

Cisema

Enabling Compliance in China

Regulatory Affairs | Quality Assurance | Clinical Research
Product Testing & Safety Certification Services

Cosmetics Services



Domestic Responsible Agent

We act as your local authorized representative in China. Our fully qualified and experienced Cosmetics Quality & Safety Managers are responsible with you for the quality of your cosmetics in China:

- » Application and management of your NMPA Online Account
- » Communication between you, Beijing MPA & NMPA
- » Monitoring and updates on cosmetics regulations
- » Coordination of import and maintenance of sales record in China
- » Mandatory product sample retention
- » Annual reporting (creation & submission)
- » Support adverse reaction monitoring and product recalls
- » Cooperate with regulatory authorities for market supervision and inspection activities.

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Filings & Registrations

We assist you in preparing and submitting filings and registrations to the NMPA for cosmetics and cosmetic ingredients:

- » General Cosmetics & Ingredients Filing
- » Special Cosmetics & Ingredients Registration
- » Provide document checklist and templates
- » Import of samples and transport within China
- » Coordinate and supervise tests in experienced local laboratories
- » Support for animal testing exemption
- » Preparation of Product Safety Assessment Report
- » Chinese label drafting
- » Receipt and reply to supplementary notice.

Testing Services

For ingredients and end-product cosmetics in certified local laboratories in China:

- » Microbiological test
- » Physical and chemical test
- » Toxicology test (such as skin irritation, eye irritation, etc.)
- » Human safety inspection (such as skin patch test, human trial test)
- » Efficacy evaluation test.

Cosmetic Ingredient Code

For ingredients that are already listed on the IECIC (Inventory of Existing Cosmetics Ingredients in China)

- » Single ingredient and formula check
- » Provide document checklist and templates
- » Technical Specification and Material Safety Data Sheet review and evaluation
- » NMPA account and application dossier preparation and submission.

Advantages of the CIC

- » Ingredients manufacturers can avoid having to pass on intellectual property & safety data to cosmetic product manufacturers.
- » Facilitates submission of cosmetic product filings and registrations by cosmetics manufacturers by avoiding having to collate and submit substantial safety data.



Quality Compliance

We help you to achieve compliance with Chinese requirements and to prepare and assist you for official NMPA inspections:

- » Review and assess your current GMP - QMS - SOPs
- » Gap analysis of your existing documentation vs. Chinese requirements
- » Assistance to close the gaps
- » Integration of all Chinese requirements into your current running GMP - QMS - SOPs
- » Drafting of separate SOPs to cover Chinese requirements
- » Pre-audits to verify the implementation of GMP - QMS - SOPs to Chinese requirements
- » Official NMPA Inspection assistance.



Why choose *Cisema*

- » In-house team of local, on-the-ground regulatory affairs, quality compliance & clinical research experts in our China offices
- » 20+ years experience
- » Added value by advising you on the best pathways and accelerating your time to market in a cost-efficient, planned, strategic way
- » Ensure you maintain control of your product registrations and retain unconstrained choice of distributor(s)
- » Provide full-cost quotation from the beginning of the project, giving price transparency and clarity for budgeting and planning.

Our locations

Hong Kong - Beijing - Munich

Hangzhou - Jinan - Qingdao - Tianjin

Chicago - London - Paris

Seoul - Tokyo

Contact us

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