

Analytical to prep scale tools for the purification of bio/pharmaceuticals

Leveraging YMC chromatography technology



Topics

Technology offering overview

HPLC columns

HPLC media – focus on Triart Prep

LPLC IEX media

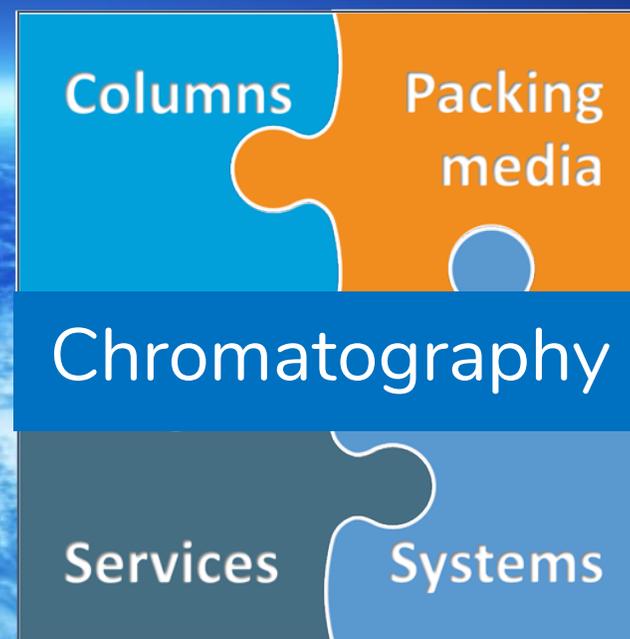
Glass columns

Prep scale systems

- Batch
- Multi-column LPLC
- Multi-column HPLC
- Summary

YMC Corporation overview

Global technology supplier of purification technologies to the pharmaceutical and biopharmaceutical industries



About: YMC products & services; Founded 1980

YMC core technologies are based on separation using LPLC and HPLC



Packing materials for chromatography

Analytical/Preparative packed columns

Synthesis/Purification Service

YMC

DAC & Glass Columns

Bio / pharmaceuticals purification systems

YMC CO., LTD.: Corporate profile

Start of business: January 1980

Consolidated sales : ~\$100 M US (~10 billion yen) (Est. FY2019 ending March 2019)

No. of employees: ~ 500 (Consolidated)

Global locations





YMC Columns and Resins for
the lab to production of bio /
pharmaceutical products



YMC core competencies

➤ Production of spherical bonded phases

- > 30 bonded phases
- 1.9 – 300 μm
- Silica, hybrid, & polymer-based bonded products
 - Up to tons/year scale

➤ HPLC columns

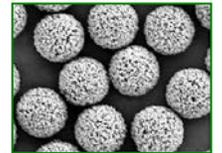
- Laboratory to Pilot Scale
- Analytical/Prep: 0.075 mm – 300mm ID
 - Prepacked Columns
- Stainless steel and glass columns

➤ Preparative chromatography systems

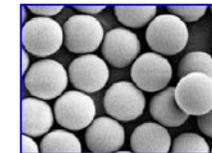
- Semi-prep & process scale



Fully-porous



Non-porous



Preparative chromatography

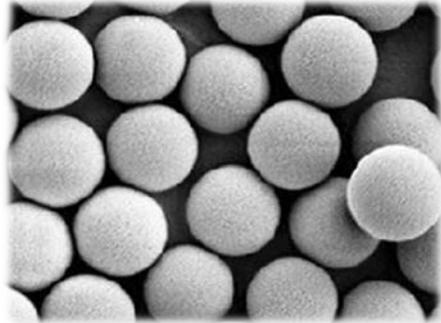
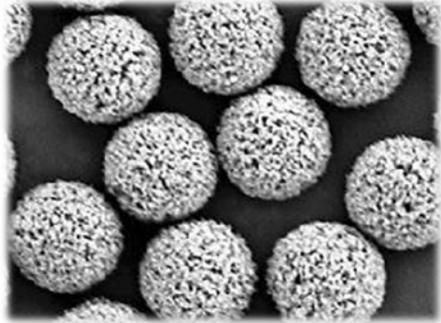
- **Dynamic Axial Compression (DAC) columns**
 - 50 → 1000 mm ID
- **Glass columns**
 - 5 → 450 mm ID
- **Bulk media**
 - 10 → 300 μm particle size



