Brochure: Solutions for pharmaceutical analysis
BR013(EN)-01-B September 2017

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Solutions for pharmaceutical analysis

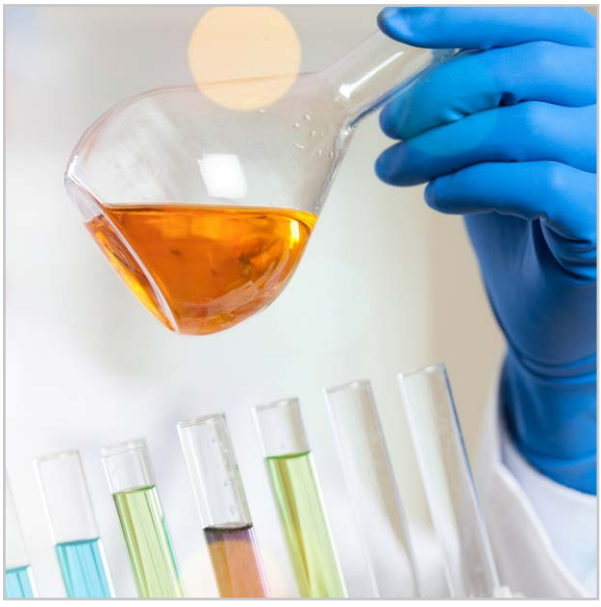
Pharmaceutical analysis systems

The pharmaceutical industry is driven by continuous development.

The challenge of bringing a drug to market has changed drastically over the last decade as business, science and regulation evolve globally. At Renishaw, we are continuously developing analytical solutions to help you succeed.

We have extensive experience designing and developing Raman systems, providing solutions with superior performance. Our systems have the potential to transform discovery, development and manufacturing in the pharmaceutical industry. A Renishaw Raman system gives you the tools to stay ahead of the competition and regulatory requirements.

> Renishaw Raman systems make pharmaceutical analysis simple. Users can obtain detailed information about the distribution of chemical species, with the simplest sample preparation. A Renishaw system provides users with practical solutions, giving reliable results without complexity.
>
> **Tim Smith, Head of Applications, Renishaw plc**



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Renishaw: at the forefront of analytical innovation.

Renishaw is a world leader in Raman spectroscopy instrumentation, with over 25 years' experience supplying Raman systems to customers worldwide. We are a global company, with a worldwide network of scientists and engineers who are on-hand to provide you with expert product, applications and technical support.

We understand the many challenges within pharmaceutical analysis and our flexible solutions have been designed with your needs in mind. Whether novice or expert, formulator or quality analyst, we have a system to meet your requirements.

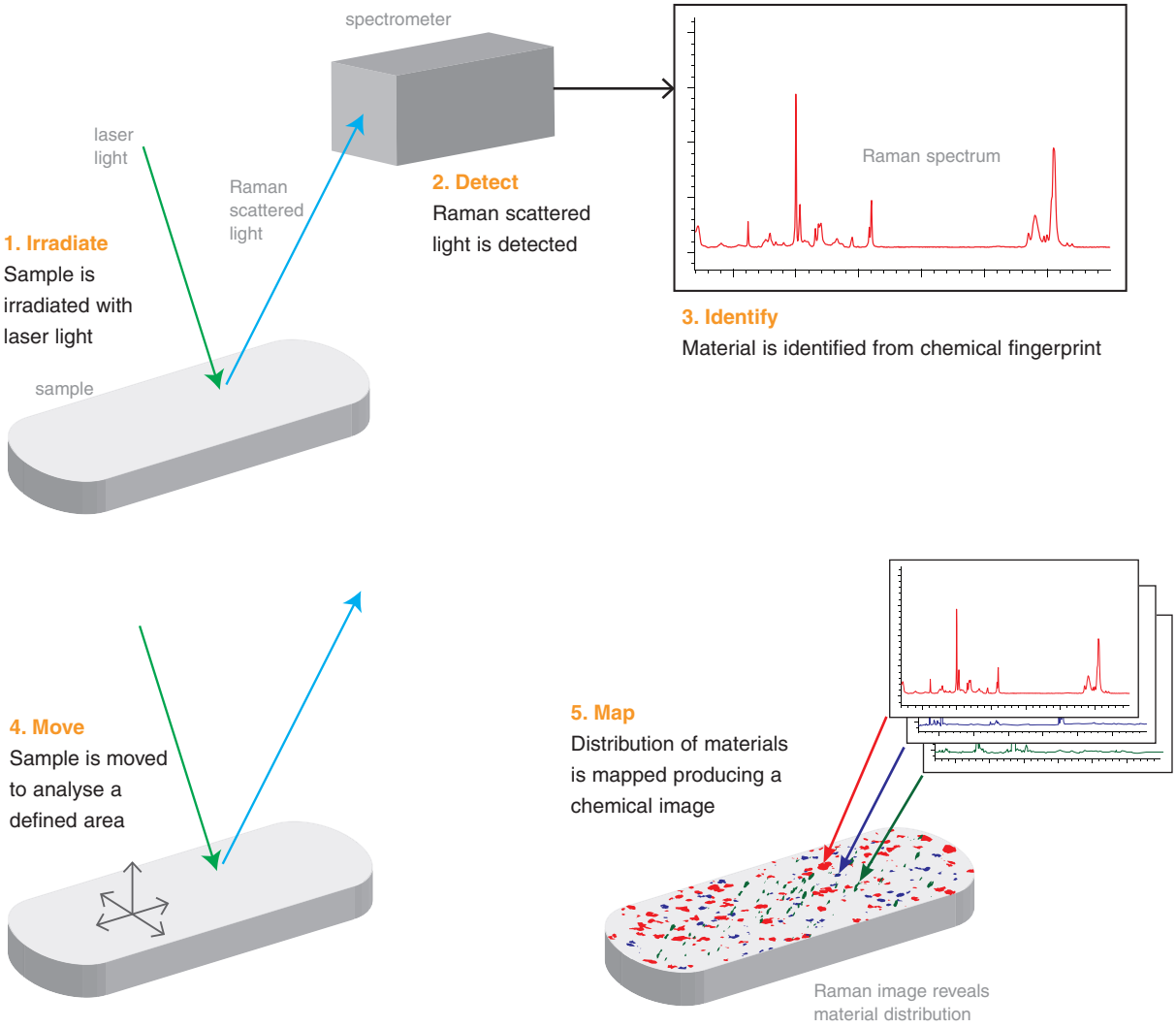
> We chose a Renishaw Raman system for multiple reasons. It delivers excellent Raman sensitivity and throughput and also offers us high potential for automation.
>
> **University of British Columbia (Canada)**

How can Raman spectroscopy help me?

Raman spectroscopy is an optical analysis technique that detects Raman scattered light. It reveals the chemical composition of materials and can determine the distribution of constituents.

- **Non-destructive;** analysis without time-consuming sample preparation
- **Flexible;** analyse formulated products, polymorphic APIs, live cells and much more
- **Spatial information;** determine the distribution of constituents within samples
- **Quantitative data;** obtain numerical metrics such as domain size statistics

Raman spectroscopy and imaging overview



1. Irradiate
Sample is irradiated with laser light

2. Detect
Raman scattered light is detected

3. Identify
Material is identified from chemical fingerprint

4. Move
Sample is moved to analyse a defined area

5. Map
Distribution of materials is mapped producing a chemical image

Raman image reveals material distribution

To find out more about Raman spectroscopy, visit www.renishaw.com/RamanExplained

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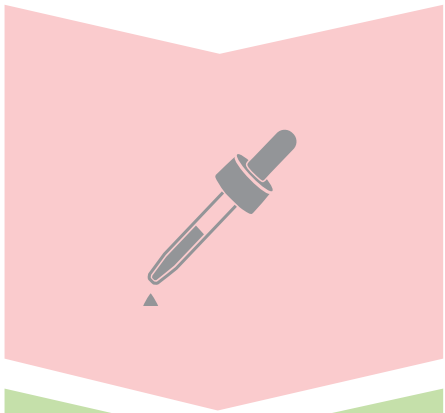
Solutions for you

Renishaw Raman systems are ideal for analysis throughout drug development and manufacture.



