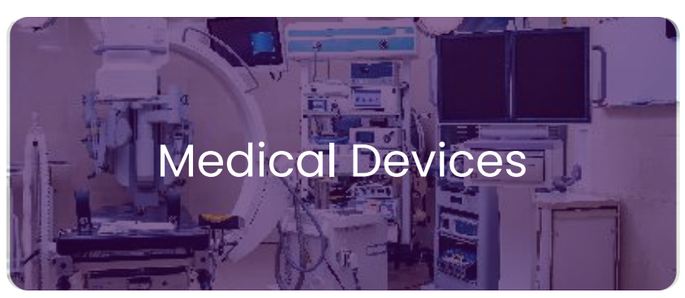
AMARANT
LIFESCIENCES

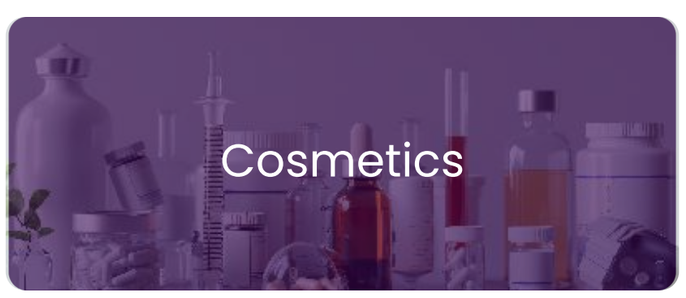
SYNERGIZING
PEOPLE. SYSTEMS.
IDEAS.

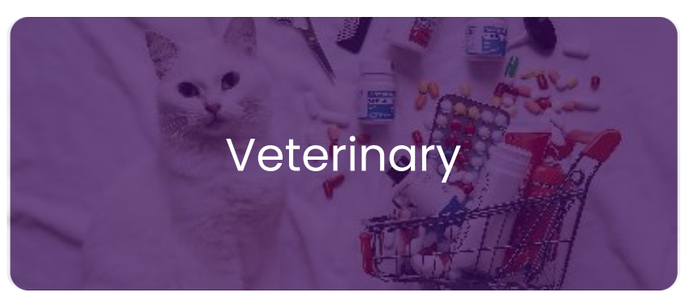
About Us

Amarant Lifesciences is a consulting organization established in 2012, specializing in the life sciences sector. With a commitment to quality and innovation, Amarant Lifesciences has achieved ISO 9001:2015 certification and successfully faced Health Authority inspections. Backed by a team of seasoned experts, Amarant Lifesciences provides specialized support in Regulatory Affairs, GMP Compliance, Pharmacovigilance, and Technology Transfer, along with expertise across several other domains. These experts possess extensive scientific knowledge on regulatory environments across India, US-FDA, EU, UK, Japan, other stringent regulatory authorities (SRAs) and emerging markets.

Industries at a Glance







Our Strategic Advantages

- Innovation-Driven Approach
- Strong Industry Experience
- Proven Expertise
- Effortless Transition Process
- Personalized Assistance

Our Services

Regulatory Intelligence

Regulatory Affairs

Quality Management

Pharmacovigilance

Technical Services

Scientific Affairs

Strategic Services

Amarant Learning

Regulatory Intelligence

- Regulatory Updates/Newsletters/Alerts
- Impact Assessment
- Regulatory Summaries
- Pharmacovigilance Requirements
- Good Manufacturing Practices/QMS updates
- Guidance Documents & Application Forms
- Ethics Committee Requirements
- Imports/Exports
- New Geographies/Dosage Forms/Novel Technologies
- Market Opportunity Analysis
- Lifecycle Management
- Labelling and Artwork Management

Regulatory Affairs

- End-to-end Regulatory Support
- Regulatory strategy & Consultation
- New MAAs, IMPDs, INDs, NDAs, ANDAs, 505(b)(2), DMFs, and CEP applications
- Registration of Dossiers in different Geographies
- Marketing Authorization Holder services for Europe/ other Regions
- US Agent Services
- QP and Batch Release Arrangements
- Dossier Publishing - eCTD/other formats
- SPL & Drug Listing
- Product Leaflet Readability Testing
- Authority Interaction/Agent Representation
- Regulatory Query Responses
- Product Life Cycle Management
- Labelling and Artwork Management
- Dossier Gap Analysis
- Risk Assessments
- Collaborations with various Stakeholders

Quality Management

- GxP and Compliances
- Gap Analysis & Remediation
- Data Integrity Audits
- Due-Diligence Audits
- Vendor Compliance
- EU-QP Audits
- Product Specific Audits
- Support Site inspections by Regulators
- Vendor Audits & Management Services
- Facility Audits - API, Finished Products, Packaging Materials, Medical Devices, Nutraceuticals, Ayurvedic Products
- Project Management

Pharmacovigilance

- ICSR Management
- Aggregate Reports
- PV System Set-up
- Literature Surveillance Cases
- Clinical Trial Cases
- Regulatory Communication
- QPPV/ Local Agent Service
- PV Audit & Gap Analysis
- Signal Management
- Safety Variations
- PV Database
- Medical Information
- Contractual Agreements
- Data Migration
- Project Management
- Training

Technical Services

- Research & Development
- Product Development
- Analytical Services
- Dossier in-licensing/out-licensing
- Clinical/BE Study Monitoring
- Contractual Agreements
- Facility Designs/Upgradation
- Contract Manufacturing Services/ Technology Transfer
- Project Management

Scientific Affairs

- Toxicology and Risk Assessments
- Clinical Affairs
- Medical Writing
- Clinical and Non-Clinical Overviews/ Summaries
- Study Designs & CRO selection

Strategic Services

- Intellectual Property Rights
- Portfolio Assessment
- Strategic Submission Planning
- Clinical and Non-Clinical Study Strategy
- Quality Strategy & GxP Requirements
- Regulatory Intelligence & Regulatory Strategy
- Premarket Approval (PMA)
- Marketing Authorization Applications
- CMOs & CROs for Various Dosage Forms
- Due Diligence

Amarant Learning

- Product Development, Analytical, Regulatory, GMP, Quality Assurance, Material Sourcing, Supply Chain, and other Technical Trainings at R&D and manufacturing facilities
- Pharmacovigilance and Scientific Affairs
- Technical and Soft Skills
- Application Based Training
- Customized Training Programs

Global Clients

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