

# YMC Group's Network

Through YMC Group's offices and sites in Japan and overseas, we secure our global supply chain and customer service. Our purification service will be soon available not only in Japan but also in Europe, the U.S. and India. We are also planning to increase our offices mainly in countries and regions where the pharmaceutical business is expected to grow.



## Worldwide Availability

YMC America, Inc.  
www.ymcamerica.com

YMC Europe GmbH  
www.ymc-europe.com

YMC India Pvt. Ltd.  
www.ymcindia.com

YMC Korea Co., Ltd.  
www.ymckorea.com

YMC Shanghai Rep. Office  
www.ymchina.com

YMC Singapore Tradelinks Pte. Ltd.  
www.ymc.sg

YMC Taiwan Co., Ltd.  
www.ymctaiwan.com



## YMC CO., LTD.

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Distributor

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From Laboratory To Plant-Scale Separation/Purification

# Custom Purification And Separation/Purification Technologies



YMC CO., LTD.  
http://www.ymc.co.jp

PB-0064E



# We now offer a complete GMP conforming custom purification service

At YMC we have developed high performance packing materials, packed columns, and separation system applicable to a range of scales from microanalysis to large-scale isolation since our foundation in 1980. Our advanced chromatography technology is evaluated and recognized as the global leading brand particularly in the field of pharmaceutical industry.

Following the recent addition of a portfolio of bio-processing products useful for purifying biotechnology-based drugs based on our rich experiences and achievements over the years, we have commenced supply of products for chiral technology.

Furthermore, we are constructing a pharmaceutical-grade purification plant to allow YMC to offer a complete custom purification service for highly value-added substances including biotechnology-based drugs.

API purification plant will be completed.

(To start operation in September 2015)



Komatsu Works (Ishikawa Prefecture) offers a purification service from several tens of grams to several tons

Komatsu Works is our R&D and manufacturing site for HPLC columns and packing materials, and all of these products are shipped from here to our customers in Japan and abroad. The custom purification service has been provided by installing large separators and large dynamic axial compression columns in our explosion-proof purification plant (FX Plant). Our new pharmaceutical-grade purification plant will open in September 2015.

## Advantages of Custom Purification

Separation and purification using chromatography may require high technology, time and cost. At YMC, we provide purification services with our accumulated experiences, know-how, and excellent equipment. Not only ensuring purification of a target substance according to your request, we will also propose an efficient separation method that may result in a cost reduction, based on our past achievements and know-how.

### Requestor

- Difficult purification method setting
- Expensive purification columns and packing materials
- Lack of separation/purification devices/facilities
- Lack of time and human resources

### Use of a service provided by YMC

- Accumulated achievements and know-how of separation/purification
- Low-cost columns and packing materials manufactured in-house
- Availability of large columns and separation devices

Supply of high-purity chemical compound

**Quick service**  
**High credibility**  
**Low cost**

## Steps for Using a Purification Service

We respond flexibly to your needs including confidentiality, GMP requirements, and budget at an initial meeting. Please feel free to consult with us to process large or small amounts of materials.

### Purification request

- Meeting of the both parties
- Signing a non-disclosure agreement
- Consideration of preparatory conditions based on a submitted sample

### Report for preparatory considerations

- Proposal of an optimal column and a most efficient separation method and approval

### Submission of an estimate

### Main purification

- Separation/purification with an optimal method

### Delivery of a purified substance and submission of a report

### Purified preparation

A biotechnology-based drug API for a clinical trial  
Chiral compound      Oligonucleotide  
Achiral compound      Peptide/protein  
Active pharmaceutical ingredient (API)  
Impurities, etc.

## Our Production Facilities Include the World's Largest Chromatographic Systems and Columns

We have large dynamic axial compression columns in a range of sizes, including one with an internal diameter of 1,000 mm, as well as systems of appropriate sizes, large concentrator, freeze-dryer, etc. The column with the internal diameter of 1,000 mm can be loaded with several hundred grams at a time, while being suitable for plant-scale purification of several tons.





We develop, manufacture, and sell separation systems suitable for laboratory- to plant-scale, with the experience of using them in our in-house custom purification services.

We choose the optimal device for each separation/purification project, depending on the target substance, purity and scale required from the wide range of techniques available, ranging from a bioprocessing system to a recycling system, an SFC system, and an SMB system, in addition to an explosion-proof system.

