



- **Clinical and Commercial Regulatory Services**
- **Regulatory Strategy**
- **Regulatory CMC**
- **EU Affiliate / Brexit Services**

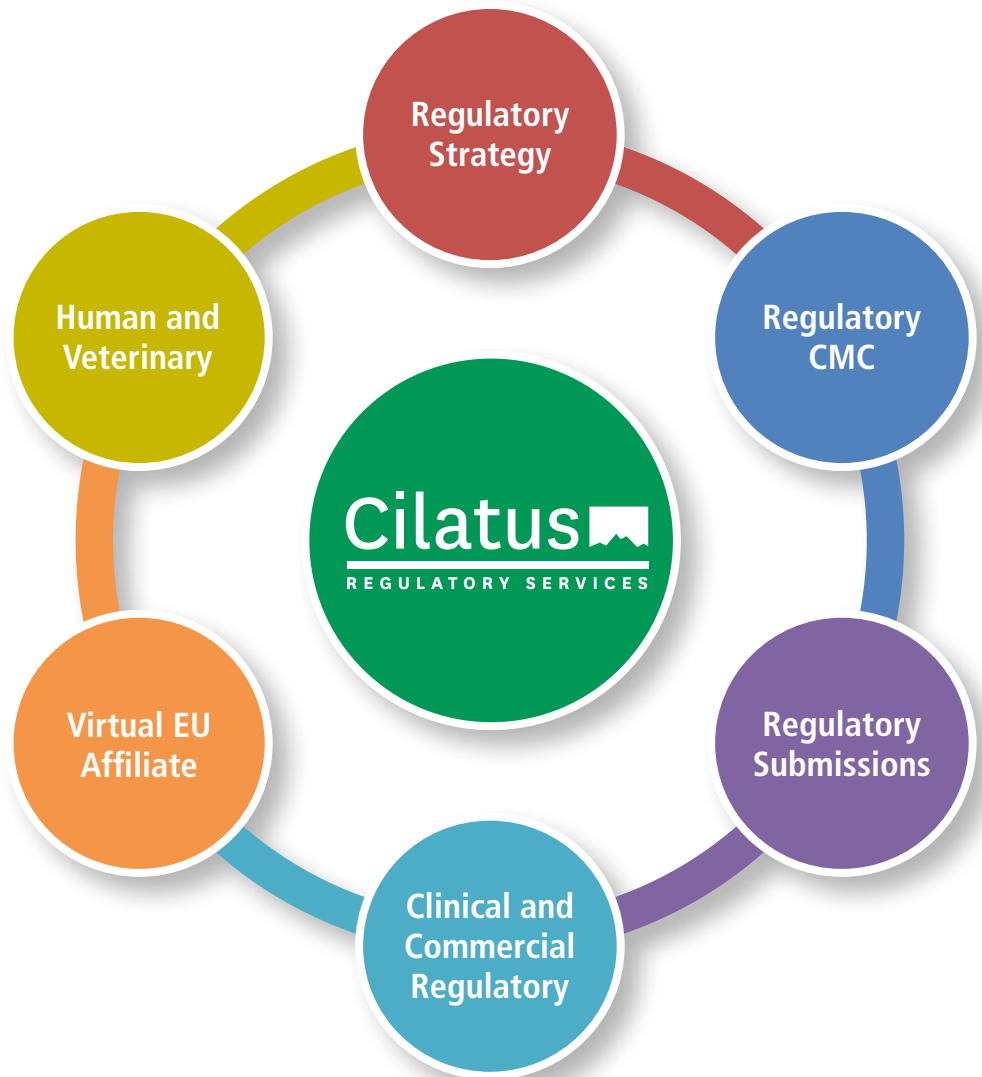
OUR BUSINESS

CILATUS

REGULATORY SERVICES

- **Regulatory Strategy:** Our expert team provides tailored global regulatory strategies for all product types at all stages of development. Licensing and lifecycle strategies, strategies for navigating regulatory pathways, scientific advice and agency engagement strategies.
- **Regulatory CMC:** Our consultants have extensive experience in CMC regulatory affairs for both large and small molecules at all stages of development. We can assist with CMC strategy development and implementation, critical reviews and authoring, QbD programs, gap analysis and remediation, tech transfer and comparability strategies.
- **Regulatory Affairs:** Our services cover clinical trial, marketing authorisation and lifecycle management for registered products. We can assist with authoring, preparing and filing of regulatory submissions, advise on EU and global regulatory requirements, management of EU, US and global registration procedures.
- **EU Affiliate & Brexit:** We provide tailored solutions to manage your Regulatory activities in the European Union (EU). We can act as a virtual EU affiliate for companies with no EU base/Regulatory office or for UK based companies dealing with Brexit. We manage regulatory filings on your behalf.

TAILORED REGULATORY SOLUTIONS AND SUPPORT





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