



Analytical Services



Our analytical expertise supports all of your drug development challenges, from discovery to commercialization.

At Veranova, we combine over 50 years of pharmaceutical excellence with a team of dedicated scientists to provide customers with robust, high-quality analytical methods throughout all phases of clinical development, cGMP scale-up, and commercialization.

Backed by our extensive knowledge, instrument capabilities, and our collaborative approach, we support your project with our leading analytical capabilities to get your compound GMP ready, on time, and at budget.





Tailored analytical services to accelerate your launch to market

Reference Standard Qualification and Impurity Isolation & Characterization

Veranova offers a robust lifecycle approach for reference standard qualifications and requalification by ensuring identity, strength, quality, purity, and potency.

Stability Testing

Across our sites, we have over 20 stability chambers available for supporting full ICH GMP and non-GMP studies.

Our chambers are available across all temperature zones, meeting our customers' stability data needs and providing confidence for their marketing authorization applications.

Through extensive forced degradation studies, we ensure that stability methods are fully robust and fit for purpose.

Potent Compound Capabilities

We carry out significant safety assessments at our Devens, MA, and West Deptford, NJ, sites, ensuring controls are in place to handle potent compounds with occupational exposure limits (OELs) down to $0.01 \mu\text{g}/\text{m}^3$ in our highly potent handling isolators and $1 \mu\text{g}/\text{m}^3$ in potent handling isolators.

Following appropriate sample preparation, potent compounds can be safely analyzed via several instruments to confirm purity and other characterization tests.

Controlled Substances

We have extensive knowledge and experience in handling and testing controlled substances, providing unique insight into the critical issues surrounding these compounds, and an excellent relationship with the relevant governing agencies such as the US Drug Enforcement Agency.

As such, Veranova is a proven leader in testing controlled substances, such as opiates, amphetamines, cannabinoids, and synthetic

stimulants. And our analytical teams diligently support the analysis of controlled substances in therapeutic classes including analgesia, CNS disorders, and anti-addiction treatments.

Compendial Methods and Assessments as per ICH Requirements

Our analytical scientists have extensive expertise in performing assessments as per Pharmacopeial General Chapters and ICH Guidelines.

Our experts will provide robust, quality-driven risk assessments to ensure that the regulatory requirements are met or exceeded. This includes detailed reports and assessments on:

- Screening & product specific methods
- Phase appropriate method qualification, validation & transfer
- Nitrosamine risk assessment & testing
- Elemental impurity risk assessment & testing
- Benzene risk assessment & testing
- Mutagenic impurity risk assessment & testing with the design of spike-fate-and-purge experiments

Analytical Services for Antibody Drug Conjugates (ADC's) and Linkers

Our state-of-the-art equipment capabilities (LC-MS/MS, NMR, SEC-MALS, and size exclusion chromatography) provide an end-to-end characterization experience in the emerging field of ADC and linkers. We deliver phase appropriate analytical methods (development and qualification/validation) for testing drug candidates of ADCs and delivering robust analytical methods for quality control use as per the ICH requirements.

Our testing capabilities cover both functional and physiochemical properties, including in process control, release and stability indicating methods. Veranova has extensive knowledge in determining the concentration and extent of drug conjugation achieved, and distribution levels of the ADC's and linkers.

