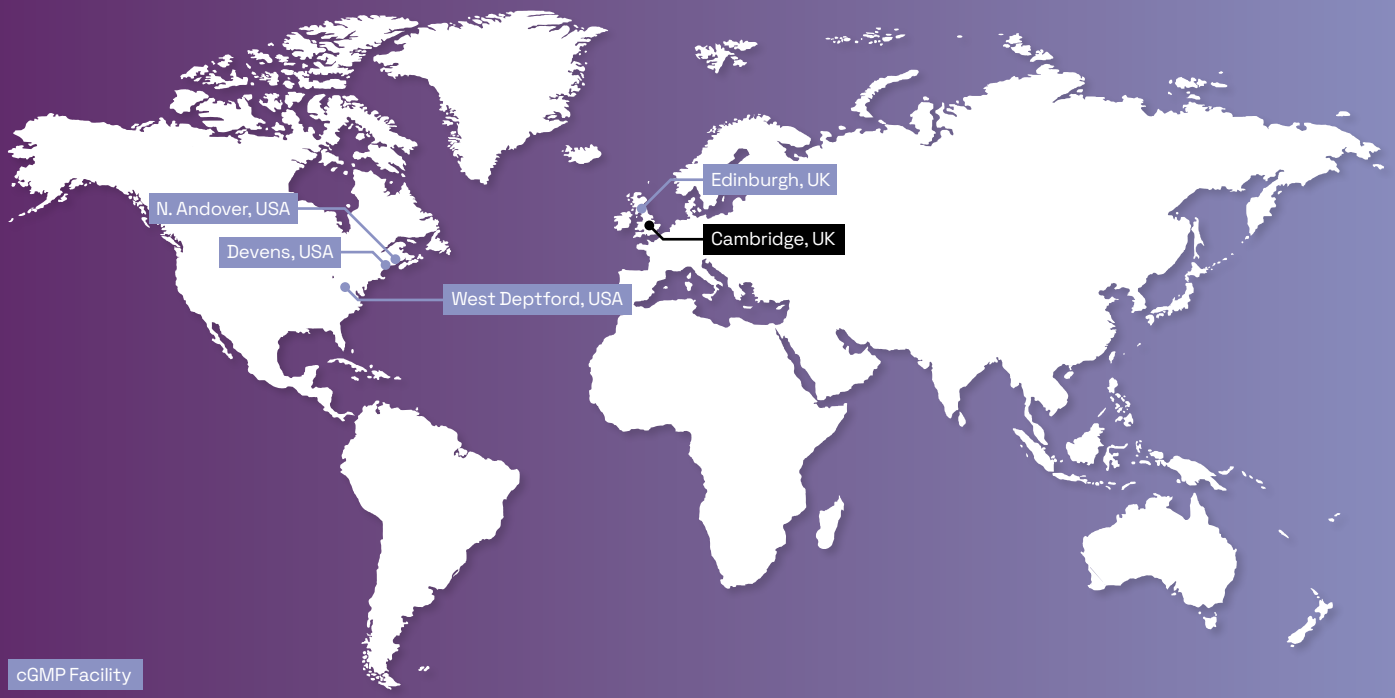
VERANOVA

Chromatography: Purification and Separation Solutions

At Veranova we offer a wide range of purification and separation solutions to support our clients' chromatography needs. Our extensive experience developing and optimizing chromatography enables robust, lower-cost separation steps in our clients' processes. Leveraging cutting-edge knowledge and instrumentation, Veranova can purify an extensive range of APIs in line with cGMP standards, including amorphous solids, lipids, drug polymer conjugates, antibody-drug conjugate (ADC) linkers and warheads, and peptide and nucleoside analogs.

To accomplish this goal, our chromatography team works closely with our analytical, chemical development and solid form experts to offer a fully integrated approach to the development process. Whether you need to purify your API to FDA standards or identify impurities in preparation for scale-up, Veranova can help support your project, from development all the way through to production on our 120 cm dynamic axial compression (DAC) column.



