

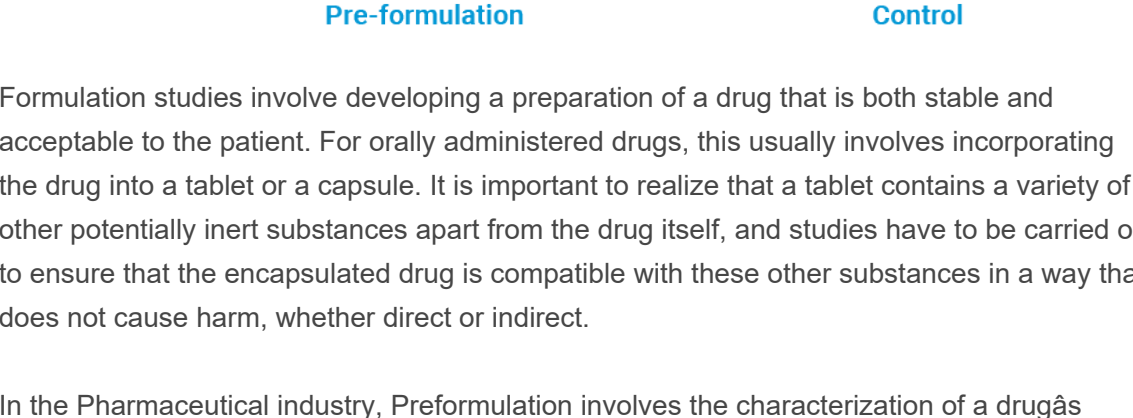


JUNE 2021, ISSUE 96

## WELCOME

Starting with this issue of *The Bridge*, we will focus each month on a certain aspect of one of Rigaku's key markets. This issue will focus on the Formulation stage of the Pharmaceutical industry. Each month we will focus on a different aspect of a key market and how Rigaku's products can be successfully used in those markets. We hope this will give our readership a broader view of Rigaku's unique position in serving and supporting today's vast technological advances.

### Workflow of the Pharmaceutical Industry



Formulation studies involve developing a preparation of a drug that is both stable and acceptable to the patient. For orally administered drugs, this usually involves incorporating the drug into a tablet or a capsule. It is important to realize that a tablet contains a variety of other potentially inert substances apart from the drug itself, and studies have to be carried out to ensure that the encapsulated drug is compatible with these other substances in a way that does not cause harm, whether direct or indirect.

In the Pharmaceutical industry, Preformulation involves the characterization of a drug's physical, chemical, and mechanical properties in order to choose what other ingredients (excipients) should be used in the preparation.

Following the Preformulation stage, Formulation studies then consider such factors as particle size, polymorphism, pH, and solubility, as all of these can influence bioavailability and hence the activity of a drug. The drug must be combined with inactive ingredients by a method that ensures that the quantity of drug present is consistent in each dosage unit; e.g., each tablet.

The amount of effort that goes into the Formulation stage is a testament to the commitment of the pharmaceutical industry to ensure that drugs are both safe and effective. Rigaku is proud to provide solutions to this critical area of the discovery and production of drugs.

## FEATURED APPLICATION NOTES



### Raman

#### Drug Product Identification Using Handheld Raman

*Rigaku Analytical Devices*

Handheld Raman spectroscopy is well accepted as a technique for raw material and excipient identification within the pharmaceutical industry. Using the correct Raman excitation wavelength can extend its capabilities into the areas of drug substance and drug product identification. It is useful for identifying drug products and drug substances, verifying API dose and placebos, and reducing material transfer.

