# RegOrbis

Navigating Regulation and Delivering Trust.

## About Us

RegOrbis is a global regulatory consulting partner delivering end-to-end Regulatory Affairs and Compliance solutions for the life sciences industry. We support pharmaceutical, API, cosmetics, nutraceutical, food supplements and healthcare companies in navigating complex regulatory environments and achieving efficient, compliant product approvals across global markets.

## Our Value Proposition

- Faster approvals with minimal deficiencies
- Global expertise with region-specific compliance
- End-to-end lifecycle support
- Flexible and cost-effective engagement models
- Client-centric, reliable delivery

## Our Core Services

- Regulatory Strategy & Planning
- Global Product Registration
- Dossier Authoring (CTD, ACTD, eCTD)
- Module 1 and Legal support
- CMC Documentation
- Regulatory Medical Writing
- Gap Analysis & Compliance Review
- Lifecycle Management
- DMF / CEP Support
- Labeling & Artwork Compliance
- Regulatory Information Management (RIM)
- Regulatory Intelligence & Advisory

## Industries We Serve

• Pharmaceutical Formulations

• Active Pharmaceutical Ingredients (APIs)

• Veterinary Products

• Herbal & Nutraceuticals

• Food Supplements

• Clinical Research Organizations (CROs)

## Global Expertise

We support clients across key global regions including Europe, North America, ASEAN, Middle East, Africa, LATAM, and Australia & New Zealand, ensuring compliance with major regulatory authorities such as US FDA, EMA, MHRA, TGA, Medsafe and more.

## Partner With Us

Whether you are planning product registration, expanding into new markets, or managing lifecycle activities, RegOrbis is your trusted partner.

## Contact Us

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