Separation Solutions

Screening and Method Development

Veranova's expert team of scientists can provide the latest in preparative chromatography technologies to support each development project. Our fully automated screening by supercritical fluid chromatography (SFC) and high-performance liquid chromatography (HPLC) enables us to quickly assess the most effective instrumentation and modalities for your chromatography scale-up needs.

A diverse range of chromatography stationary phases, solvents and modifiers can be rapidly screened, enabling quick development of optimal preparative separation conditions for all types of APIs. Meanwhile, our mass spectroscopy-coupled instrumentation allows our team of expert scientists to tackle the purification of molecules without a chromophore.

Controlled Substances

Veranova has over 50 years' experience in the development and manufacturing of controlled substances. We can perform purification of controlled substances at manufacturing scale and are licensed for Schedule I-V compounds.

Chiral Separations

Chiral separation is a vital step in the development process. At Veranova, we can perform chiral separations for starting materials, catalysts, intermediates, and APIs.

Applying our cutting-edge SFC capabilities, we identify the optimal chiral separation method for each API. Crucially, using supercritical CO_2 as a solvent allows SFCs to operate at much higher flow rates than HPLC, resulting in quicker cycle times. The majority of SFC methods are isocratic, accelerating purification times even further through the use of stacked injections.

Impurity Isolations

At Veranova, we can rapidly isolate and identify impurities from intermediates and APIs, streamlining the development process. These can then be synthesized by our team of chemists for use as markers in further analytical investigations.

Post-purification, we use our extensive analytical expertise to accurately identify unknown impurities. Veranova's analytical instrumentation capabilities include:

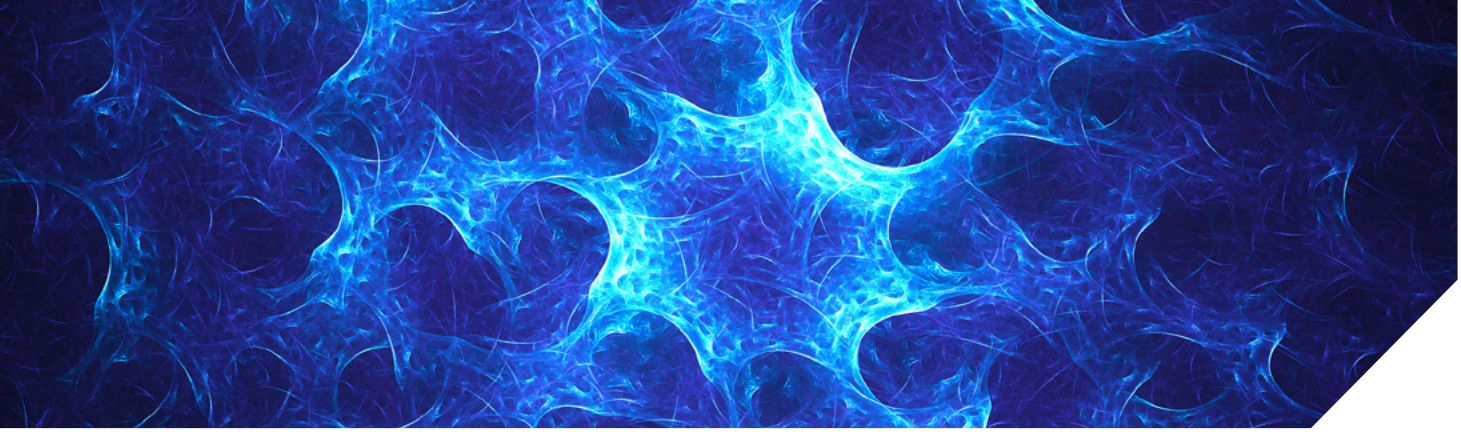
- NMR
- Mass spectroscopy (MS)
- UV-Vis spectroscopy
- Fourier-transform infrared spectroscopy (FTIR)
- Raman spectroscopy
- X-ray powder diffraction (XRPD)
- Polarimetry

Purifications

Our team of separation scientists can efficiently identify and develop the right purification methods for your project, ensuring the isolation of high purity APIs at every step of your process. Veranova can provide GMP purifications across a full range of chromatography techniques, from smaller quantities to the metric tons required for large-scale manufacture.