BioPro IEX

BioPro IEX (Ion Exchange media)

- **Novel hydrophilic polymer particle**
 - Methacrylate base particle
 - Low Non-specific Adsorption
 - SCX and SAX Phases
 - Porous and Non-Porous
- **Non-porous: 3 μm, 5 μm, 6 μm**
 - High Efficiency
 - Increased Resolution
- **Porous: 5, 10, 20, 30 & 75 μm**
 - Prep/Purification Applications

> BioPro IEX Column			
> BioPro IEX QF	> BioPro IEX SF	> BioPro IEX QA	> BioPro IEX SP
Hydrophilic non-porous polymer		Hydrophilic porous polymer	
3, 5		5	
$-\text{CH}_2\text{N}^+(\text{CH}_3)_3$	$-\text{CH}_2\text{CH}_2\text{CH}_2\text{SO}_3^-$	$-\text{CH}_2\text{N}^+(\text{CH}_3)_3$	$-\text{CH}_2\text{CH}_2\text{CH}_2\text{SO}_3^-$
For increasing resolution and throughput High efficiency with low operating pressure Suitable for characterization of biopharmaceuticals and quality control		Suitable for laboratory-scale purification High binding capacity and high recovery of biomolecules	
			

Leading hybrid silica technology

YMC-Triart

Hybrid-Silica separation media

➤ 9 phase chemistries

- C18, C18 ExRS, C8, Phenyl, PFP
- Bio C18, Bio C4
- SIL, Diol-HILIC

➤ Chemically durable

- Across broad pH ranges

➤ Physically durable

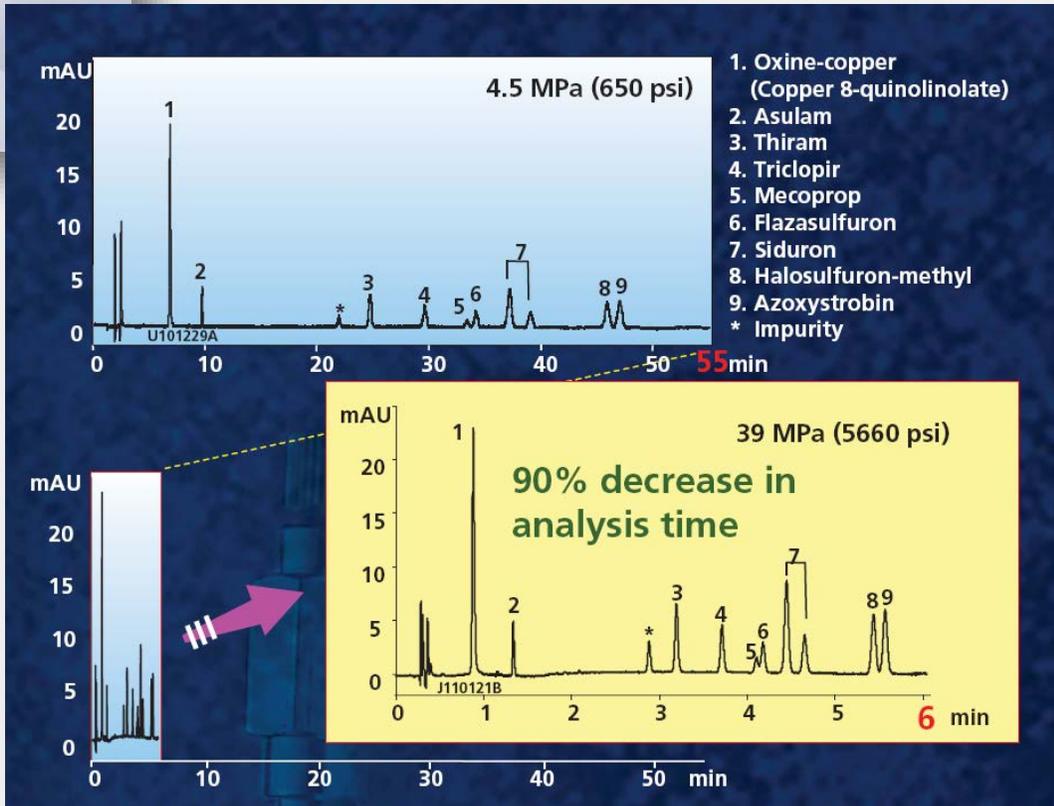
- At high temperature and pressure

➤ Thermal stability

- Wide temperature range

➤ 1.9 μm → 50 μm particle sizes

- UHPLC → Purification
- Fully scalable across particle sizes



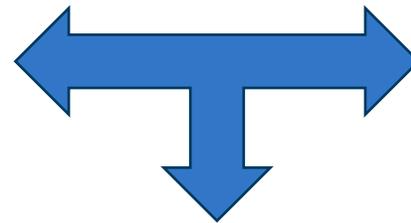
Why YMC-Triart?

