



Cisema

Navigating regulation, empowering innovation



About Us



Paving the Way for Your Success in Asia

Cisema simplifies regulatory pathways, guiding you through every step of the product lifecycle in various Asia Pacific markets.

With our expertise, we ensure your success by navigating complex regulations and bringing your products to market quickly and efficiently.

We deliver exceptional results - going beyond regulatory standards to provide tailor-made solutions that meet your business needs.

About Us

Cisema

Regulatory affairs, quality assurance, clinical research, product testing & safety certification support services for China, Hong Kong, South Korea, Taiwan, Singapore, Malaysia, Vietnam, Indonesia, the Philippines, and Thailand.

20+ years'
experience

- German-founded & Western-owned specialty services provider since 2002.
- Salespeople close to our customers, speaking their language: English, Chinese, German, Japanese, Korean, French, Spanish, Italian.
- Experienced teams with diverse, multinational backgrounds in nimble, independent provider.
- Professional service with transparent pricing.

Industries supported:

- Medical Devices
- In-Vitro Diagnostics (IVDs)
- Pharmaceuticals
- Biotech
- Cosmetics
- Health Food, Supplements & Disinfectants
- Veterinary Drugs
- Industrial Goods & Consumer Goods



100+ staff across the globe; 10 offices

Locations

Cisema

Head Office

Cisema (Hong Kong) Limited
7/A Shun Pont Commercial Building
5-11 Thomson Road, Wan Chai
Hong Kong

Other Locations

Asia-Pacific: Beijing | Hangzhou | Qingdao | Tianjin | Tokyo | Seoul | Taipei
| Singapore | Penang | Ho Chi Minh City | Jakarta | Bangkok | Manila

Europe: Munich

North America: Chicago



A person wearing a white lab coat and blue gloves is using a compound microscope. The person's hands are visible, adjusting the eyepiece and the stage. The background is a solid blue color.

Our Key Services

Medical Device & IVD Services

Cisema

We provide a comprehensive range of services, from registration services across markets to specialist clinical services including trials (China only), local authorized representative services so you don't need to setup local companies in each market and many other initiatives.

Pre-Registration

- Regulatory Pathway
- Feasibility Studies
- Clinical Trial Protocol Design
- CRO China Clinical Trials

Registration

- Legal Agent / Authorized Rep
- Regulatory Filings & Registrations for Medical Devices & IVDs
- Testing Support at certified test labs
- Clinical Evaluation writing
- Medical Device Master Files (MDMF)
- Labelling Support

Post-Registration

- Post-Market Surveillance
- Advertisement Support
- CRO Post-Market Clinical Follow-ups & Observational Studies
- Overseas Factory & In-Country Audits
- GMP, QMS, SOP Adaptation
- Quality Control Support

BioPharma Services



We provide a comprehensive range of services, from one-off project-based deliverables to specialist consulting or ongoing partnership solutions for larger initiatives.



 Development & Strategy Consulting

From target to implementation and product extension and redevelopment

 Regulatory Affairs

Bringing innovations to market – from submission to launch, supporting local affiliates and expansion.

 Pharmacovigilance

During clinical trials and post-market

 Quality Management & Compliance

Optimizing efficiency, product compliance & market coverage locally

Cosmetics Services

Cisema

Regulatory Affairs



- Domestic Responsible Agent



- Pre-Evaluation & China Conformity Check
- New Special Cosmetic Registrations
- New General Cosmetic Filings
- New Ingredient Registrations/Filings



- Cosmetic and Ingredient Testing



- Cosmetic Ingredient Code Applications

Quality Compliance



- Overseas & Domestic Factory Inspections

**GMP
QMS
SOP**

- Gap Analysis
- Adaptation to Chinese Standards
- Audits of Registrant/Filer & Entrusted Manufacturers in China and overseas



- Staff Awareness Training

Health Food, Supplements, Disinfectants

Cisema

Regulatory Affairs



- China Responsible Agent



- Pre-Evaluation & China Conformity Check
- **Health Food** Filing & Registrations
- **Supplement** Filings & Registrations
- **Disinfectants** Registrations
- **Veterinary Device** Registrations
- Certificate Transfers



- Health Food & Supplement Product & Ingredient Testing
- Disinfectants Testing
- Veterinary Device Testing

Quality Compliance



- Overseas & Domestic Factory Inspections

GMP
QMS
SOP

- Gap Analysis
- Adaptation to Chinese Standards
- Audits of Registrant/Filer & Entrusted Manufacturers in China and overseas



- Staff Awareness Training

Sourcing & Quality Control



- Cisema has supported customers effectively in China for sourcing and quality assurance for 20+ years, with a strong network and large supplier database. We support you to identify and select the most suitable suppliers and then develop those suppliers to ensure quality expectations are met and sustained.
- We also now support Sourcing & Quality Control services in Taiwan and throughout Southeast Asia (Singapore, Malaysia, Vietnam, Indonesia, Philippines and Thailand).
- Comprehensive quality assurance management services:
 - Supplier factory audit
 - Sampling
 - Initial production inspection
 - During production inspection
 - Pre-shipment inspection
 - Container loading inspection

Industrial & Consumer Goods: CCC & CML

- Support for 20 product groups, esp. Motor vehicles, electronics and toys, to obtain Compulsory (CCC) and/or Voluntary Certifications in China.
- Full-service support for manufacturers to obtain the “SELO license” (CML) type approval for design and manufacture of pressure bearing products to Chinese specifications.
- Regulatory Communications directly with key China regulators, esp.
 - SAMR (State Administration for Market Regulation)
 - China Special Equipment Inspection and Research Institute (CSEI)
 - Special Equipment Licensing Office (SELO)
 - CNCA (Certification and Accreditation Administration of the People's Republic of China)
 - CCAP (China Certification Centre for Automotive Products)
 - CTC (China Building Material Test & Certification Group)
 - HQC (Beijing Zhong Hua Quality Certification Co. Ltd.)
 - CQC (China Quality Certification Centre)
 - CCLC (Certification Center of Light Industry Council)
- Factory inspections and pre-audit support.



Audit Services



Cisema supports factory audits in China and overseas, driven by increasing global regulatory requirements and supply chain strengthening.

- Supplier audits
- NMPA overseas factory inspections
- CCC audit
- CML/SELO audit
- ISO9001 & ISO13485 audits
- GMP / GDP / GSP audit
- IATF16949 audit
- VDA 6.3 audit
- APQP, FMEA, PPAP, SPC, MSA audit
- Run & Rate audit
- Formel Q audit
- QRQC audit and Implementation



Why Partner with Us

Our Mission

Our mission is to empower innovation by guiding global companies through Asia Pacific's regulatory, quality and clinical landscape. With local expertise and global standards, we enable manufacturers to deliver safe and effective products to their patients and users.

1. Power your market entry with fast, reliable regulatory, quality and clinical pathways
2. Bridge global innovation with Asia Pacific's unique requirements
3. Turn compliance into a competitive advantage with expert execution



Thank you.

Cisema



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