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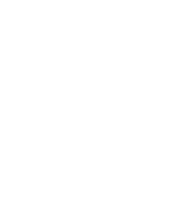
### XRD

#### Observation of Dehydration Process of Hydrate by XRD-DSC Simultaneous Measurement Under Temperature and Humidity Atmosphere

*Rigaku Corporation*

The crystal systems of pharmaceuticals and foods may change due to factors such as temperature and humidity. The climate of Japan in particular exhibits extreme changes in temperature and humidity, with hot and humid summers, and dry, low-temperature winters; these are poor conditions as an environment for synthesizing pharmaceuticals or storing foods. Therefore, there is a need to conduct measurement beforehand under various atmospheric conditions and determine what sort of changes these materials undergo in the actual environment. Thus we evaluated thermal changes and changes in the crystal structure of pharmaceuticals by simultaneously measuring X-ray diffraction (XRD) and differential scanning calorimetry (DSC) while varying humidity.

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### XRD

#### Quantitative Analysis of Polymorphic Impurities in a Drug Substance by the Calibration Method Using a Benchtop X-ray Diffractometer

*Rigaku Corporation*

Polymorphic forms and hydrates are different in solubility and absorption, so it is important to control and evaluate them during drug development and manufacturing. Here is an example where we calculated the amount of polymorphic impurities in a drug substance using a high-speed 1D detector, which can obtain intensity data sufficient for qualitative and quantitative analysis in a short period of time, with a benchtop X-ray diffractometer to obtain diffraction data and perform quantitative analysis by the calibration method.

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### EDXRF

#### Palladium Catalyst in Pharmaceuticals

*Applied Rigaku Technologies*

Palladium is a common catalyst in the manufacturing of pharmaceuticals. Pills and tablets are ground to homogeneous powder to test for any retained spent Pd as well as other heavy metals such as unwanted Cd, Pb, Hg and Br as part of the quality control process. The Pd is also monitored during the recovery of the catalyst material. Cellulose is a common medium for pharmaceuticals and testing is often done in pills ground to powder or cellulose powder itself. For quality control and manufacturing purposes, Rigaku NEX DE EDXRF analyzer is an excellent tool for the measurement of trace heavy elements and other elements of interest in pharmaceutical products.

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## FEATURED PRODUCTS



### Progeny

Progeny is a technologically advanced handheld Raman spectrometer, expertly designed for processes including incoming material receiving, the warehouse, clean room, laboratory analysis and mobile lab. With the push towards 100 percent raw material inspection, the Progeny handheld Raman analyzer enables users to reduce workflow steps and make immediate decisions. Progeny's software provides fast and simple PASS/FAIL results, helping to achieve leaner manufacturing processes and lower costs per analysis without compromising quality.

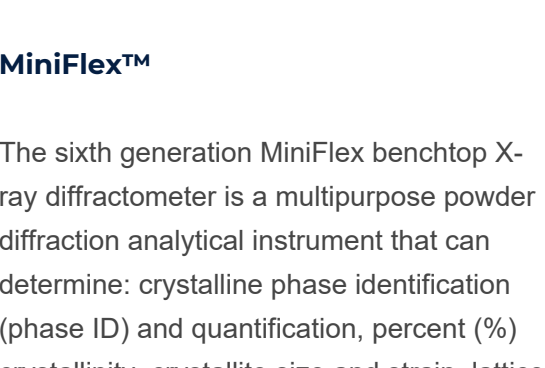
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### SmartLab®

Rigaku SmartLab is the newest and most novel high-resolution X-ray diffractometer (XRD) available today. Perhaps its most innovative feature is the new SmartLab Studio II software, which provides the user with an intelligent User Guidance expert system functionality that guides the operator through the intricacies of each experiment. It is like having an expert standing by your side.

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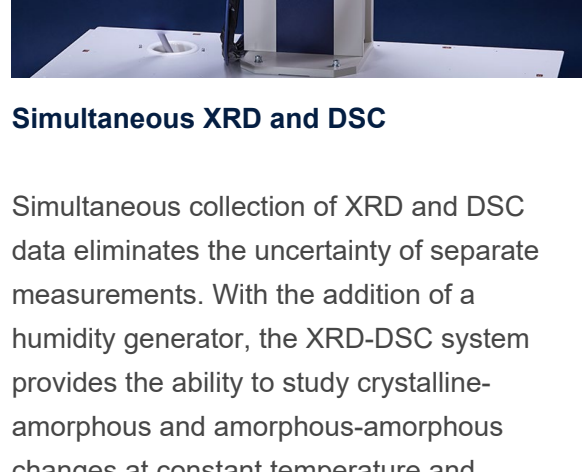


### MiniFlex™

The sixth generation MiniFlex benchtop X-ray diffractometer is a multipurpose powder diffraction analytical instrument that can determine: crystalline phase identification (phase ID) and quantification, percent (%) crystallinity, crystallite size and strain, lattice parameter refinement, Rietveld refinement, and molecular structure. It is widely used in research, especially in material science and chemistry, as well as in industry for research and quality control. It is the newest addition to the MiniFlex series of benchtop X-ray diffraction analyzers from Rigaku, which began with the introduction of the original MiniFlex XRD system decades ago.

MiniFlex XRD system delivers speed and sensitivity through innovative technology advances, including the HyPix-400 MF 2D hybrid pixel array detector (HPAD) together with an available 600 W X-ray source and new 8-position automatic sample changer.

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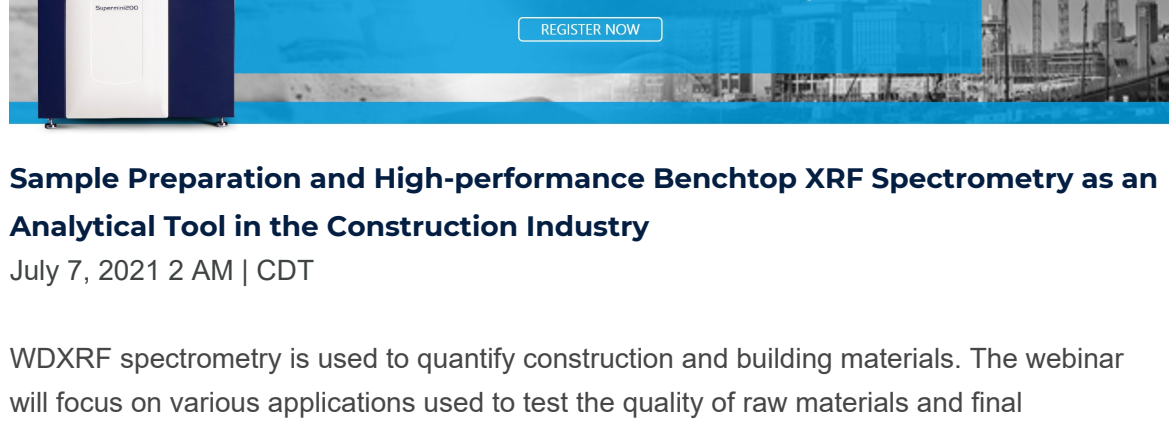
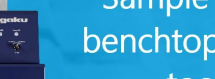


### Simultaneous XRD and DSC

Simultaneous collection of XRD and DSC data eliminates the uncertainty of separate measurements. With the addition of a humidity generator, the XRD-DSC system provides the ability to study crystalline-amorphous and amorphous-amorphous changes at constant temperature and variable humidity or variable humidity at constant temperature.

