**Job Title:** Regulatory Affairs Associate
**Location:** IKP Knowledge Park, Bengaluru
**Reporting to:** Associate Vice President, Medtech Regulatory

## About IKP Knowledge Park

IKP Knowledge Park (IKP) is a leading science park and incubator dedicated to advancing cutting-edge R&D in India. We have a pioneering legacy of more than two decades of nucleating and nurturing life sciences and engineering innovation. We focus on sectors like biotech, health tech, and agri-tech, helping innovators move from the lab to the real world. By partnering with government, industry, non-profits, academia and investors, we create a supportive environment for startups and SMEs to thrive and grow. Our work is centred at our 200-acre park in Genome Valley Hyderabad and our Bengaluru maker space (IKP EDEN at Koramangala, Bengaluru), reaching across India and the world through various innovation programs and services. We are at the cusp of next phase of growth which is founded in our belief that science and technology are key to shaping a better tomorrow through deep & expansive societal impact. More at <https://ikpknowledgepark.com/>

## The Role

IKP COMPASS supports medical device, IVD, diagnostics, and healthtech companies in building quality systems and achieving audit-ready certification and regulatory approval. Our engagements span product safety evaluations, quality certifications (ISO 13485, ISO 9001, ISO 45001), and regulatory submissions to CDSCO (India), EU Notified Bodies, and the US FDA, with hands-on support through implementation, internal audits, and certification or regulatory audits.

As a Regulatory Affairs Associate, you will manage the regulatory workstream across multiple client engagements simultaneously, guiding medtech, IVD, and software-driven healthtech startups through CDSCO licensing, EU MDR CE marking, and US FDA 510(k) submissions. You will convert complex regulatory requirements into clear submission roadmaps, prepare and coordinate regulatory dossiers, follow up on technical documentation and evidence, and work closely with founding teams throughout the submission and regulatory review process. This is a client-facing, multi-project role requiring strong execution, stakeholder coordination, and the ability to manage multiple regulatory timelines concurrently.

## Key Responsibilities

1. **CDSCO Licensing (India)**
    - Classify devices under India's Medical Device Rules (MDR) 2017 (Class A/B/C/D) and determine the applicable licensing pathway.
    - Compile and submit manufacturing and import licence applications and device registration dossiers to CDSCO.
    - Draft and review Device Master Files, technical files, and labelling for compliance with Indian requirements.
    - Respond to CDSCO queries and represent client interests through to licence approval.

2. **EU CE Marking:**
   - Support conformity-assessment strategy under EU MDR and help select the appropriate Notified Body route.
   - Compile technical documentation per MDR Annex II/III — device description, risk management file, clinical evaluation, usability engineering file, and biocompatibility evidence, among others.
   - Coordinate with Notified Bodies on submission review, queries, and audit scheduling.

3. **US FDA 510(k):**
   - Support predicate device identification and substantial-equivalence analysis.
   - Help compile 510(k) submission packages, aligning test evidence to FDA-recognized consensus standards.
   - Track and respond to FDA Additional Information (AI) requests.

4. **Risk Management, Usability & Software Lifecycle:**
   - Own or review risk management files per ISO 14971 — hazard identification, risk analysis/evaluation, and residual risk sign-off — as evidence for every submission.
   - Support usability engineering activities per IEC 62366-1, including use-related risk analysis, formative evaluation planning, and summative usability study documentation.
   - Review software development and maintenance documentation for software-containing devices per IEC 62304 (software safety classification, architecture, verification records) where applicable.
   - Coordinate with COMPASS's Product and Process pillars so regulatory strategy, test planning, and QMS documentation stay aligned from day one of an engagement.

5. **Client & Programme Management:**
   - Own the regulatory timeline across several concurrent client engagements — dossiers, authority correspondence, and internal milestones.
   - Advise founding teams in plain language on regulatory strategy, device classification, and market-entry sequencing (typically India first, then EU/US).
   - Track evolving CDSCO, MDR, and FDA guidance, and flag implications proactively to clients and the COMPASS team.

**Qualifications & Experience:**

- Bachelor's or Master's degree in Biomedical Engineering, Pharmacy, Life Sciences, Medical Devices, or a related field.
- 4 - 6 years of hands-on regulatory affairs experience in medical devices or IVDs specifically (not general pharma), ideally spanning CDSCO and at least one of EU MDR/CE or US FDA.
- Demonstrated experience independently compiling and submitting a CDSCO licence application or device registration.
- Working knowledge of ISO 13485 QMS documentation and hands-on experience with ISO 14971 risk management files as they support regulatory submissions.
- Comfort reading and applying regulatory text directly — India MDR 2017, EU MDR 2017/745, 21 CFR 807.

**Preferred / Good to Have:**

- Hands-on experience with Software as a Medical Device (SaMD) or Software in a Medical Device (SiMD) submissions, including software safety classification under IEC 62304.
- Experience preparing or reviewing usability engineering files under IEC 62366-1, including summative usability studies.
- Prior experience in a consulting, incubator, or multi-client advisory setting, rather than a single-company in-house regulatory role.
- Familiarity with electrical/medical equipment standards (IEC 60601, IEC 61010) sufficient to interpret test reports.
- RAC (Regulatory Affairs Certification) or an equivalent credential.
- Direct experience liaising with CDSCO officials or EU Notified Body reviewers.

**Skills & Competencies:**

- Strong technical writing — able to produce dossier-ready documentation, not just review it.
- Comfortable with ambiguity: many client startups have no existing documentation, so this role frequently builds from a blank page.
- Stakeholder management across founders, testing labs, Notified Bodies, and CDSCO.
- Organized under multiple concurrent deadlines across different clients and product types.
- Based in Bengaluru, with willingness to travel occasionally to client sites and IKP's Hyderabad campus.

**What IKP Knowledge Park Offers:**

- A front-row seat across India's medtech ecosystem — engagements span diagnostics, connected devices, surgical tools, SaMD/SiMD products, and lab equipment startups, not a single product line.
- Direct mentorship from IKP Knowledge Park's regulatory, quality, and manufacturing leadership.
- Ownership of the regulatory pillar on client engagements from day one.
- CTC of ₹12–14 LPA, commensurate with experience.

**To apply:**

Send your resume, along with a short note on your CDSCO / EU MDR / US FDA submission experience, to raghavendrap@ikpknowledgepark.com by mentioning subject line as CV for Regulatory Affairs Associate