Silica → Traditional base particle

- Standard chemical durability
 - Narrow pH range
 - Typically 2-7.5
- Narrow temperature range
 - Typically up to 50°C
- Good mechanical strength
 - More fines than hybrid-silica
- Monomerically bonded
 - Some are polymerically bonded
- Scalability issues for prep

YMC-Triart → Hybrid-silica base particle

- Increased chemical durability
 - Wide pH range
 - C18, Bio C18, & C8 = 1-12
 - Bio C4 & Phenyl = 1-10
 - PFP = 1-8
 - Diol-HILIC = 2-10
- Wide temperature range
 - Up to 90°C
- High mechanical strength
 - Less fines than silica → Better for prep
- Polymerically bonded
 - Less susceptible to cleavage at low pH
- Fully scalable to prep



Higher Durability

More Versatility

Better Performance

YMC Glass Columns

From lab to
production scale



Laboratory scale glass columns I

ECO

Glass columns for low and medium pressure applications

- ✓ Easy piston adjustment
- ✓ Heating/cooling jacket for temperature sensitive applications
- ✓ 1 m long glass bodies for SEC applications

Available ID's: 10, 15, 25, 50, 70, 80 mm

Available Lengths: 120, 200, 450, 750, 1000 mm



Laboratory scale glass columns II

ECO^{PLUS}

Glass columns for medium and high pressure applications

- ✓ Easy assembly with Quick-Lock system
- ✓ Faster runs due to higher pressure limits
- ✓ Highest reproducibility from calibrated glass body

Available ID's:	5, 10, 15, 25, 35, 50 mm
Available Lengths:	125, 250, 500 mm



Pilot / production scale glass columns I

YMC Pilot^{PLUS}

Glass columns for pilot & production scale BioLC applications.

- ✓ Bubble-free column packing due to drain function
- ✓ Easy unpacking with removable column body
- ✓ 100% biocompatibility

Available IDs: 70, 100, 140, 200 mm

Available Lengths: 500, 850 mm



Pilot / production scale glass columns II

YMC Pilot

Glass columns for pilot & production scale applications.

- ✓ For temperature sensitive applications
- ✓ Solvent resistant version available
- ✓ Longer bed length range for SEC applications

Available IDs*: 100, 140, 200, 300 mm

Available Lengths*: 500, 850 mm

*customisation possible



The key advantages of YMC glass columns

- ✓ **Full compatibility** with all common separation modes
- ✓ **Increased throughput** possible due to **higher pressure limits**
- ✓ **Improved chromatographic results** due to homogeneously packed column bed
- ✓ **Fast and easy maintenance**
- ✓ **Excellent column performance**
- ✓ **High cost efficiency**





YMC systems

From lab to production scale



Broad range of YMC chromatography system manufacture

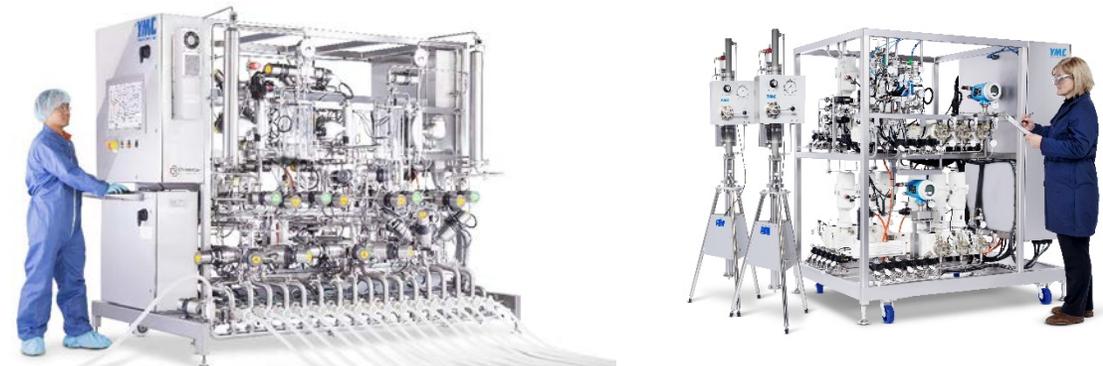
- Lab/bench: HPLC / FPLC



- Pilot: LPLC & HPLC



- Production: GMP production scale LPLC, HPLC, TFF, BID



All systems are available for single column batch or twin-column continuous models

