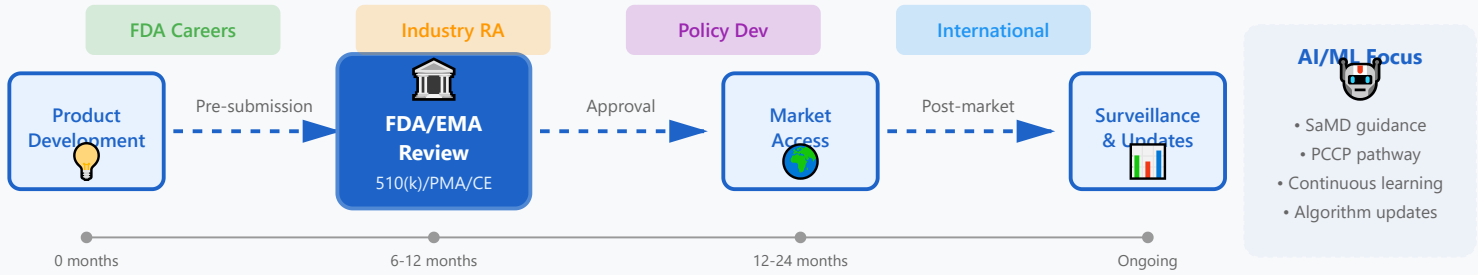
Regulatory Affairs Pathways



FDA/Government Roles

- Medical device reviewer (CDRH)
- Digital health specialist
- Policy development analyst
- AI/ML guidance development

Industry Regulatory

- Regulatory affairs manager
- Submission strategy lead
- 510(k) and PMA specialist
- Quality & compliance director

Policy Development

- AI/ML medical device guidance
- International harmonization
- Standards development (ISO, IEC)

Global Opportunities

- EMA, PMDA, Health Canada roles
- Global regulatory strategy
- Market access planning

🎓 **Required Expertise:** RAC certification • Clinical + technical knowledge • Regulatory pathway mastery • GxP understanding

🏛️ FDA/Government Regulatory Roles

FDA & Government Positions

Public Service in Medical Device Regulation

📝 Medical Device Reviewer (CDRH)

Review and evaluate medical device submissions for safety and effectiveness. Work directly with manufacturers to ensure regulatory compliance.

- → Evaluate 510(k), PMA, and De Novo submissions
- → Assess clinical data and technical documentation
- → Conduct benefit-risk analysis
- → Provide regulatory feedback to sponsors

💻 Digital Health Specialist

Focus on software as a medical device (SaMD), AI/ML algorithms, and digital therapeutics regulation.

- → Review AI/ML-based medical devices
- → Evaluate software validation and verification
- → Assess cybersecurity and data privacy
- → Guide digital health policy development

🔬 Policy Development Analyst

Shape regulatory frameworks and guidance documents that define how medical devices are evaluated.

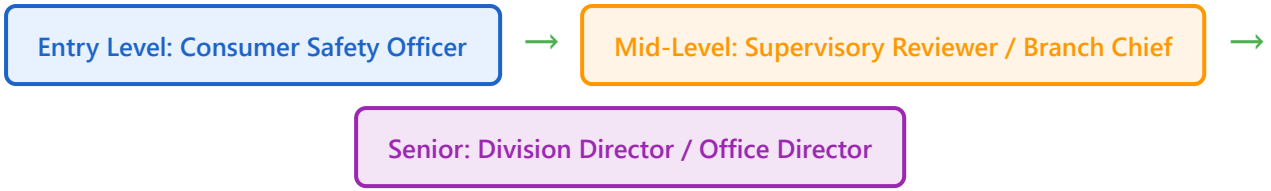
- → Draft guidance documents
- → Conduct regulatory science research
- → Analyze emerging technologies
- → Coordinate with international agencies

🤖 AI/ML Guidance Development

Pioneer new regulatory approaches for continuously learning and adaptive AI systems.

- → Develop PCCP framework implementation
- → Create AI validation standards
- → Establish real-world performance monitoring
- → Design algorithm change protocols

📊 Career Progression Path



💰 **Salary Range:** $70,000 - $180,000+ (GS-11 to GS-15/SES level)

💡 **Real-World Example**

As an FDA reviewer, you might evaluate an AI-powered diabetic retinopathy screening device. Your role involves assessing the algorithm's performance across diverse patient populations, reviewing validation studies, evaluating the predetermined change control plan (PCCP) for algorithm updates, and ensuring the device meets safety and effectiveness standards before market authorization.

