JIUZHOU Pharmaceutical | Raybow Pharmaceutical

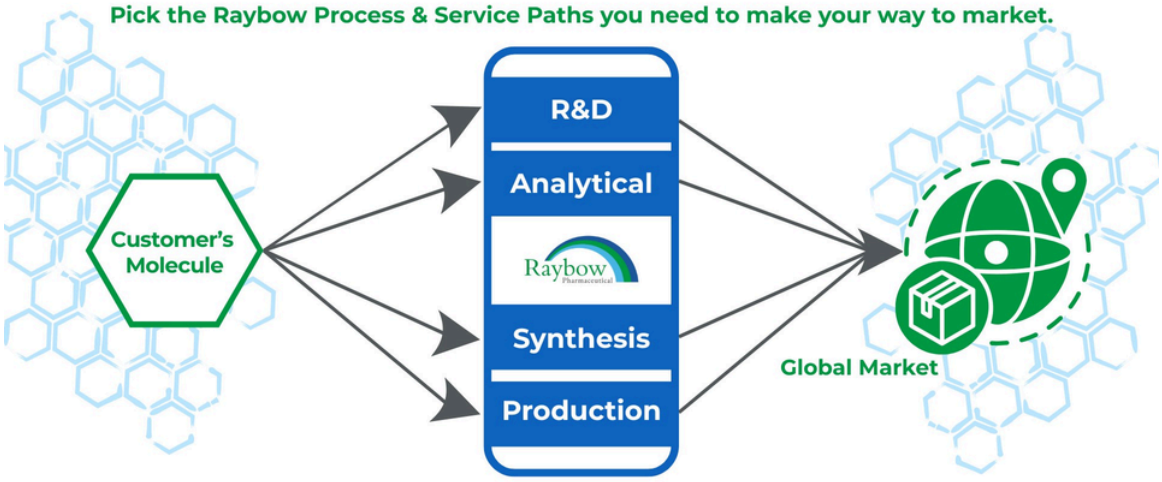
Molecule to Market: Your Trusted Partner

Synthetic Services Menu Items

Raybow USA's Synthetic Services are custom-fit to meet the specific demands of each project, ensuring that your goals are not just met, but exceeded.

Our highly qualified chemists coordinate closely with you every step along the way, ensuring the efficient use of resources and expertise.

	Product Stage		
Service	**Development / Pre-GMP**	**Phase 1 cGMP, Fit-for-Use**	**Phase 2 Validated / Scaled GMP**
Route Scouting	Feasibility studies, 1–3 route options, lab notebook summary	Refined route selection with limited robustness data	Confirmed, fully optimized synthetic route with validation runs
Process Development	Early optimization (yield, purity, scalability)	Robustness studies, critical parameter assessment	Full process characterization, CPP/CQA control strategy
Non-GMP API Production	Gram to low kilogram (for tox/PK studies)	---	---
GMP API Production	---	Kilo-scale GMP API batches for Phase 1	Multi-kilo GMP batches for Phase 2; reproducibility demonstrated
Tech Transfer	Basic transfer package	Formal tech transfer with batch records and SOPs	Full tech transfer dossier (validation-ready)
Impurity Synthesis	Non-GMP impurity or metabolite synthesis	GMP impurity standard synthesis	Validated impurity reference standard batches
Salt/Polymorph Screening	Small-scale screen (non-GMP)	GMP screen with limited characterization	Full solid-state characterization (XRPD, DSC, TGA, hygroscopicity)
Cleaning Studies (Synthetic Equipment)	---	Feasibility studies of cleaning procedure	Validated cleaning procedure (per regulatory expectations)
Documentation / Reporting	Internal R&D report	GMP batch records, Certificate of Manufacture	IND/IMPD-ready CMC documentation package



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Synthetic Services Package Examples

Ask about creating Custom Packages to suit your needs.

Sample Development Package

Route Feasibility

Intended for: Early evaluation of API synthesis, tox/PK supply

Includes:

- Route scouting (2–3 options, fit-for-purpose only)
- Early process optimization runs
- Non-GMP API supply (up to ~100 g)
- Internal R&D report

Add-ons:

Salt screen, impurity synthesis

Sample Phase 1 Package

GMP Supply & Qualified Process

Intended for: GMP API supply for tox studies and first-in-human batches

Includes:

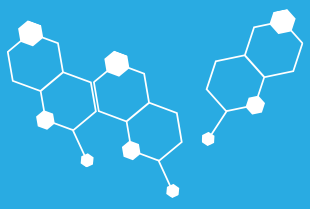
- Process optimization + robustness assessment
- cGMP API production (kilo-scale)
- GMP impurity synthesis (as required)
- Limited polymorph/salt characterization
- Batch records + Certificate of Manufacture

Add-ons:

Tech transfer package, cleaning feasibility

Sample Phase 2 Package

Validated GMP Process



Intended for: Multi-kilo GMP batches and IND/IMPD submission

Includes:

- Fully characterized, validated synthetic process.
- Multi-kilo cGMP API batches.
- Cleaning validation package.
- Full salt/polymorph characterization.
- IND/IMPD-ready process development and manufacturing reports.

Add-ons:

Tech transfer dossier, validated impurity standards

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