Standard flow rate and load according to internal diameters of columns

Internal diameter of a column (mm I. D.)	4.6	10	20	50	100	200	500	1000
Cross-sectional ratio	1.0	4.7	19	118	473	1,890	11,800	47,300
Flow rate (mL/min)	0.5	2.4	9.5	60	235	950	6,000 (6 L)	24,000 (24 L)
	1.0	4.7	19	120	470	1,900	12,000 (12 L)	47,000 (47 L)
Load (mg)	5	25	100	600	2,500	10,000	60,000 (60 g)	240,000 (240 g)

Bioprocessing Systems and Columns

Optimal for chromatographic purification for manufacturing a biotechnology-based drug

■ Separator BioStream

- Completely manufactured in Japan and suitable for cGMP
- Sanitary design for ease of cleaning
- Maximum flow rate: up to 30 L/min
- Can be customized to your needs

■ YMC Pilot Columns

- All the wetted parts are made of non-metallic materials
- Easy adjustable plunger height
- Wide range of internal diameters, e.g. 100, 140, 200 mm, etc.
- Many options are also available



HPLC Systems and Dynamic Axial Compression Columns

Optimal for purification of low molecular compounds, peptides and chiral compounds

■ K-Prep systems

- Processes volumes from lab- to plant-scale
- Fully automated operation via PC is possible
- Maximum flow rate: Up to 25 L/min
- Compatible with GMP/explosion-proof operation

■ Axial compression columns DAD/DAU

- Axial compression columns pack automatically
- Superior column performance, endurance and reproducibility achieved by constant pressurization
- Internal diameters from 50 to 1,000 mm
- Compatible with GMP/explosion-proof operation





## Particle Technology

### High Performance Packing Materials to Achieve Highly Efficient, Low Cost Purification

Because all of YMC's packing materials go through thorough quality control and are identified with minimal lot variations, they are highly evaluated and used by customers across many industries including drugs, foods and chemistry in Japan and other countries. Our packing materials are registered on DMF (Drug Master File) for proven safety.

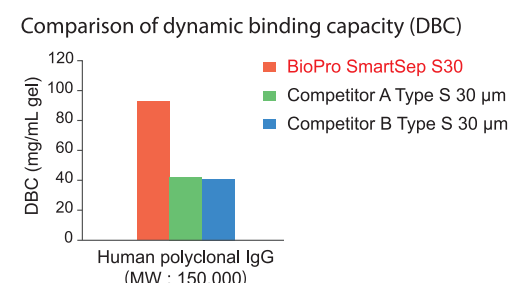
We offer a broad portfolio of high performance packing materials made of silica gel, polymer-based ion exchange media, and organic hybrid silica, as well as one for chiral separation. We propose optimal separation conditions using those packing materials for our custom purification service, for highly efficient, low cost processing.



### Ion Exchange Media BioPro and BioPro SmartSep

-Optimal for separation of proteins and nucleic acids for biotechnology-based drugs-

BioPro and BioPro SmartSep are ion exchange media used for initial (capture) to final purification (polishing), based on hydrophilic polymers with minimal non-specific adsorption and strong/weak ion-exchange matrices. With high dynamic binding capacity (DBC) and high recovery for proteins, they allow rapid processing of large volumes, which demonstrates the high productivity in purification of many types of proteins and nucleic acids used for biotechnology-based drugs.

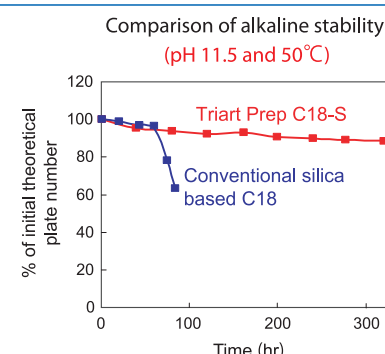


### Organic Hybrid Silica Packing Material YMC-Triart Prep

-Excellent stability-

YMC-Triart Prep is the bulk packing material for HPLC purifications based on organic hybrid silica. This highly stable product can be washed with alkaline solution. It also has a high mechanical strength so its particles can be subjected to repeat repacking.

With its high chemical and mechanical stability, YMC-Triart Prep can be used repeatedly over a long period, resulting in high cost-efficiency.