Example: HPLC lab system - The YMC Contichrom[®] CUBE

Specifications:

CUBE 30: 0.1 - 36 mL/min

CUBE 100: 0.1 - 100 mL/min

100 bar system

UV-LED Detectors at 280 & 254 nm,
optional external detector 190-500nm

CUBE System



Fraction collection and other ancillary instruments





Core industrial scale standard systems by YPT



Batch chromatographic systems



YMC EcoPrime® HPLC and LPLC
using digital pump drive technology

YMC Contichrom® TWIN & CUBE

based on ChromaCon's CaptureSMB and MCSGP

Multi-column continuous HPLC & LPLC chromatographic systems



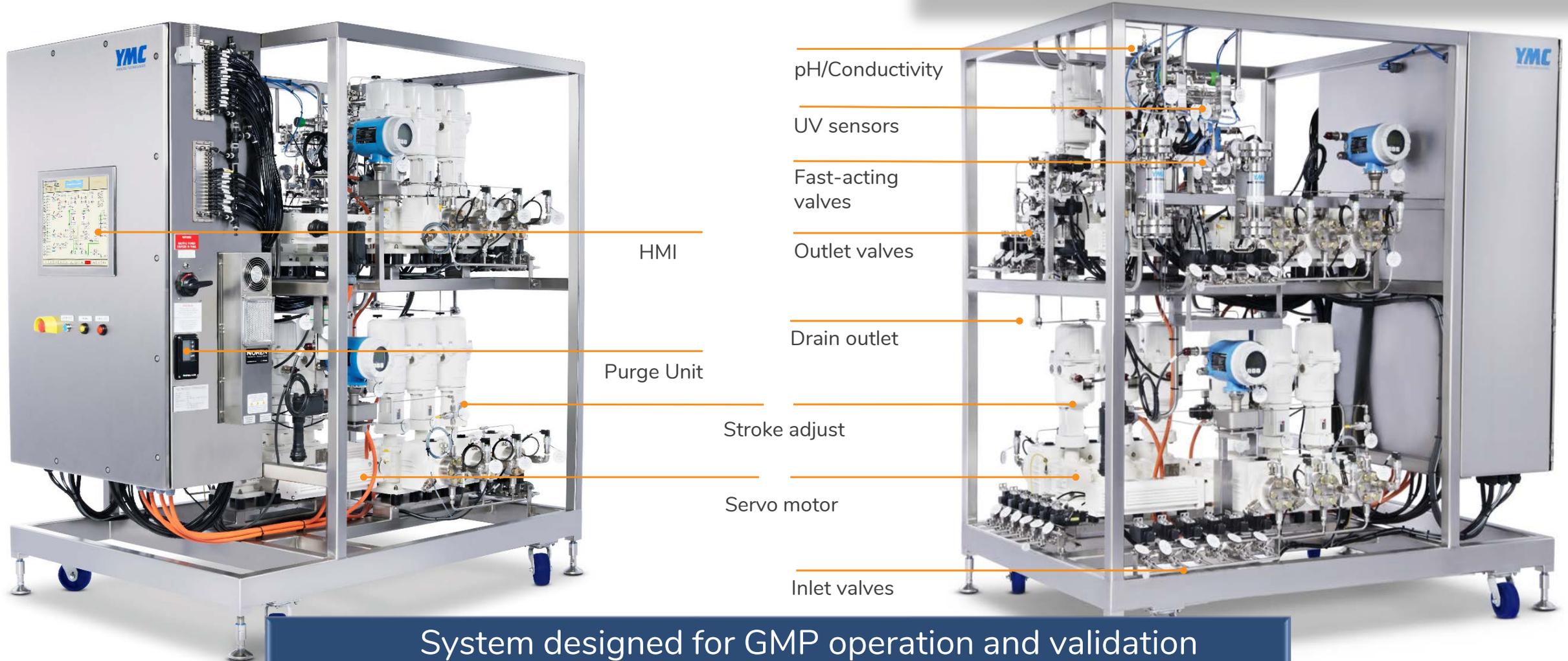
Buffer dilution systems

YMC buffer dilution
MilliporeSigma buffers, bags and services



Example: Primary components of a Contichrom TWIN HPLC system

- UL Class 1 div 2 hazardous location
- CE conformity, including ATEX zone 2
- Supports 21 CFR part 11 compliance
- Enables GAMP 5 compliance