Drug discovery

- Protein structure analysis
- High throughput assay/screening
- Live cell imaging studies

Chemical development

- Solid form optimisation
- Polymorph identification
- High throughput crystallisation
- Stability studies

Drug formulation

- Identification of critical quality attributes
- Product stability studies
- Scale up validation
- Reverse engineering

Quality manufacturing

- Monitoring critical quality attributes
- Root cause failure analysis
- Screening for counterfeits
- Contamination analysis

Drug discovery

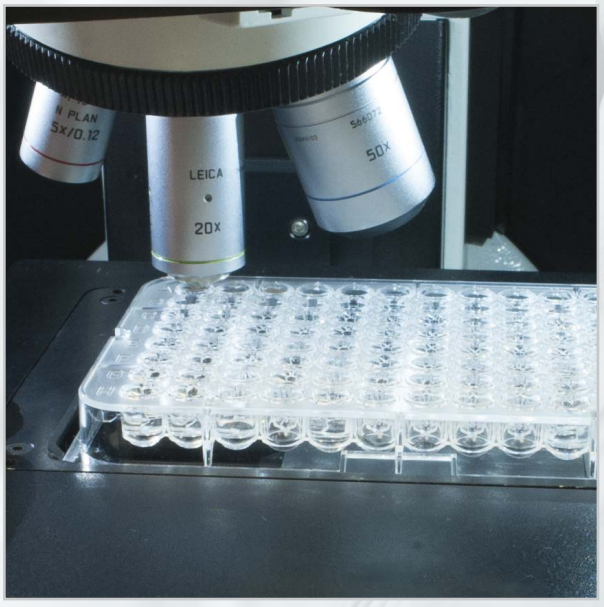
With heightened regulatory pressures, toxicity concerns and demand to increase productivity, innovative approaches to discovery are essential. By providing rapid, non-contact, non-destructive analysis of both drugs and biological material, Renishaw Raman systems help you improve the quality of your drug development pipeline.

Protein structure analysis

Use Raman spectroscopy to analyse protein conformations and local environments, both in solution and crystalline form. You can analyse samples in aqueous solutions, preserving biological activity, allowing the study of subtle conformational changes as they occur.

High throughput assay/screening

Speed up discovery and development of drug candidates with high-throughput techniques using Renishaw's automated Raman systems. Rapid, non-contact, non-destructive analysis allows simple *in situ* measurements of batches of samples, with little or no sample preparation.



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Live cell imaging studies

Raman spectroscopy is ideal for live cell studies. It can reveal intracellular concentrations of biomolecules under normal physiological conditions, without the need for labelling. From receptor/target identification to cellular drug metabolism, it has applications throughout drug discovery. Use Raman imaging to monitor cellular drug uptake and distribution. Collect quantifiable results and gain valuable insights into drug delivery pathways.

Chemical development

We understand that extensive chemical development is essential in the drug development process, and is required to fully understand the physiochemical properties of candidate drugs. Renishaw Raman systems have been used extensively in this area to investigate and optimise the API solid forms.

Solid form optimisation

Variation in API solid forms (e.g. polymorphs, solvates, hydrates, salts and co-crystals) affects solubility, bioavailability and manufacturability. Use a Renishaw Raman system to identify, investigate and optimise your API solid form.

Polymorph identification

Polymorphs are different crystalline forms of the same molecule, that can have vastly different physiochemical properties. Different polymorphic forms produce different Raman spectra, allowing them to be unequivocally distinguished. Use Renishaw Raman systems to monitor *in situ* formation and measure samples with little or no preparation.

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High throughput crystallisation

The appearance of new polymorphic forms in later stages of drug development can have dire consequences, with severe financial implications. Many companies therefore invest in extensive polymorphic studies during early development. Renishaw Raman systems, with their high levels of automation and rapid data collection, are ideally suited to polymorph monitoring during high throughput (HT) crystallisation studies.

Stability studies

Understanding the stability of solid API and excipient forms over time and under varying environmental conditions is critical when considering storage stability and patent protection. Renishaw Raman systems provide a comprehensive and integrated solution for investigating phase transformations; such as polymorphic changes and anhydrate-hydrate transitions.

Drug formulation

We understand the importance of creating robust and compliant formulations, when developing pharmaceuticals. Following a quality by design (QBD) approach ensures product understanding and effective risk management. Renishaw Raman systems allow tablets, creams and powders to be studied with ease. You can perform rapid, non-destructive measurements of rough and uneven surfaces without sample preparation.

Identification of critical quality attributes

During drug formulation, it is essential to identify critical quality attributes (CQA) so that product integrity can be monitored and assured. Renishaw Raman systems can rapidly identify domains and measure their size and distribution, parameters that can affect dissolution rates and bioavailability.

Product stability studies

It is important to understand the stability of a formulated product to ensure the patient receives the correct dose of the correct active ingredient. Renishaw Raman systems can quickly identify if formulations contain the right compounds and ensure they have not undergone any chemical transformations.

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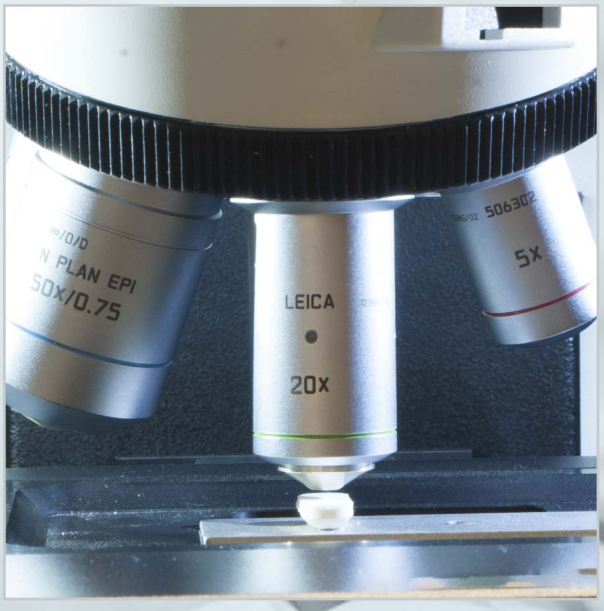
Scale up validation

Transferring formulation from research to production is challenging. It is essential that the final product is identical to that characterised during development. Use Renishaw Raman systems during scale up to verify the consistency of formulations and validate processing methods.

Reverse engineering

When replicating patent-expired formulations it is desirable to avoid expensive lengthy development. De-formulate products easily: use Renishaw Raman systems to determine the composition, domain size and distribution of APIs and excipients within formulations.



Quality manufacturing

Pharmaceutical dosage forms are complex, and it is challenging to control product quality. Raman spectroscopy is extensively used for identification of raw materials, but now you can use it throughout quality assurance and control. Renishaw Raman systems analyse rapidly and non-invasively giving information you cannot get from other analytical techniques.

Monitoring critical quality attributes

Once identified in formulation development, critical quality attributes (CQA) should be monitored throughout scale up and manufacture to avoid changes to product quality. Use Renishaw Raman systems to rapidly, reliably, and quantifiably monitor CQA such as domain identity, size and distribution.

Root cause failure analysis

Various analytical methods can identify a failed product, however, discovering the root cause of a failure can be time consuming and costly. Renishaw Raman systems provide detailed information on the location and composition of domains within formulations, helping to determine where in the manufacturing process the failure occurred.

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Screening for counterfeits

A counterfeit product may contain the incorrect ingredients or the wrong quantity of API. Simple analysis may incorrectly identify the latter as genuine product. Use Renishaw Raman systems to differentiate and quantify APIs and excipients within samples, unequivocally identifying counterfeits.

Contamination analysis

Renishaw Raman systems are ideal for studying and identifying contaminants. They have the resolution to see small particles (down to micron sized), can unambiguously identify unknowns using a spectral library, and do not damage samples.

Our products

Renishaw Raman systems combine the highest performance with ultra-fast data collection. You can generate information rich chemical images and see the composition and distribution of compounds in intricate detail. Coupled with Renishaw's powerful software our systems enable you to analyse a broad range of samples with quantifiable results. Our products have the functionality and validation required to meet the specific challenges of pharmaceutical regulations.

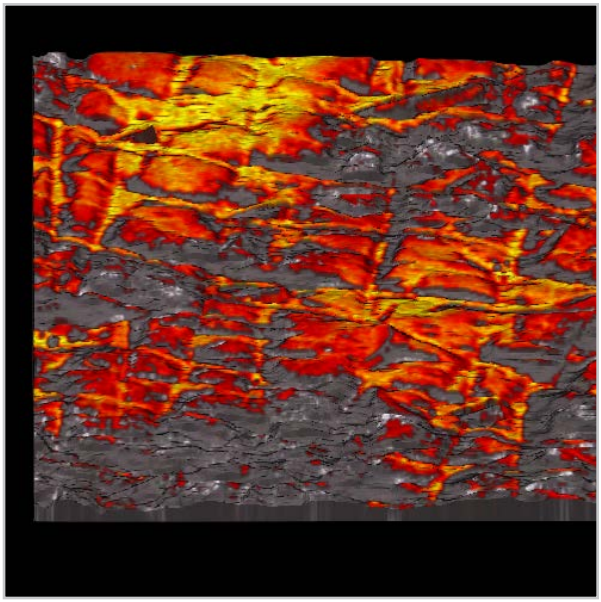
RA802 Pharmaceutical Analyser

Renishaw's RA802 system is designed exclusively for the pharmaceutical industry. The RA802 is a chemical imaging system optimised for routine analysis with the speed, automation and precision you need for reliable results. It is ideal for use in busy laboratories where the rapid analysis of multiple samples is required and space is at a premium.

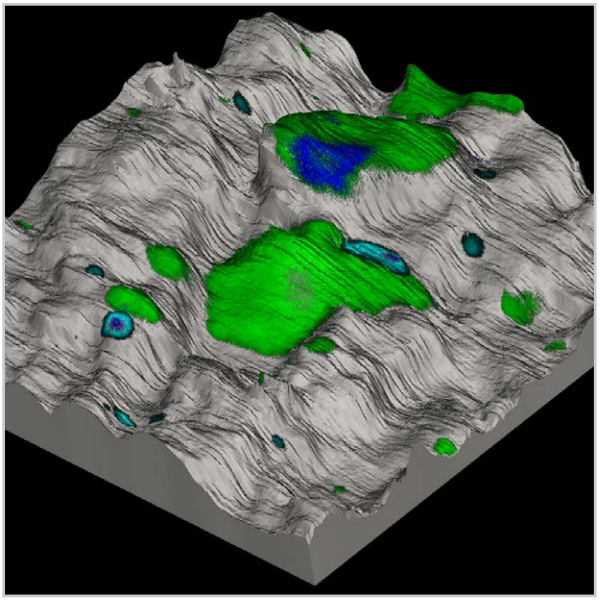
inVia™ confocal Raman microscope

Renishaw's inVia is a fully configurable research grade Raman microscope. Scientists worldwide trust inVia and its unparalleled flexibility. It can be upgraded, modified and customised, without compromising performance. Add accessories, lasers, fibre optic probes or combine with other analytical techniques. Whatever configuration you choose, you will have the most flexible Raman system on the market.

