DANFORTH HEALTH regulatory

Commercial Regulatory Services

Where regulatory strategy meets commercial execution to drive compliant growth and sustained product success

What We Do

From launch through lifecycle management, life science companies must navigate complex and evolving regulatory requirements while enabling impactful, compliant communication.

Advyzom's Commercial Regulatory team bridges regulatory, commercial, and medical functions — ensuring that promotional activities and marketed products meet regulatory expectations while supporting business growth and patient access.

Who We Serve

We support emerging to mid-sized life science companies preparing for launch, scaling commercialization, or managing marketed products in a dynamic regulatory environment.

We act as an extension of our clients' commercial and medical teams — providing the insight, responsiveness, and trust needed to successfully launch and sustain products in the US market.

Our Capabilities

Advertising & Promotion (Ad/Promo)

Promotional Review & FDA Submission

- Review US promotional and educational materials for compliance with FDA regulations, PhRMA Code, and client SOPs
- Ensure claims are accurate, substantiated, and balanced with risk
- Participate in PRC/MLR review committees
- Manage FDA submissions (e.g., Form 2253)

Regulatory Strategy for Commercialization

- Advise brand teams early to shape compliant messaging
- Translate labeling into compelling, compliant claims
- Align promotional and market access claims with TPP and development strategy

Labeling Alignment and Global Consistency

- Ensure all materials align with approved labeling (PI, IFU, device labeling)
- Partner with global teams for cross-market consistency

Scientific Exchange and Pre-Launch Readiness

- Guide compliant scientific exchange and pre-launch communications
- Establish guardrails with legal/compliance to mitigate pre-approval risk
- Support MLR review and SOP development

SOPs and Training

- Develop SOPs for PRC/MLR and scientific exchange
- Deliver targeted compliance training

Marketed Products

Lifecycle Regulatory Strategy & Execution

- Advise on post-approval changes, indication expansions, and issue resolution
- Lead lifecycle planning and execution (supplements, labeling updates, line extensions)
- Maintain global product registrations (NDAs, BLAs, MAAs)

Post-Marketing & Phase IV

- Support PMRs/PMCs and Phase IV requirements
- Partner cross-functionally to ensure timely execution

Labeling & Safety

- Lead labeling strategy and updates (USPI, SmPC, CCDS)
- Ensure alignment with current safety and efficacy data
- Support pharmacovigilance and safety reporting

Compliance & Risk Oversight

- Collaborate across PV, quality, medical, and commercial teams
- Support REMS and critical issue management

For additional information visit www.advyzom.com.

ADVYZOM™ A Danforth Health Company