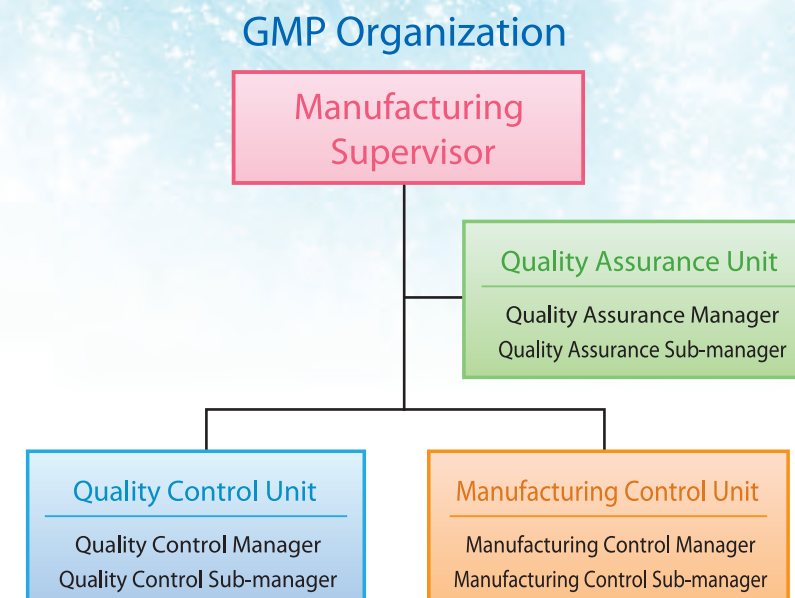
### Chiral Separations - CHIRAL ART

-Polysaccharide derivative functionalized packing materials to reduce chiral purification cost-

CHIRAL ART is a range of packing materials for isolating optical isomers using a polysaccharide derivatives as chiral selectors. Due to their high steric recognition ability, they allow separation of a broad range of chiral compounds. They are also useful for isolating cis-trans isomers and position isomers. With their high cost-effectiveness, they can be used for a variety of purposes.

## GMP Support

In the Komatsu Works, our Quality Assurance and Quality Control Units established a GMP organization independent from our Manufacturing Control Unit. Under our strict quality control system, we can purify a large volume of an active pharmaceutical ingredient for a clinical trial by using our large scale facilities that can be validated.



## Out Network in Japan

### YMC CO., LTD.

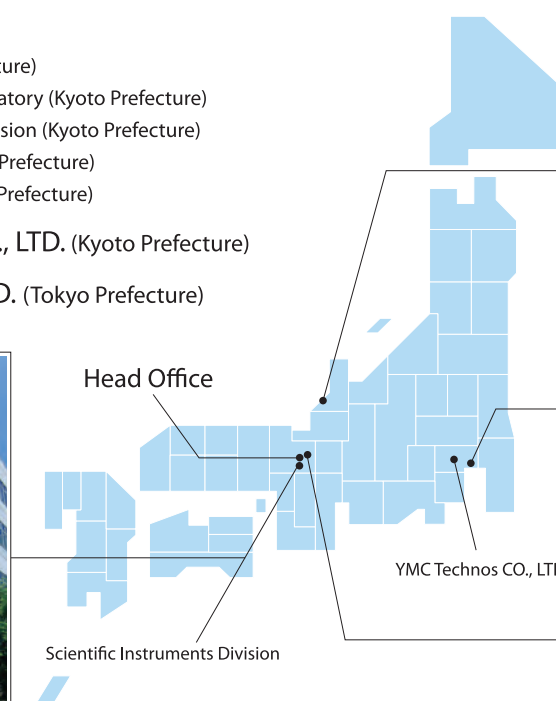
- Head Office (Kyoto Prefecture)
- Chiral Technologies Laboratory (Kyoto Prefecture)
- Scientific Instruments Division (Kyoto Prefecture)
- Komatsu Works (Ishikawa Prefecture)
- Tokyo Sales Office (Tokyo Prefecture)

### YMC Engineering CO., LTD. (Kyoto Prefecture)

### YMC Technos CO., LTD. (Tokyo Prefecture)



Systems and columns manufacturing facility  
YMC Engineering CO., LTD. (Kyoto Prefecture)



Facility for purifying from several tens of grams to several tons  
Komatsu Works (Ishikawa Prefecture)



Facility for purifying from several milligrams to several tens of grams  
Chiral Technologies Laboratory (Kyoto Prefecture)