Industry Regulatory Affairs

Corporate Regulatory Positions

Bringing Medical Devices to Market

Regulatory Affairs Manager

Lead regulatory strategy and manage the submission process for medical device approvals.

- → Develop comprehensive regulatory strategies
- → Manage cross-functional regulatory teams
- → Interface with FDA and notified bodies
- → Oversee product labeling and instructions

Submission Strategy Lead

Design optimal regulatory pathways to achieve fastest, most efficient market clearance.

- → Determine appropriate submission type
- → Conduct regulatory gap analyses
- → Develop clinical trial strategies
- → Create submission timelines and budgets

510(k) and PMA Specialist

Expert in preparing and submitting FDA regulatory applications for medical devices.

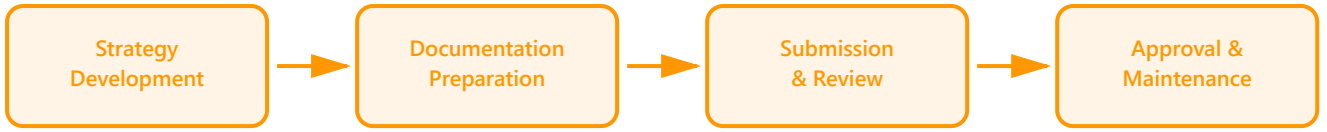
- → Prepare 510(k) substantial equivalence reports
- → Compile PMA modules and clinical data
- → Respond to FDA deficiency letters
- → Manage predicate device searches

Quality & Compliance Director

Ensure ongoing regulatory compliance and quality system maintenance throughout product lifecycle.

- → Implement QSR/ISO 13485 systems
- → Manage post-market surveillance
- → Oversee CAPA and complaint handling
- → Prepare for regulatory inspections

Typical Project Flow



💰 **Salary Range:** $85,000 - $200,000+ (varies by company size and experience)

21 CFR Part 820 | ISO 13485 | Clinical Evidence | Risk Management | GxP Systems | FDA Interactions

💡 **Real-World Example**

At a medical device startup developing an AI-powered ECG monitor, you'd lead the regulatory strategy. This includes determining whether to pursue 510(k) clearance or De Novo classification, identifying predicate devices, designing clinical validation studies, preparing the submission package with algorithm performance data, and managing FDA Q-submissions and pre-submission meetings to optimize the pathway to market.

Policy Development & Standards

Regulatory Policy & Standards

Shaping the Future of Medical Device Regulation

AI/ML Medical Device Guidance

Develop frameworks and guidance documents for regulating artificial intelligence and machine learning medical devices.

- → Create predetermined change control plans
- → Define algorithm validation requirements
- → Establish performance monitoring standards
- → Address bias and fairness considerations

International Harmonization

Work on global alignment of medical device regulations through international working groups.

- → Participate in IMDRF working groups
- → Align FDA, EMA, and PMDA requirements
- → Develop mutual recognition agreements
- → Create global regulatory pathways

Standards Development (ISO, IEC)

Contribute to international standards that form the technical foundation of regulatory requirements.

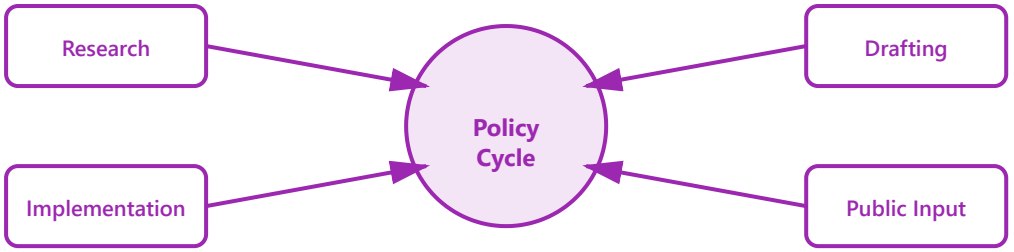
- → Draft ISO 13485 quality standards
- → Develop IEC 62304 software standards
- → Create AI/ML specific standards
- → Lead technical committee work

Regulatory Science Research

Conduct research to inform evidence-based regulatory policy decisions.

