

DOC	JD-HMT-A02
TYPE	Internship position description
TRACK	Healthcare & MedTech
LEVEL	Student / early career

Regulatory Affairs Intern, FDA and EU Submission Support

Regulatory pathway research, predicate and comparison analysis, submission document assembly, and labeling review support for FDA and European filings

KEY TO TERMS USED

510(k)	The most common FDA route: showing a device is equivalent to one already cleared.
EUA	Emergency use authorization. A temporary FDA route used during a declared emergency.
PREDICATE	The already-cleared device that a new one is compared against.
INTENDED USE	The exact wording of what a product is for. It drives testing, labeling, and claims.
IVDR	The European regulation governing in vitro diagnostic devices.
SUBMISSION	The assembled package of evidence filed with a health authority.

INTENDED ROLE

Every device and diagnostic has to answer one question before it can be sold: which regulatory pathway does it take, and what evidence does that pathway demand? This role supports that work. You will research published guidance and public submission databases, build structured comparisons, and help assemble the sections of a submission package. The emphasis is on careful reading and honest sourcing, not on knowing regulation by heart before you start.

PRINCIPAL DUTIES

- Research publicly available FDA guidance, regulations, and European requirements relevant to a given product type.
- Search public databases for cleared comparison products and summarize their intended use, technology, and testing.
- Build structured comparison tables that show how a product aligns with or differs from prior cleared devices.
- Help assemble and format submission sections, checklists, and indexes against the applicable requirement list.
- Review labeling, instructions for use, and promotional claims against the stated intended use, and flag any unsupported claim.
- Maintain a sourced research log so that every regulatory statement in a working document can be traced to its origin.
- Use approved AI tools to speed up reading and drafting, then verify every citation and requirement against the original source text.

EXAMPLE ASSIGNMENTS

Assignments depend on active studies, authorized data access, and the internship timeline. Examples may include:

- A regulatory pathway assessment for a device or diagnostic, with the requirement list each pathway would trigger
- A comparison analysis of cleared products with a structured table of intended use, technology, and testing
- A submission readiness checklist mapping each required section to its current status and owner

YOUR FIRST TWO WEEKS

- Read the applicable guidance for one product type and list every requirement it triggers.
- Search the public clearance database and shortlist candidate comparison devices.
- Draft the comparison table and fill it for the first two devices.
- Start the sourced research log, with a citation for every statement you record.

ABOUT HOPKINS MEDTECH

Hopkins MedTech Group LLC is a U.S. company working in medical technology and in vitro diagnostics. Its work covers clinical performance studies, protocol development and site coordination, data review and quality assurance, and regulatory support for United States and European pathways. The group is also exploring AI and digital health through an early-stage research initiative in facial and skin analysis.

REQUIRED QUALIFICATIONS

- Currently pursuing, or recently completed, a degree in regulatory science, life sciences, biomedical engineering, public health, law, or a related field, or able to show equivalent self-study or project work.
- Strong reading stamina for dense technical and legal text, and the ability to restate it accurately in plain language.
- Rigorous sourcing habits, including the instinct to cite the original document rather than a secondary summary.
- Clear written English and comfort building structured tables, checklists, and document indexes.
- Willingness to say what the source actually supports, including when the answer is that the evidence is not there.
- No prior regulatory affairs, consulting, or professional internship experience is required.

PREFERRED QUALIFICATIONS

Not screening criteria. Coursework, labs, personal projects, and self-study all count as evidence.

- Coursework or self-study in regulatory affairs, quality systems, health policy, or medical device development
- Familiarity with terms such as intended use, predicate device, clearance, or conformity assessment
- Any research project that required tracking and citing a large number of primary sources

WHAT YOU WILL GAIN

- Learn how regulatory pathways are actually chosen and what evidence each one demands.
- Practice reading primary regulatory sources and turning them into requirement lists a team can work from.
- Understand why intended use wording drives testing, labeling, and marketing claims downstream.
- Leave with a sourced regulatory research portfolio that demonstrates precision under scrutiny.

DATA HANDLING, PRIVACY, AND RESPONSIBLE AI

Interns work only with data and documents they have been explicitly authorized to access. Patient-identifiable information, study data, client-confidential files, and proprietary materials must never be uploaded to public or unapproved AI services, shared outside the project team, or stored on personal accounts or devices. AI tools may be used only

DELIVERABLES

- A pathway assessment memo with the applicable requirements and their sources
- A comparison table of cleared products with full citations
- A submission readiness checklist with an open items list for the project lead

SUPERVISION AND EVALUATION

Interns report to a named project lead, meet on a set weekly cadence, and receive written feedback on each deliverable. Work is evaluated on accuracy and traceability of sources, documentation quality, responsiveness to feedback, judgment about what to escalate, and disciplined use of approved AI tools. We expect steady learning and iteration rather than polished perfection on the first day.

WHAT WE DO NOT EXPECT

- Prior internship experience, or a name-brand employer on your CV.
- Knowing the regulations, tools, or vocabulary before you start; the terms box above is where most people begin.
- Certainty. Saying what the evidence does not support is treated as a strength, not a gap.

APPLICATION AND SELECTION

An application is a CV plus a short note naming the track you want and one project from this document you would like to work on, and why. First-round interviews are with the project lead who would supervise the work, not with a screening panel.

where the project lead has approved them for that task, and all AI-assisted work must be independently verified before it enters any deliverable. The intern and the project lead remain accountable for the final result.

Hopkins MedTech Group LLC provides equal internship and employment opportunities without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, veteran status, or any other legally protected characteristic. Internships are educational in nature; interns do not provide medical advice, make regulatory determinations, or represent the company to any health authority, client, or study site. The AI and digital health initiative described here is early-stage research, not a cleared, approved, or clinically validated product. Assignments, data access, duration, and supervision are confirmed in the final project description.