Purifications for HPAPIs

Veranova's extensive expertise in highly potent API (HPAPI) development, manufacturing and purifications allows us to implement the correct safety and handling procedures with confidence. We have developed HPAPI purifications on most of the ADC programs we've worked on over the last 10 years. We are able to purify HPAPIs at every scale, from early development to manufacturing.



Chromatography Capabilities

At Veranova, we have the instrumentation and expertise to offer a full range of preparative chromatographic modalities, available at every scale from development to manufacturing.

Veranova's chromatography and separation capabilities include:

- Normal phase and reverse phase chromatography
- Ion exchange chromatography
- Hydrophilic interaction liquid chromatography (HILIC)
- Solid-phase extraction
- Chiral separation
- Size exclusion chromatography

HPLC

HPLC enables even the most challenging compounds to be produced and delivered at high purity. HPLC can be a valuable tool to isolate and identify hard-to-ionize impurities.

Agilent 1290 preparative HPLC-MS	(1 - 100+ g)
YMC K-Prep 1500G	(100 g - 20 kg)

Medium Pressure Liquid Chromatography (MPLC)
Dynamic Axial Compression (DAC) Columns (Plant Scale)

Veranova has DAC columns available at every scale of GMP manufacturing purification. Our team of purification scientists optimize the purification methods to obtain the maximum loading and highest possible purity for every compound.

50 cm diameter	(30+ kg)
1 m diameter	(100+ kg)
1.2 m diameter	(200+ kg)

Automated MPLC Chromatography Instruments

Veranova is equipped with Automated MPLC Column Purification Systems (Biotage Teledyne), allowing consistent and efficient scale-up.

CombiFlash NextGen 300+	(10 mg – 150 g)
CombiFlash Torrent	(0.5 – 300 g)
Biotage 400	(1 - 8 kg)

MPLC Flash Columns (Kilo Lab Scale)

30 cm diameter	(500 g – 3 kg)

SFC

Veranova's SFC expertise, coupled with our world-leading range of instrumentation, allows us to purify or chirally separate challenging molecules quickly and efficiently at every stage of development. SFC is usually thought of as a normal phase technique. However, with the use of additives or water, SFC can separate molecules typically thought of as 'too polar' for normal phase.

Shimadzu Nexera preparative SFC	(10 mg – 100+ gs)
Novasep 20/30	(10 mg – 100+ gs)
Novasep Supersep 100	(1 - 10 kg scale)
Novasep Supersep 200	(10-100 kg scale)

Post-Separation Processing and Solvent Removal for Isolations

Veranova can perform an array of post-separation techniques to accommodate your drug development needs. These include:

- **Thin film evaporators** for rapid solvent removal during API isolation and solvent recovery
- **Lyophilizers** for heat-sensitive APIs and hard-to-isolate solids
- **Large-scale rotary evaporators** for solvent removal in the development and kilo labs
- **Solid phase extraction** to enable on-column separation and concentration
- **Crystallization** to eliminate impurities during API isolation

Veranova's analytical team offers complete analytical characterization and QC testing to meet GMP requirements. From impurity isolations to production-scale purifications, Veranova offers a full scope of chromatography instrumentation and techniques, enabling us to provide support at every step along your drug development journey.

With over 50 years' experience navigating the challenges of the global healthcare industry, Veranova's drug development solutions enable better products and a faster route to market.

To find out more visit VERANOVA.COM

or email INFO@VERANOVA.COM

Find out more about our chromatography capabilities on our website: