CRMO®

Outsourcing Partner for the

PHARMACEUTICAL INDUSTRY

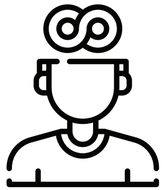
www.crmopharmmatecch.com

CRMO Pharmmatecch

About CRMO Pharmmatecch

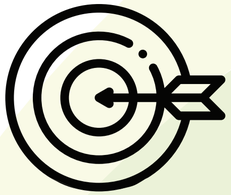
CRMO Pharmmatecch is an Ahmedabad, India based company established with a vision of providing complete outsourcing solutions to Pharmaceutical Industry. The firm is managed by highly experienced, energy driven, techno-commercial professionals having vast experience in contract research and manufacturing sector.

CRMO offers consulting services covering cGMP Product Outsource, cGMP Audit & Compliance Services, Pharmaceutical & Technology Transfer Project Management and Commercial Production Monitoring. We have wide experience in Indian and International market and we fully understand the requirements of Regulatory agencies such as USFDA, EDQM, MHRA, TGA.



Our Philosophy

GMP should be a life style integrating productivity, quality, health, safety. Authentic audit and support to meet quality systems help the environment and create a safe and healthy society at large.



Our Mission

To provide complete outsourcing and GMP solution under one roof and set a new heights of services by introducing latest & transparent practices, attention to detailing and down to business approach.

cGMP
Product Outsource

cGMP
Product Outsource

CRMO specialises in Identifying, finalizing and monitoring suitable outsourcing partners befitting customer's requirements for contract manufacturing and tech transfer projects. Due to our vast experience with the Indian Pharma Industry, we have generated a database of good manufacturing facilities in India. These facilities have been identified based on detailed audits, surveys and technical feasibility studies.

We have emerged as a preferred partner for sourcing APIs, advanced stage intermediates of including those of the near patent expiry APIs, covering various therapeutic groups, nutraceuticals and herbicides, drug intermediates and niche specialty chemicals as well select Formulations.

Pharmaceutical Product Outsource Services

CRMO Pharmmatecch will ensure that these projects are handled and executed with the international quality standards with due respect to Safety, Health and Environment (SHE), GMP compliance etc. CRMO is in a unique position to offer a single point of contact for

Identifying suitable outsourcing partner/s

Facilitating audit

Execution of the entire custom-manufacturing project on behalf of the customer

cGMP Audit Services

cGMP Audit Services

Regulatory agencies worldwide are authorized to conduct unannounced inspections, though some are scheduled. In Pharmaceutical Industry, facing such inspections and exhibiting complete compliance is a very challenging task. Preparations before Inspections and demonstration of compliance post inspection with respect to the observations become key to future supplies to regulated market places.

cGMP Audit Services

CRMO has both the qualities understanding of local situations and awareness about International bench marks. CRMO has been appointed by international Pharma companies as third party GMP auditors and monitor for GMP compliance at their suppliers manufacturing sites in India on their behalf.

The range of audit services provided by CRMO is as follows

- Internal cGMP Audits
- GLP Audits
- Contract Manufacturers Audit
- Quality Systems Evaluation
- Compliance Gap Assessments
- Mock FDA Audits
- Pre Approval Inspection Support
- API and Formulation cGMP Audits
- Labelling and Packaging Audits
- Supplier Audits
- Surveillance Audits
- Validation Audits
- Training Audits
- Designing Training Programs

cGMP Compliance Services

cGMP Compliance Services

Our team of experts from India, USA and Europe provide Industry with various services that can help them sail through such inspections successfully. We assist companies prepare compliance reports and response to audit observations as well help them implement CAPA as per regulatory guidelines.

Besides regulatory inspections, many customer audits take place at the manufacturing sites. We prepare sites for successful customer audits so that the continuity of supplies can be maintained.

GMP Compliance Services

- Quality Management Services
- Validation & Qualification
- Regulatory Agency Documentation
- QA & RA Set Up Support

Pharmaceutical & Technology Transfer Project Management

Pharmaceutical & Technology Transfer Project Management

Pharmaceutical Outsourcing has been called, “One of the greatest organizational and Industry structure shift of the century”.

CRMO offers unmatched pharmaceutical project management services to the International Pharmaceutical Industry.

Because of the following attributes, we feel that we are well positioned to take care of diverse contract manufacturing and Pharmaceutical technology transfer project management activities.

- CRMO has a proven track record of managing many outsourcing projects on behalf of many US, European and Japanese Companies.
- We have in-depth knowledge of Indian Pharmaceuticals and Chemical Industry.
- We’ve understanding of Outsourcing trends and their growth drivers.
- CRMO shares excellent rapport with leading Indian manufacturers.
- CRMO is backed by competent techno commercial work-force.

Pharmaceutical & Technology Transfer Project Management

Pharmaceutical & Technology Transfer Project Management

Scope of Pharmaceutical Project Management Services

- Identification of the suitable supplier
- Project design phase
- Project execution phase
- Project approval phase
- Post-approval support phase

Benefits of choosing CRMO Pharmmatecch

CRMO Pharmmatecch is strategically located in India to cater to the needs of the MNCs by being their “Eye and Ear” in India, thereby making our services extremely cost-effective.

In case of any emergencies/ project delays. CRMO would ensure that quick attention is given to such emergencies and all necessary support is provided to the suppliers to tackle the delays and keep the project on track.

During all important milestones of Project (Like exhibit batches, regulatory audits) CRMO representatives shall be present with the suppliers to physically verify the status, thus, cutting down the expenses for the MNCs on overall resources including travel costs and time.

Commercial Production Monitoring

Commercial Production Monitoring

Monitoring the supplier to ensure uninterrupted commercial production, consistent quality and timely delivery is of utmost importance.

CRMO representatives visit the manufacturing site at regular intervals and keeps vigilant watch on behalf of client companies.

CRMO ensures that

- cGMP is not compromised at any point in time .
- Product release is as per approved specifications and using validated MoA
- Product quality form all batches is thoroughly checked before each consignment is shipped.
- Any grievances or complaints from the Buyers are promptly attended and proper investigations are carried out.
- Production planning and Raw material inventory planning at the manufacturing site is constantly monitored to ensure timely deliveries.
- Any technical assistance needed for improving process efficiency , yield improvement, throughput enhancement, energy cost saving , etc is provided and changes are made effective only through Change control procedures.
- Periodic review of documentation is carried
- During regulatory and customer audits necessary support is provided.

Our Clientele

CARBOGEN AMCIS
A Dishman Group Company

polpharma

Takeda

TCI

Shelys
An Aspen Group Company

CADILA PHARMACEUTICALS LIMITED

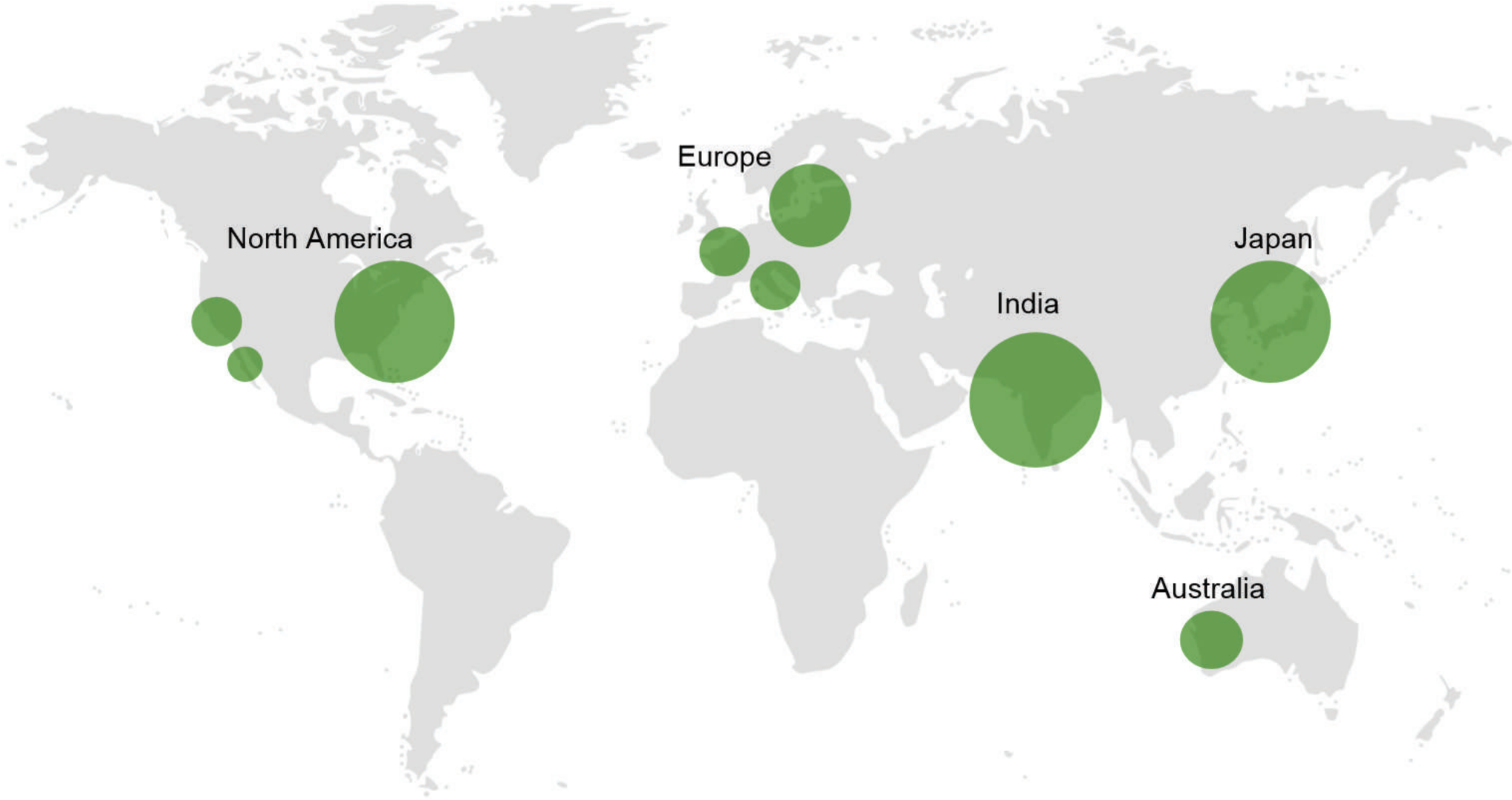
Hamari Chemicals, Ltd.

SOLVAY

SEPRACOR

NATCO

Our Network



Contact Us

INDIA Address

608 B, Pinnacle, Corporate Road, Nr Prahladnagar Auda Garden
Prahladnagar, Ahmedabad - 380015 India

crmo@crmopharma.com

USA Address

46, Delaware Avenue, Middlesex,
NJ-08846. USA

Thank You