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Uniting Fundamentals and Advanced Tools to Accelerate Drug Development

Real-time Process Insight and Control

Continuous Monitoring for Smarter, Sustainable Manufacturing

The Data-driven Future of Pharmaceutical Development

Smarter Decisions, Stronger Medicines: The Role of Advanced Analytics

This custom ebook is sponsored by Thermo Fisher Scientific and presented in partnership with *BioPharm International* and *Pharmaceutical Technology*.

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INTRODUCTION

The Industry at an Inflection Point

Advanced analytics are helping pharma and biopharma to address mounting pressures, accelerating timelines, ensuring quality, and meeting sustainability goals by turning data into a foundation for smarter manufacturing.

Today's pharmaceutical and biopharmaceutical industries face substantial pressures on multiple fronts: tightening regulations, increasing market competition for novel products, and rising research and development costs. To respond to these forces, companies are re-evaluating their production systems from start to finish, leveraging data and advanced analytics–from discovery and development of new molecules through clinical programs to the approval stage and beyond–with an emphasis on increasing efficiency through leveraging advanced technology.

As research and development labs look to assure quality and consistency while accelerating innovation in their products, advanced analytical technologies can help them pursue smarter, data-driven manufacturing–and provide a boost to their endeavors.

This eBook will explore the sophisticated tools and techniques that pharma and biopharma manufacturers can use to improve their control over their processes. While some traditional analytical methods will never go out of style, certain advanced instruments can help these innovative companies confidently make faster, data-informed decisions as they develop novel compounds in an already-complex manufacturing system.

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Uniting Fundamentals and Advanced Tools to Accelerate Drug Development

The industry is shifting toward smarter, data-driven decision-making across the value chain. As analytics move from batch testing to continuous, in-line insight, developers can better anticipate challenges, streamline processes, and build quality by design into every stage of development.

FEATURING INSIGHTS FROM:
Anil Kane, PhD, MBA
Global Head of Technical & Scientific Affairs
Pharma Services
Thermo Fisher Scientific

The pharmaceutical industry is rapidly transitioning toward smarter, data-driven decision-making. What was once a process dominated by batch testing and reactive quality checks is evolving into one where analytics are embedded at every stage of the value chain, creating a continuous flow of information that supports earlier and more confident decisions. This transformation is not only about improving efficiency—it is about building quality by design (QbD) into development from the outset, reducing risk, and accelerating the path from molecule to medicine.

In this article, Anil Kane, PhD, global head of technical and scientific affairs at Thermo Fisher Scientific, discusses the expanding role of analytics in all stages of development, from preclinical characterization through commercial manufacturing. He explains how the adoption of foundational techniques, advanced tools, and real-time analytical technologies is enabling more predictive, connected, and science-driven development.

Q Why are analytics so essential throughout the drug development lifecycle? At what stages do they matter most—R&D, manufacturing, or beyond?

Dr Kane: Analytics are absolutely critical at every stage of both drug-substance and drug-product development. Even in the preclinical phase, robust analytics allow us to understand the molecule—its solid-state properties, polymorphs, hydrates, solvates, and more. These may seem basic, but they are foundational to development success.

Strong, phase-appropriate analytical testing early on generates the data that guide formulation strategy, process design, and clinical planning. Across the Pharma Solutions Group (PSG), the Thermo Fisher Scientific group that supports drug substance manufacturing for both small molecules and large-molecule biologics and manufactured drug products (e.g., sterile injectables and oral solid dosage forms), we conduct these tests as soon as a client brings a molecule to us using both standard and advanced techniques. This group implements QbD across all drug-substance and drug-product sites and maintains comprehensive in-house capabilities, including high-performance liquid chromatography and gas chromatography systems, to ensure support from discovery through commercialization. There is often a fine line between "basic" and "advanced," but both sets of tools are essential.

VIDEO
Advances in Small-Molecule Manufacturing

If we don't understand whether a molecule is crystalline or amorphous, for example, we're already behind. Techniques such as differential scanning calorimetry (DSC) and powder X-ray diffraction (PXRD) help us characterize those traits correctly from day one. Those insights guide everything that follows—from formulation design through late-stage development.

Q You've emphasized the importance of fundamentals. What analytical techniques remain indispensable despite all the innovation in the field?

Dr Kane: Foundational tests are still essential, and we don't want partners to overlook them. Measurements like melting point, boiling point, or determining crystalline versus amorphous state will always be core components of development.

At Thermo Fisher, we also rely on early-stage tools such as texture analyzers, dissolution and particle-size analyzers, PXRD, and viscosity or density systems. We complement these with optical microscopy, thermal analysis, near-infrared (NIR) and Fourier-transform infrared (FTIR) spectroscopy, and thermogravimetric analysis (TGA). Together, these methods provide a thorough understanding of molecular behavior and help identify potential challenges early in development. Across the PSG network, we have all of these capabilities in-house—including high-performance liquid chromatography (HPLC), gas chromatography (GC), and ultra-performance liquid chromatography (UPLC) systems—to ensure comprehensive support from discovery through commercialization.

Q Where do advanced analytics and predictive tools come into play during early development?

Dr Kane: During the preclinical stage, we apply analytics to understand absorption, distribution, metabolism, excretion, and pharmacokinetics profiles—how a molecule is absorbed, distributed, metabolized, excreted, and how it behaves pharmacokinetically.

We also employ predictive modeling and machine-learning platforms. For example, Quadrant 2™, our AI/ML-based tool, predicts solubility and bioavailability. ASAP (Accelerated Stability Assessment Program) helps us evaluate molecular stability far earlier than traditional methods.

We use compaction-simulation software to study powder behavior, and we blend wet-chemistry analytics with modern, data-driven approaches. All of this supports faster, more informed decisions before entering costly clinical stages.

Q How do frameworks like QbD and Process Analytical Technology (PAT) help the industry make earlier and more confident decisions?

Dr Kane: QbD and PAT are central to enabling earlier decision-making. At Thermo Fisher Scientific, we apply QbD across all drug-substance and drug-product sites—small molecules, biologics, and finished-dose forms.

Regulators, including the U.S. FDA and the EMA, expect QbD studies to demonstrate product robustness before pivotal trials or major submissions such as New Drug Applications or Biologics License Applications.

Within this framework, PAT tools allow us to generate continuous, actionable data. Sometimes this involves conventional methods like HPLC or UPLC; other times it involves real-time spectroscopy such as NIR or Raman.
The value comes from integrating these tools into the process itself so we can act on data as it's produced—not weeks later.

Q Can you share tangible examples of how PAT enables real-time insight at your sites?

Dr Kane: At one of our US manufacturing sites, we operate a continuous-manufacturing suite where NIR spectroscopy is embedded directly in the tablet press. The probe assesses every tablet's content in real time, automatically accepting or rejecting tablets within validated specifications.

In another facility, we use hot-melt extrusion to convert crystalline materials into amorphous forms and apply NIR to measure coating and uniformity. We also embed NIR probes in mixers and granulators to monitor blend uniformity, especially for highly potent compounds with very low active-ingredient loads.

These examples demonstrate the shift from traditional batch testing to continuous, data-rich monitoring that supports real-time release (RTR) strategies.

Q So you're essentially measuring quality as production happens, rather than afterward?

Dr Kane: Exactly. PAT gives us real-time visibility into every step of manufacturing. If a parameter starts to drift, we can correct it immediately instead of relying on end-of-batch testing. This makes PAT a powerful enabler of both QbD and continuous manufacturing.

Q How do you ensure that analytics remain connected across different divisions, teams, or technologies?

Dr Kane: We treat analytics as a continuum. Each step informs the next. The continuous-manufacturing suite is one example, but the principle extends across facilities. In another site, at-line and in-line PAT tools measure coating thickness and blending uniformity. These insights support RTR, reducing inefficiencies and strengthening compliance.

We also collaborate closely with Thermo Fisher's analytical-technologies division. For instance, at-line Raman systems complement our in-line NIR setups. Using both provides a fuller analytical picture and exemplifies how cross-divisional collaboration elevates science.

Analytics, formulation, and manufacturing no longer operate in silos. Under QbD and PAT, they are tightly interconnected.

Q Any final thoughts on Thermo Fisher's approach to advancing analytics-driven development?

Dr Kane: Everything we've discussed—QbD, PAT, continuous manufacturing—comes back to generating data that enable earlier, smarter decisions. That's what helps our partners shorten development timelines and build confidence in product quality.

Our analytical technologies team works hand-in-hand with the PSG to combine instrumentation expertise with process and formulation knowledge. Together, we translate scientific understanding into scalable, practical solutions.

Ultimately, our goal is to be a science-first partner—helping companies move molecules efficiently from discovery to delivery, and turning innovation into real therapies for patients worldwide.

ABOUT THE EXPERT

Dr Kane has more than 25 years of experience in the science and business of taking molecules through the entire drug development process, spanning early-stage development to scale-up and commercial manufacturing and includes technical transfers between global sites and drug life cycle management. Dr Kane received his Bachelors, Masters and PhD degrees from the Bombay College of Pharmacy, University of Bombay, India, and served as a post-doctoral fellow at the School of Pharmacy, University of Cincinnati, Ohio. He has also earned an executive MBA from Richard Ivey School of Business, University of Western Ontario, Canada. Dr Kane is a member of various international pharmaceutical professional organizations and is often asked to speak about scientific topics on formulation, technology, and other technical aspects at major industry events. He has published many articles in international journals and delivered many talks at meetings and conferences across the globe.

Analytics that strengthen the drug lifecycle

From discovery through release, advanced analytics keep decisions clear, processes aligned, and products moving forward

The journey from molecule to medicine is complex, and every phase depends on clear, reliable information. Advanced analytics provide that clarity, helping teams understand materials earlier, make faster decisions, and maintain quality as projects move from discovery into development and commercial production.

In early research, sensitive analytical tools maximize insight from limited material while reducing downstream surprises. As processes scale, real-time and at-line techniques support robust formulation decisions, reveal how materials behave under changing conditions, and enable smoother transfer into manufacturing.

During commercial production, continuous monitoring and rapid identity testing help maintain consistency, reduce deviation risk, and keep quality on track. When each stage is supported by dependable data, the entire value chain benefits, from fewer bottlenecks to stronger confidence in every batch.

Working with a partner whose technologies span the full lifecycle helps teams build a more connected, predictable path from idea to patient.

Advanced analytics across the value chain

Discovery and R&D
Identify promising molecules early with sensitive, low-volume analytical insight.

Process development
Optimize formulations and scale-up with data that reveals details of material behavior.

Manufacturing and QA
Monitor processes in real time to protect yield, quality, and regulatory readiness.

Fill, finish & release
Verify identity and packaging integrity quickly to enable confident batch release.

Learn more at **thermofisher.com/discovery-to-production**

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Real-time Process Insight and Control

New analytical technologies such as in-line Raman spectroscopy are giving scientists unprecedented real-time visibility into bioprocesses, transforming monitoring and control from reactive to predictive and unlocking a new level of process confidence.

Biological processes can happen astonishingly quickly, or frustratingly slowly, depending on the exact conditions and active reactants. In the world of drug development, when these processes are applied to biopharmaceutical experiments they must be continuously monitored to ensure the processes are accurate, safe, and reliable, and consistently result in a high-quality product. A lack of real-time visibility to developments in these processes can result in a lack of process control, and thus, an inability to prepare a viable and consistently reproducible end product.

SIDEBAR

A real-world example of Raman spectroscopy and hot-melt extrusion:

Advanced analysis of acetaminophen in a polymer matrix

In a study performed by the University of Maryland School of Pharmacy, with assistance from subject matter experts at Thermo Fisher Scientific, Raman spectroscopy was employed to quantify acetaminophen in Soluplus, a polymer matrix, during the hot-melt extrusion (HME) process. The setup involved feeding blends of acetaminophen and Soluplus into an extruder under controlled conditions, with concentrations of acetaminophen ranging from 0% to 50%. The Raman process probe, installed at the die of the extruder where the extrudate emerges, collected spectra at regular intervals and thus provided continuous monitoring of the extrusion process.

This capability or Raman PAT to provide real-time feedback is particularly beneficial in HME processes, where maintaining consistent product quality is vital to pharmaceutical manufacturers.

This integration of Raman spectroscopy in pharmaceutical manufacturing aligns with the industry's shift towards more

This need for continuous insight has made real-time analytics a cornerstone of next-generation pharmaceutical manufacturing. Process analytical technologies (PATs) like Raman spectroscopy can address this need. Using Raman-based PAT for process monitoring, especially in-line monitoring, offers key benefits that help improve processes and ensure their safety. Not only is Raman extremely sensitive to the composition and structure of a molecule, but it also enables the accurate characterization of samples.

Some Raman analyzers can be connected to specialized accessories like sampling probes to investigate different conditions. For example, the Thermo Scientific™ MarqMetrix™ All-In-One Process Raman Analyzer can be hooked up to a process ball probe designed to withstand exposure to harsh chemicals and extreme conditions, or to a bioreactor probe with a threaded

BLOG
Why use Raman for Process Monitoring?

