celegence

Combination Product Regulatory Services

For Drug-Led and Device-Led Products

We specialize in

Regulatory Strategy & Classification
Determining correct PMOA and most efficient approval pathway

Global Market Access
Supporting multi-region submissions(FDA, EMA, PMDA, NMPA)

GMP & QMS Integration
Aligning pharmaceutical GMPs and device QSR/MDR compliance

Clinical & Post-Market Compliance
Ensuring regulatory adherence from development through post-market surveillance

Get in touch to find out more

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With strong Pharmaceutical and Medical Device teams, Celegence delivers integrated regulatory support for both drug-led and device-led combination products — **from strategy to submission and beyond.**

Combination products integrate drug, device, and/or biological components, and are regulated by both pharmaceutical and medical device authorities, with distinct pathways based on primary mode of action (PMOA):

1. Drug-led: governed under NDA/BLA (FDA) or EMA Medicinal Product Regulation, with device aspects assessed for compliance
2. Device-led: requires PMA, 510(k), or MDR 2017/745 approval, with drug-related considerations reviewed separately
3. Global considerations: varied regional pathways (PMDA in Japan, NMPA in China), necessitating strategic alignment

Key Combination Product Services:

- Regulatory strategy development
- Regulatory submissions preparation
- Medical writing
- Regulatory compliance
- Regulatory intelligence
- Training & education
- Classification & risk assessment
- Quality & compliance assurance
- Post-market surveillance