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## UPCOMING RIGAKU WEBINARS

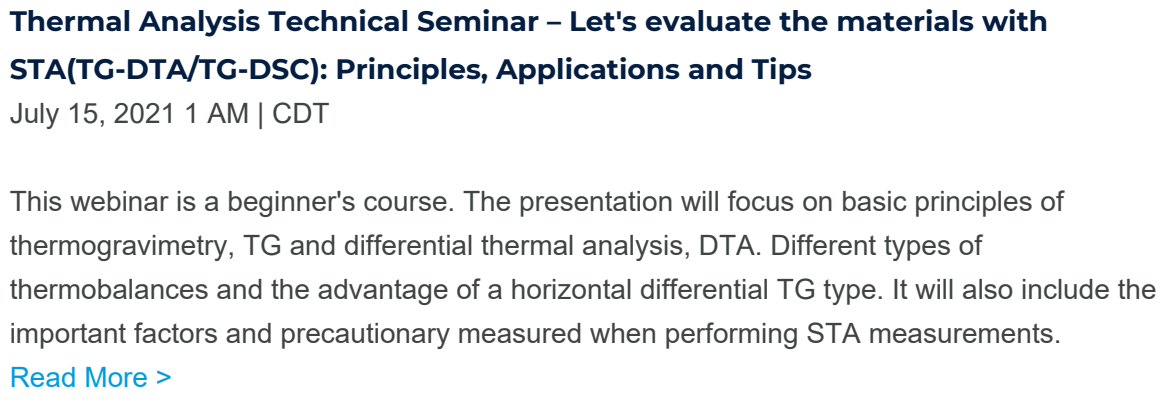


### Sample Preparation and High-performance Benchtop XRF Spectrometry as an Analytical Tool in the Construction Industry

July 7, 2021 2 AM | CDT

WDXRF spectrometry is used to quantify construction and building materials. The webinar will focus on various applications used to test the quality of raw materials and final construction and building materials. The most important is the sample preparation of the various types of materials to obtain accurate and precise results. During the 90-minute complimentary webinar you will be hosted by the Product Manager from Retsch on sample preparation and the XRF Specialist from Rigaku on the accurate analysis of the various materials used in the construction sector.

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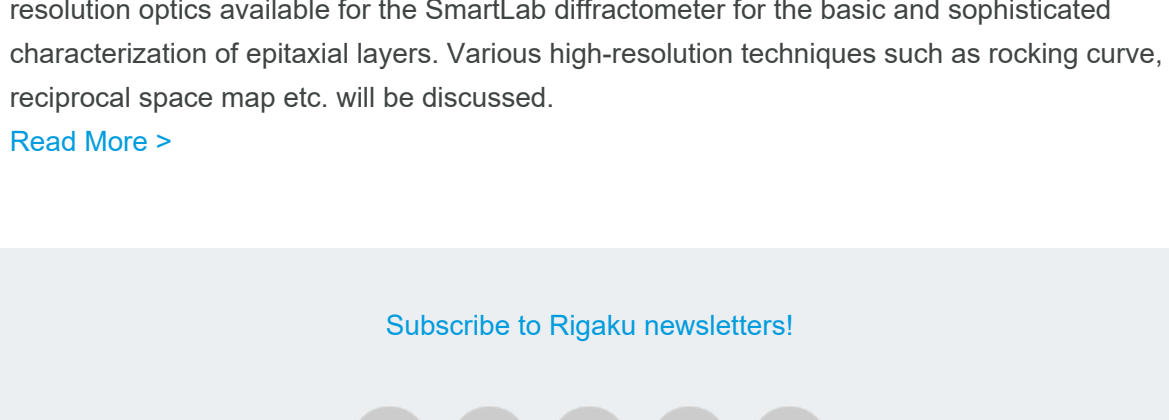


### Thermal Analysis Technical Seminar – Let's evaluate the materials with STA(TG-DTA/TG-DSC): Principles, Applications and Tips

July 15, 2021 1 AM | CDT

This webinar is a beginner's course. The presentation will focus on basic principles of thermogravimetry, TG and differential thermal analysis, DTA. Different types of thermobalances and the advantage of a horizontal differential TG type. It will also include the important factors and precautionary measured when performing STA measurements.

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### TOPIQ | SmartLab XRD Solution for Semiconductor Materials

July 21, 2021 10 AM | CDT

High-resolution X-ray diffraction is a versatile and powerful tool in semiconductor materials and devices. Quick and non-destructive characterization of thickness, composition, quality, orientation, lattice strain, etc. are possible by XRD. This webinar will cover different high-resolution optics available for the SmartLab diffractometer for the basic and sophisticated characterization of epitaxial layers. Various high-resolution techniques such as rocking curve, reciprocal space map etc. will be discussed.

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