PUBLIC BUSINESS CAPABILITY BRIEF

GLOBAL PARTNERSHIP CAPABILITY PROFILE

CMO · CDMO · TECHNOLOGY TRANSFER

Hainan Hailing Chemipharma Co., Ltd.
Manufacturing and technology collaboration for suitable chemical-medicine projects

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Non-confidential profile. Product availability, capacity, registration status, market eligibility, timeline and final scope are confirmed only through current project review and formal documentation.

A practical route from project fit to controlled execution

Hainan Hailing Chemipharma Co., Ltd. is presented in this profile as a pharmaceutical manufacturing and technology-collaboration partner for suitable chemical-medicine projects. The public capability scope covers sterile injectable, oral solid and semi-solid dosage platforms, together with project-specific CMO, CDMO and technology-transfer discussions.

Every opportunity begins with a non-confidential preliminary assessment. Technical, regulatory, quality, capacity, supply and commercial feasibility are confirmed against current records before the parties define a project plan or exchange protected information.

Publicly presented dosage-form platforms

Platform	Dosage forms	Potential cooperation scope
Sterile manufacturing	Sterile lyophilized powder injections; sterile powder injections; terminally sterilized small-volume injections	Product-specific feasibility, technology transfer, scale-up, validation planning and agreed commercial manufacturing
Oral solid dosage	Tablets; capsules	Development or transfer assessment, process scale-up, registration-support interface and agreed manufacturing
Semi-solid dosage	Creams; ointments	Formulation/process assessment, transfer, scale-up and agreed manufacturing

Capability listing does not imply that every product, molecule, strength, market or batch size is currently available. Suitability is established through a product-level review.

Cooperation models

Model	Business objective	Typical controlled work
CMO	Manufacture an appropriately defined product under an agreed scope	Technical feasibility, quality agreement, transfer/qualification where required, manufacturing, testing, packaging and supply responsibilities
CDMO	Connect suitable development work with scale-up and manufacturing	Formulation/process work as agreed, analytical interface, scale-up, validation planning, documentation and manufacturing
Technology transfer	Transfer a product, process, method or manufacturing capability between defined parties	Due diligence, gap assessment, knowledge package, method/process transfer, training, demonstration and acceptance criteria
Product & registration cooperation	Evaluate a product and target-market pathway	Dossier-gap review, local partner interface, registration planning and supply model—subject to current product and market status

Stage-gated collaboration

Stage	Purpose	Decision evidence
1 · Preliminary assessment	Screen non-confidential product, market and cooperation fit	Dosage form, target market, project stage, timing, cooperation model and short objective
2 · NDA & due diligence	Create a controlled basis for technical and commercial review	Mutual NDA where appropriate, document list, access rules, product/regulatory/quality gap assessment
3 · Joint project plan	Define scope, responsibilities and the critical path	Work breakdown, quality responsibilities, evidence package, budget, milestones and go/no-go criteria
4 · Transfer / development	Execute the agreed technical work	Approved protocols, controlled data, training, engineering or development evidence and issue log
5 · Scale-up / validation	Demonstrate process and method readiness	Predefined acceptance criteria, qualification/validation evidence, deviation handling and regulatory-impact review
6 · Registration / supply	Support the confirmed market pathway and agreed manufacturing	Dossier interface, release responsibilities, supply plan, change control and lifecycle governance

What helps us assess a project

- Dosage form and product category; target market or country pathway.
- Current project stage: early evaluation, development, scale-up/validation, registration or commercial supply.
- Preferred cooperation model: CMO, CDMO, technology transfer, product/registration or another defined route.
- Expected timing, approximate non-confidential scale range and desired outcome.
- Known regulatory or technical constraints that can be described without disclosing protected information.

Confidentiality starts with a focused first contact

DO NOT INCLUDE IN THE FIRST SUBMISSION
Patient information, health records, prescription files, complete formulations, process secrets, unpublished regulatory files, customer-confidential information, pricing terms or other trade secrets.

If the preliminary fit is positive, the parties can agree a mutual NDA, purpose-limited access, a controlled document list and the appropriate technical review team before further information is exchanged.

03 · QUALITY AND REGULATORY CONTEXT

Evidence-aware public statements

China regulatory compliance

Hainan Hailing operates under applicable Chinese pharmaceutical manufacturing requirements and ongoing regulatory supervision and compliance inspections. China has discontinued the former drug-GMP certification and certificate system; this profile therefore does not use an outdated claim of being a “China GMP-certified enterprise.”

U.S. FDA inspection experience

Hainan Hailing underwent an on-site U.S. FDA inspection in July 2021. In its October 2021 90-day decisional letter, the FDA classified the inspection as VAI and confirmed that the inspection was closed.

This inspection history is not an FDA certification, facility approval, product approval or endorsement. Product- and market-specific regulatory status must be established through the applicable current records.

Project quality governance

- Quality responsibilities and decision rights defined before technical execution.
- Product-specific due diligence, gap assessment and risk-based project planning.
- Controlled document, method, process, validation and change-management interfaces.
- Deviation, investigation, CAPA, release, complaint and recall responsibilities agreed for the project.
- Target-market requirements confirmed with the responsible regulatory parties.

Market work follows execution readiness

Southeast Asia is a practical first focus because Hainan-based teams can work across short travel distances and limited time-zone differences. The Middle East may support higher-value registration, supply and localization discussions. Europe and the United States generally require longer, evidence-intensive pathways. Latin America can be evaluated selectively. Every market remains subject to product, partner, regulatory, payment and supply-chain assessment.

Focus	Potential route	Key early questions
Southeast Asia	Local partner, registration, supply, CMO/CDMO or selected transfer	Which country first? Who owns the local pathway? What evidence and supply model are required?
Middle East	Registration, supply, localization and technology cooperation	What is the procurement/market-access route? What local-content or transfer expectation applies?
U.S. / Europe	Selective CMO/CDMO and technical cooperation	What approved or development-stage product is in scope? Which regulator and quality evidence govern the project?
Latin America	Country-specific product and registration collaboration	Which national pathway, partner, dossier and payment model support a durable launch?

Regional interest does not imply existing product approval, active registration, commercial availability or guaranteed supply in a named market.

Start with a preliminary assessment

Use the secure project-inquiry form at stevenyiqingli.com or contact lyq@cjrf.com. The website form requests only the minimum non-confidential information required for an initial fit assessment and provides a reference number for each successful submission.

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Document control

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Disclaimer: This profile is for general business introduction and preliminary cooperation discussion. It is not medical advice, a product label, a binding offer, a regulatory approval, a certification or a guarantee of product availability, capacity, registration, pricing or timeline. Final scope and current facts must be confirmed through formal documentation and the responsible project teams.

Public frameworks referenced

- U.S. FDA — Contract Manufacturing Arrangements for Drugs: Quality Agreements (Guidance for Industry).
- U.S. FDA — Process Validation: General Principles and Practices (Guidance for Industry).
- ICH Q9(R1) — Quality Risk Management; ICH Q10 — Pharmaceutical Quality System.
- WHO Technical Report Series No. 1044, Annex 4 — Technology transfer in pharmaceutical manufacturing.

Review and update policy

This profile is reviewed before public issue and should be rechecked whenever the dosage-form scope, regulatory status, contact route or cooperation model changes. The version number and review date allow partners to identify the current public edition before circulation.