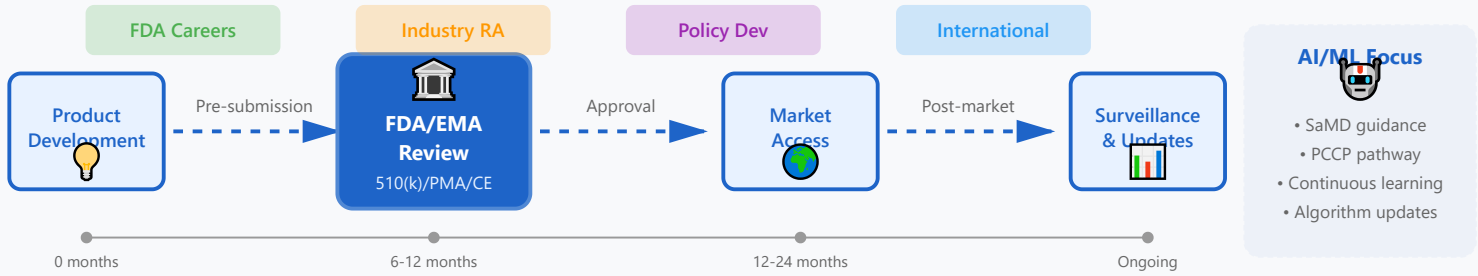
Regulatory Affairs Pathways



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

Global Opportunities

- EMA, PMDA, Health Canada roles

- International harmonization
- Standards development (ISO, IEC)

- Global regulatory strategy
- Market access planning

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