements. Compile and submit reportable events to relevant regulatory authorities in timely manner. Handle recalls and field actions, if required
- Conducted internal audits and supported external regulatory audits
  Performed risk assessments and implemented corrective actions
  Monitored and improved quality management systems (QMS)

Document Officer

KUMAR ORGANIC PRODUCTS LIMITED, BENGALURU

07/2013 - 07/2017,

Achievements/Tasks

- Inoculum preparation.
- Seed development in Shake flask. Handling of Microbial fermentors 30L and 300L and.CIP .
- Handling of Microbial fermentors 30L and 300L and.CIP
- Upstream process development for broth. § Development and optimization of different feeding strategies in fementor to get high cell density and productivity.

Programme Devlopment Manager

Ambedkar Institute Of Higher Education, Patna *01/2011 - 03/2012,*

Achievements/Tasks

- Programme Development and Planning of different projects pertaining to professional and technical courses.
- Developing and maintaining a detailed project plan.
- · Managing co-ordination of the partners and working groups engaged in project work.

EDUCATION

Masters In Biotechnology

Bengaluru

05/2005 - 08/2007, *Bengaluru*