- → Evaluate new technologies
- → Assess clinical trial methodologies
- → Study real-world evidence approaches
- → Analyze regulatory effectiveness

Policy Development Cycle



💰 **Salary Range:** $80,000 - $160,000+ (academic, government, or industry think tanks)

💡 Real-World Example: AI/ML Guidance Development

You might lead development of FDA guidance on "Continuous Learning AI Systems in Medical Devices." This involves researching current AI technologies, consulting with industry stakeholders, analyzing real-world implementation challenges, drafting technical recommendations for validation approaches, coordinating public comment periods, and finalizing guidance that will shape how AI medical devices are regulated for the next decade.

🎯 Key Organizations

- FDA/CDRH
- ISO TC 210
- IEC SC 62A
- IMDRF
- AAMI
- ANSI

Global Regulatory Opportunities

International Regulatory Careers

Navigating Multi-Regional Medical Device Markets

EU European Medicines Agency (EMA)

Work with European regulatory authorities on medical device regulation under MDR/IVDR frameworks.

- → Evaluate CE marking applications
- → Support notified body assessments
- → Implement Medical Device Regulation
- → Coordinate EUDAMED database

JP PMDA (Japan)

Navigate Japanese pharmaceutical and medical device regulatory requirements.

- → Manage Shonin approval processes
- → Work with SAKIGAKE designation
- → Handle JPAL/J-GCP compliance
- → Interface with MHLW regulations

CA Health Canada

Canadian medical device licensing and regulatory compliance.

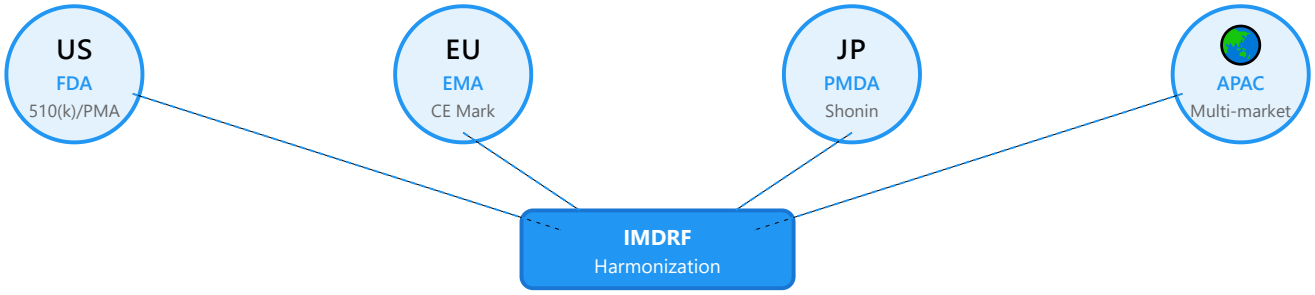
- → Prepare MDEL applications
- → Navigate Class II-IV pathways
- → Manage CMDCAS certifications
- → Coordinate with provincial regulations

Asia-Pacific Markets

Expand into emerging regulatory markets across Asia-Pacific region.

- → NMPA (China) registrations
- → TGA (Australia) compliance
- → KFDA (South Korea) approvals
- → HSA (Singapore) submissions

Global Regulatory Landscape



🎯 Global Regulatory Strategy

Coordinate multi-regional submissions for simultaneous market access:

- → Develop parallel submission strategies
- → Manage CTD/eCTD formats
- → Coordinate clinical trial requirements
- → Optimize approval timelines

📊 Market Access Planning

Strategic planning for global product launches:

- → Conduct regulatory landscape analysis
- → Prioritize market entry sequence
- → Manage reimbursement strategies
- → Navigate pricing regulations

💰 **Salary Range:** $90,000 - $220,000+ (varies significantly by region and company)

💡 **Real-World Example: Global Launch Strategy**

Leading regulatory strategy for an AI-powered diagnostic imaging device across three major markets. You'd coordinate FDA 510(k) submission in the US, CE marking under EU MDR with a notified body, and PMDA Shonin approval in Japan. This requires understanding different clinical evidence requirements, managing multiple languages and formats, coordinating with local regulatory consultants, and ensuring the device meets varying technical standards while maintaining a unified global product design.

MDR/IVDR

IMDRF GHTF

ICH Guidelines

Multi-lingual

eCTD/CTD

Cultural Competency