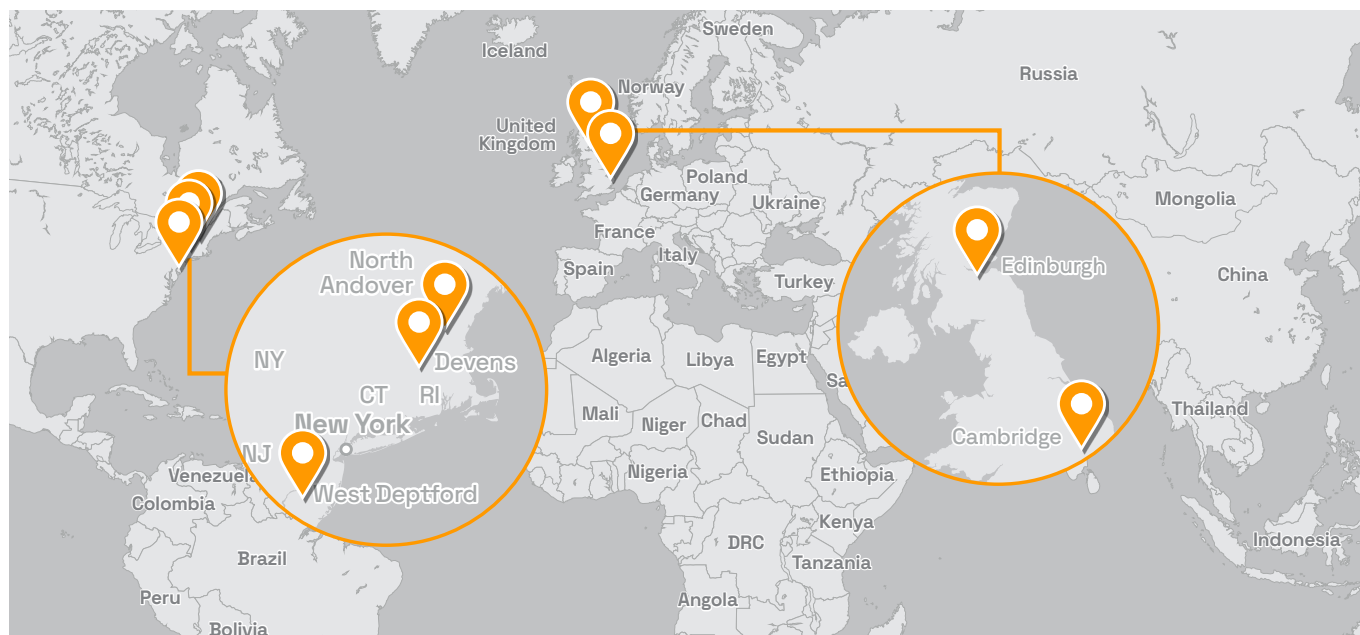
Advance your science with Veranova

Our Sites

Across our global network of sites, we can help ensure quality control for your analytical method development, qualification, validation, and transfer from non-GMP to cGMP.

We support your simplest and most challenging regulatory and project requirements, with:

- Over 7000 sq. ft. of analytical laboratory space
- State-of-the-art instrumentation
- Proven capabilities of over 50 scientists



DoE Capabilities

Each of our sites can conduct a statistical design of experiment (DoE) to determine initial method parameters and/or aid with robustness testing to facilitate AQBD principles of lifecycle management [ICHQ12].

Instrumentation Capabilities

Our extensive instrumentation capabilities allow the examination of a diverse range of compounds/APIs for existing and future innovator products and support a wide range of testing for gathering more information or supporting DMF submissions.

Ultra-high-performance liquid chromatography (UPLC) systems	Diverse range of detectors including: ultraviolet, photodiode array, charged aerosol detector and mass spectroscopy detectors
High-performance liquid chromatography (HPLC) systems	A wide selection of detectors including: variable wavelength, diode array, charged aerosol, mass spectroscopy and refractive index detectors
Liquid chromatography (LC) multi-column switching systems	Rapid column selection in method development and ruggedness testing
Supercritical fluid chromatography (SFC)	Variable wavelength detector
Gas chromatography systems	Headspace/direct injection systems. Diverse range of detectors including: flame ionization, mass spectrometry, electron capture and flame photometric detectors
Ion Chromatography	Systems with conductivity and UV detectors
Spectroscopy	NMR, UV-Vis, Fourier transform infrared spectroscopy (FTIR), RAMAN, ICP/MS, ICP/OES, X-ray powder diffraction, polarimetry
Physical and Chemical	Thermal gravimetric analysis, differential scanning calorimetry, dynamic vapor sorption, pKa determination, scanning electron microscope, microscopy (optical and hot stage) PSD-laser diffraction



A CDMO that manages complexity with confidence

At Veranova, backed by our wide-ranging knowledge and capabilities, we provide the industry with a first-class mix of leading analytical, synthetic chemistry, and solid form and particle engineering services. Our integration of systems ensures a high-quality approach to getting compounds GMP ready and provides our customers with cost savings, through efficient and more sustainable processes.

How can Veranova support your project's needs?

- **Phase appropriate method development** throughout preclinical, clinical, and commercial phases, reinforced by **qualification, validation, and transfer of all analytical method development** across sites.
- **Integrated process and product development approach** to enable **full analytical support for regulatory starting materials**, intermediates and APIs, and dynamic in-process control strategies.
- Characterization of APIs and precursors using **advanced analytical techniques** and **state-of-the-art instrumentation**, such as HPLC, UPLC, GC, IC, ICP-MS, ICP-OES, NMR, XRPD, and laser diffraction.
- **Experienced scientific team** delivering **method development, optimization, and validation** in line with ICH, FDA, MHRA, EMEA, and ANVISA requirements.
- **Rapid method development**, leveraging **advanced analytical techniques** and **multicolumn screening** of analytical methods.



To find out more visit
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