HMI

Purge Unit

Stroke adjust

Servo motor

Inlet valves

pH/Conductivity

UV sensors

Fast-acting valves

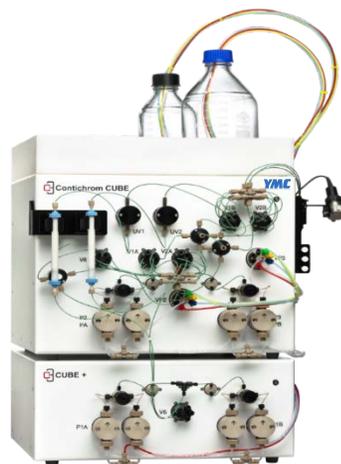
Outlet valves

Drain outlet

System designed for GMP operation and validation

Components are proven, industrial, purpose selected for this application

Contichrom® TWIN systems scale seamlessly from bench to pilot to production systems!



Contichrom CUBE 30



Contichrom TWIN MCSGP 100

Not just chromatography: Standard and custom designs



LPLC chromatography systems



Cell harvest systems (OEM)



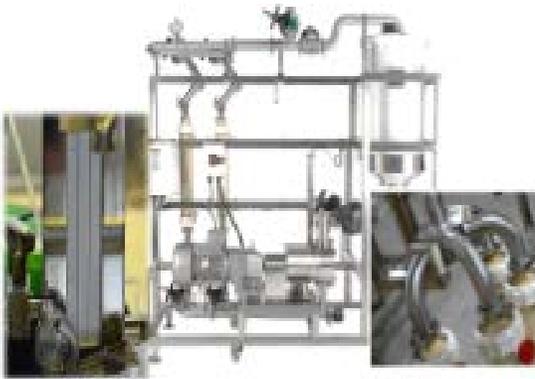
HPLC systems (batch)