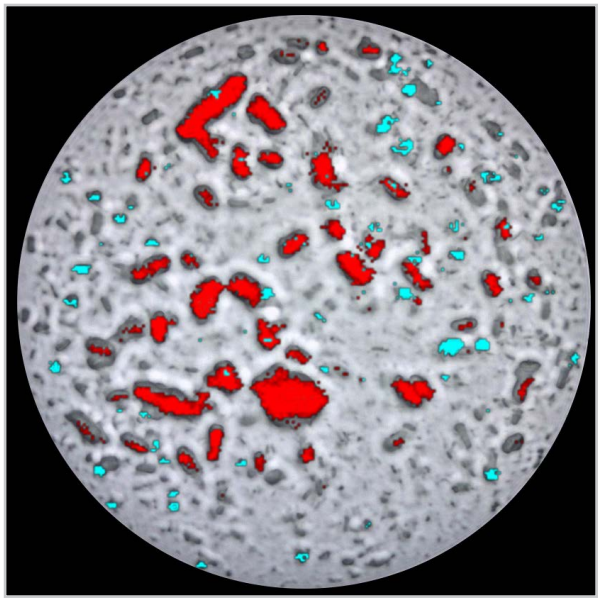
Results



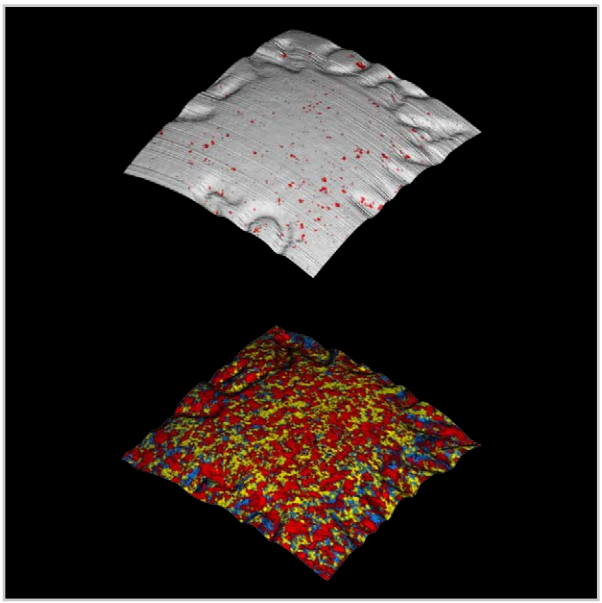
Distribution of ibuprofen gel (orange) on skin.



Powder mixture showing two polymorphic forms (green/blue) of an API.



Allergy relief spray showing the distribution of API (cyan) and micro crystalline cellulose (red).



Outer surface of counterfeit and authentic tablets revealing differences in constituents.

For more information about Renishaw Raman systems and their applications in the pharmaceutical industry, please contact us at raman@renishaw.com or discover more at www.renishaw.com/raman

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About Renishaw

Renishaw is an established world leader in engineering technologies, with a strong history of innovation in product development and manufacturing. Since its formation in 1973, the company has supplied leading-edge products that increase process productivity, improve product quality and deliver cost-effective automation solutions.

A worldwide network of subsidiary companies and distributors provides exceptional service and support for its customers.

Products include:

- Additive manufacturing and vacuum casting technologies for design, prototyping, and production applications
- Dental CAD/CAM scanning systems and supply of dental structures
- Encoder systems for high-accuracy linear, angle and rotary position feedback
- Fixturing for CMMs (co-ordinate measuring machines) and gauging systems
- Gauging systems for comparative measurement of machined parts
- Laser and ballbar systems for performance measurement and calibration of machines
- Medical devices for neurosurgical applications
- Probe systems and software for job set-up, tool setting and inspection on CNC machine tools
- Raman spectroscopy systems for non-destructive material analysis
- Sensor systems and software for measurement on CMMs
- Styli for CMM and machine tool probe applications

For worldwide contact details, visit www.renishaw.com/contact

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