



Impurity isolation for
characterization,
process
development,
regulatory support*
and quality control

N-Rich[®] Impurity Insight Service

“I need to know what my impurities are.”

“I need to isolate impurities to make analytical standards.”

“I need to purify and enrich the charge variants in my product to better characterize my process.”

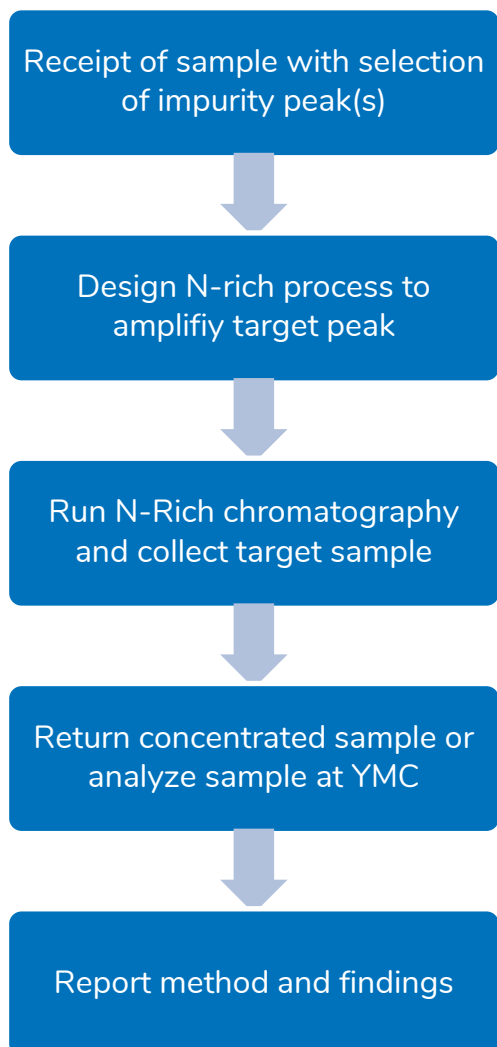
*An FDA /CEDR Guidance for Industry “Impurities in Drug Substances” (Nov. 1999) cited that there should be a 0.1 percent threshold above which isolation and characterization of individual impurities should apply to chemically synthesized drug substances.

N-Rich Impurity Identification

Save time and resources in concentrating impurities with low presence

Our N-Rich technology, can quickly amplify one or more impurities (or charge variants) present in your material. This is possible with separations that are difficult and with very low concentrations that typically require significant time and effort to isolate. Studies that were not possible or were prohibitively resource intensive, can be accomplished with the concentrated and highly purified material generated by the N-Rich technology. This has proven to be highly useful in supporting regulatory documentation and during drug development. The typical turnaround time is just several weeks. The service is available for many oligonucleotide, peptide, and protein solutions.

N-Rich service workflow:



Only a few weeks to receive:

- ✓ Sample of concentrated / purified impurity for your further work
- ✓ Report on method used
- ✓ Impurity isolation report

N-Rich services by YMC delivers:

- Time-savings for you by letting our experts in impurity amplification accelerate the process. By delivering results faster you can expediate using these insights vs. resourcing an internal purification and enrichment process
- Cost reduction by improving productivity in your lab by outsourcing the specialized impurity or charge variant isolation and reduce a tedious workflow.

Good to know:

- Contichrom CUBE systems equipped with proven automation for isolation, purification and amplification will be used for the study.
- Successful track record of impurity enrichment over years of contract work with global leaders in pharma and biopharmaceutical production.
- Analysis performed using verifiable protocols on industry standard HPLC analytics.
- Samples available for confirmation by your lab.
- Regular progress updates.
- A final report is provided.

YMC



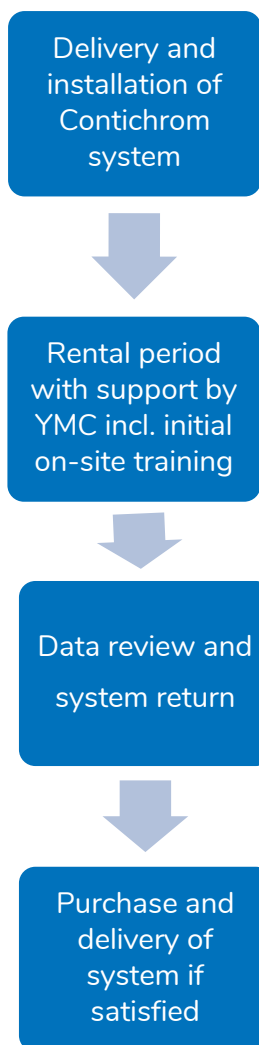
N-Rich Technology Options

Options for contract service or develop your own capabilities leveraging our N-Rich instrument.