Buffer in-line dilution systems



TFF systems



Simulated Moving Bed HPLC



Blending systems

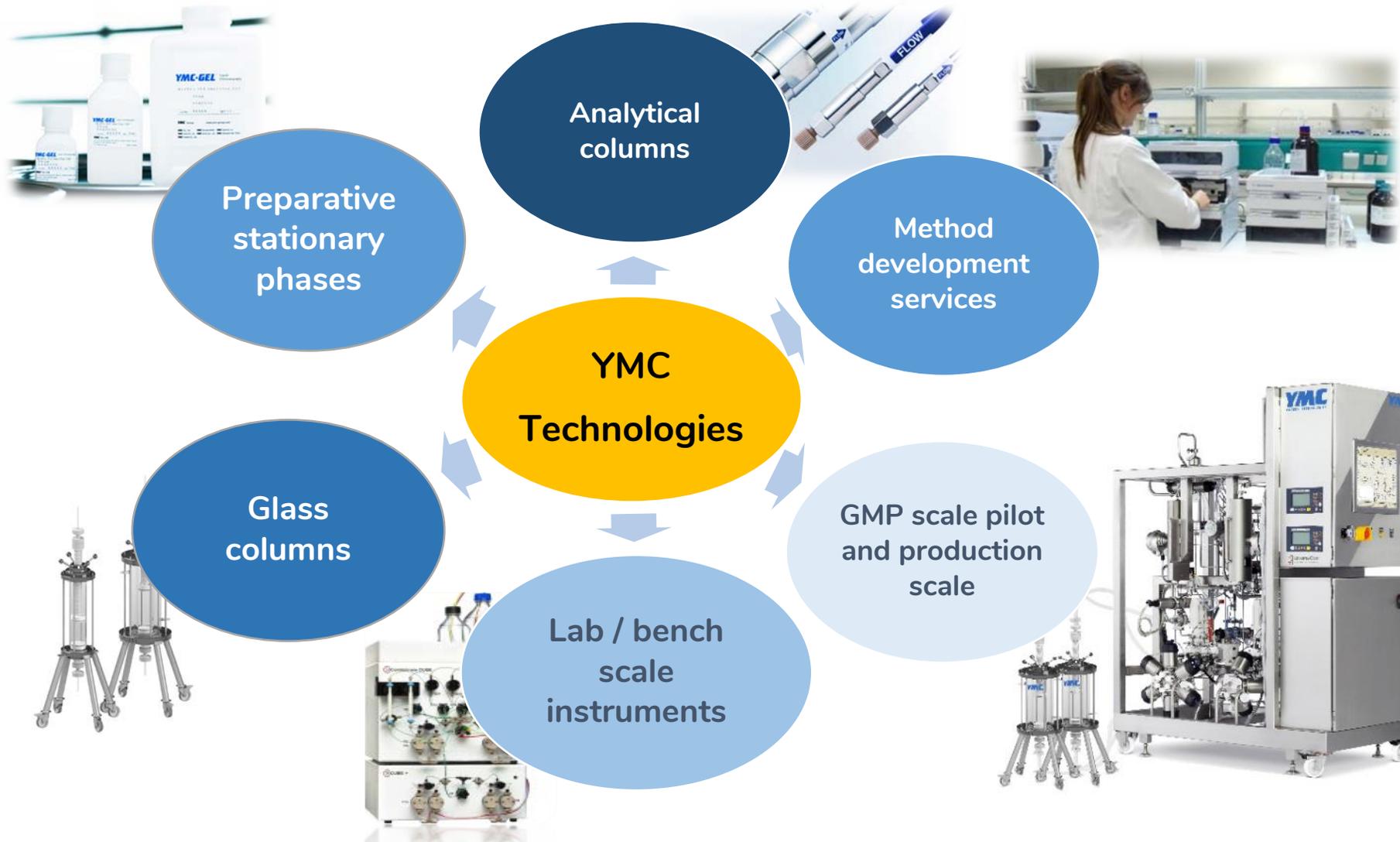


Buffer / formulation systems



A sampling of some GMP scale systems produced at YPT

Summary: Full line of lab to production purification technologies



YMC Corporate mission:
“Strive to contribute to the future of science and society by separation and purification technologies.”

YMC Vision:
As a global leader of separation and purification technologies and products.

Webinars with companion content

MCSGP GMP HPLC



Automation /operation



Process characterization



Virus clearance study



Webinar videos available on YMC Process Technologies YouTube

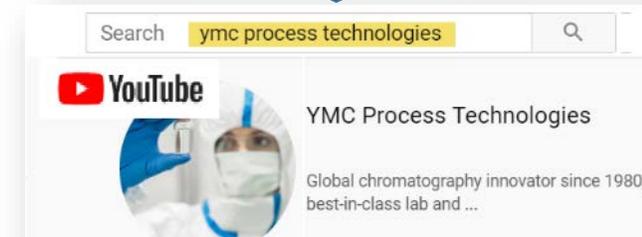
Sequential batch



Other functionality



Reports and recipes





The future provides broader solutions for our customers

YMC Co., Ltd. assumed all rights and production for the EcoPrime suite of systems in late 2018 from LEWA-Nikkiso America, Inc. and the Contichrom portfolio from ChromaCon AG in 2019. These acquisitions bring a broad spectrum of chromatographic resins, and columns ideal for large and small molecule purification in a continuous process format.

Ordering information To order the products, please contact your regional sales representative.

YMC Process Technologies
Bio/Pharma Systems' Group
8 Charlestown Street
Devens, MA 01434
Tel: +1 978 487 1100
www.ymcpt.com
sales@ymcpt.com

Headquarters: YMC Co., Ltd.
YMC Karasuma-Gojo Building
284 Daigo-cho, Karasuma
Nishiiru, Gojo-dori,
Shimogyo-ku, Kyoto, 600-8106
Japan
Tel: +81-75-342-4515
FAX: +81-75-342-4550
www.ymc.co.jp
sales@ymc.co.jp

Regional Offices:
www.ymcamerica.com
www.ymc-europe.com
www.ymcindia.com
www.ymchina.com
www.ymckorea.com
www.ymc.sg.com
www.ymctaiwan.com

ChromaCon AG
Technoparkstr. 1
8005 Zürich, Switzerland

sales@chromacon.ch
www.chromacon.ch

Tel: +41 44 445 20 11

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