N-Rich Insight Services enable you to assess the process using our in-house expert resources on a contract basis, or we can train your staff on the Contichrom system at your site and provide you a knowledge to get you started. Regular meetings are offered to accompany your evaluation.

Rental of equipment is available should you want hands-on experience before acquiring the instrument.

Rental Option Workflow



Refer to the brochure on the [Contichrom CUBE here](#) for full instrument specifications and capabilities

Acquire a Contichrom system equipped with N-Rich methodology.

Benefits:

- ✓ Your own In-house capability to perform N-Rich at will
- ✓ Support throughout rental or permanent installation
- ✓ Unit provides additional capabilities for your lab to investigate continuous purification as well as standard HPLC functionality

Rental or purchase advantages:

With Contichrom rentals, you gain hands-on experience with the CUBE instrument. Use your own internal resources to drive your projects and to assess the advantages of N-Rich as well as other continuous chromatography .

Whatever processes works best for you:

- Contract YMC to perform service in our global labs
- Rent a unit for your evaluation
- Purchase a unit enabling your lab direct control over leveraging this unique method.

Other capabilities for your consideration:

Our Insight Lab Services also can provide you:

- Method development
- Resin screening and recommendation
- Continuous chromatography feasibility studies using [CaptureSMB](#) and [MCSGP](#) techniques



N-Rich Process - Getting Started

I want to investigate how my company can leverage the N-Rich technology – where do I start?

Our labs are located in every major region. Select a lab or sales office in your region from the list below. You'll be put in contact with business development manager who can work with you to look at what is the optimum way for you to get started; contract service, equipment rental or purchase of an instrument equipped with N-Rich methodology.

More information in these forms are available for you to review:

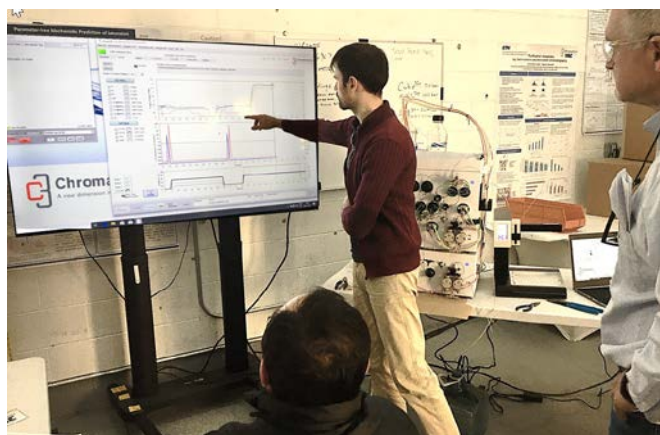
- Application note on N-Rich: [App Note](#)
- Third party peer reviewed paper (fee for access): [3rd Party Paper](#)
- On-demand 30-minute webinar on N-Rich: [Webinar](#)
- Case study on N-Rich: [Case Study](#)
- Brochure on the Contichrom CUBE instrument equipped with N-Rich: [Brochure](#)
- More lab services by YMC: [Services brochure](#)

YMC America, Inc
Process Technologies &
Insight Services lab
8 Charlestown Street
Devens, MA 01434
Tel: +1 978 487 1100
www.ymcpt.com
sales@ymcpt.com

YMC ChromaCon AG
Europe lab
Technoparkstr. 1
8005 Zürich, Switzerland
sales@chromacon.ch
www.chromacon.ch
Tel: +41 44 445 20 11

More Regional Labs:
www.ymc-europe.com
www.ymcindia.com
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www.ymctaiwan.com

Headquarters & labs: 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



Workshops: Hands-on training on continuous chromatography

Of note:

- Workshops are held in Europe, US, India, Korea and Japan
- A certificate of participation is provided

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