SIDEBAR (CONTINUED)

advanced, data-driven approaches. By enabling continuous monitoring and providing immediate feedback, Raman spectroscopy helps in identifying and addressing process deviations promptly, thereby reducing the risk of product failures and ensuring compliance with regulatory standards. This study from the UM School of Pharmacy underscores the ongoing importance of adopting innovative technologies to improve manufacturing efficiency and product quality. As the industry continues to evolve, staying informed about such advancements can provide a competitive edge and open up new opportunities in the pharmaceutical field.

APPLICATION NOTE
Real-time Quantification and Quality Assessment of API

adapter for universal integration into bioreactor platforms, or to yet another type of probe. Because these probes use laser light to excite samples for measurement, and because that laser light can pass thorough clear containers, the probes enable Process Raman instruments to perform in-line material analysis without the need for sample preparation.

With the rapid feedback provided by Raman analysis, scientists can be notified immediately of any significant inconsistencies or errors, allowing them to make corrections in real time. This enables observers to identify potential failures or risks before they turn into quality issues. In this way, the advanced analytical technology directly enables smarter, more agile pharmaceutical manufacturing.

Real-time process insight with Raman Spectroscopy

When every second shapes your product, real-time data matters

Hot-melt extrusion (HME) is a cornerstone of modern formulation, enabling improved solubility, enhanced bioavailability, and scalable paths from bench to production. Even so, teams benefit from seeing how materials behave as conditions change in real time.

In collaboration with the University of Maryland School of Pharmacy, Thermo Fisher Scientific demonstrated that integrating the Thermo Scientific™ MarqMetrix™ All-In-One Process Raman Analyzer directly into an HME line delivers continuous, quantitative insight into API concentration, solid-state form, dispersion uniformity, and polymer interactions, without stopping the run or pulling samples.

For development, scale-up, and manufacturing groups, this combination enables earlier visibility, faster optimization, and greater confidence that decisions are guided by live data. Together, HME and in-line process Raman support QbD, reduce variability, and help teams move with scientific certainty.

Real-time data that changes the process

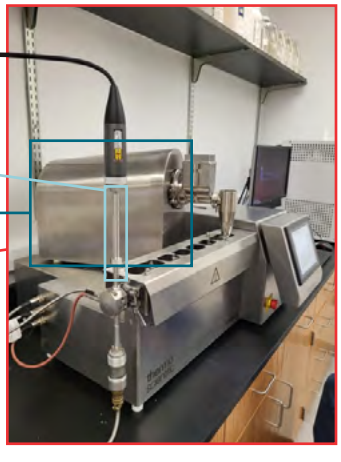
1.4%	**Prediction error (RMSEP)** near–HPLC accuracy, delivered continuously
16 sec	**Between spectra** high-frequency monitoring as the material evolves
0	**Samples pulled** elimination of manual interruptions and offline delays
24/7	**In-line visibility** continuous tracking of concentration, form, and interactions

Real-time process Raman enables teams to detect quality shifts *as they begin*, enabling earlier interventions, smoother scale-up, and more confident decisions.

Read the full study

Questions? Ask a specialist

Thermo Scientific™ MarqMetrix™ All-In-One Process Raman Analyzer



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Continuous Monitoring for Smarter, Sustainable Manufacturing

By bringing continuous, data-rich feedback into every stage of production, process mass spectrometry empowers manufacturers to make informed decisions sooner, thus reducing waste, improving yield, and ensuring compliance.

Pharmaceutical manufacturers must balance production efficiency, sustainability, and regulatory compliance. To do this, adjustment and control of various parameters must be enacted on a real-time, as-needed basis. An advanced analytical technique that can provide feedback to enable this control is process mass spectrometry (MS).

Process MS can be applied across many stages of pharmaceutical and biopharmaceutical production. Mass spectrometers can monitor fermentation and cell culture processes in real time. When solution chemistry is being used, process MS can help produce quantitative

SIDEBAR

Mammalian cell cultures monitored for viability using process mass spectrometry

Process analytical technology (PAT) is used by biopharmaceutical companies to ensure that product quality is maintained, defined by the process' critical quality attributes (CQAs). At the University College of London, a group of scientists teamed up with Thermo Fisher Scientific to use a process mass spectrometry to monitor the viability cell concentration (VCC) of a fed-batch mammalian cell culture.

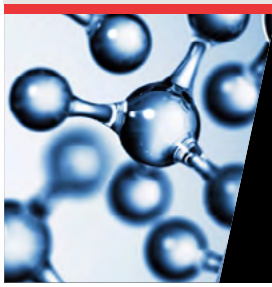
Within the cell culture step, many of the techniques used to gather information about the cells and how they are growing, such as pH, dissolved oxygen, and temperature, are either contingent on other elements of the process or set by the user, and thus are not suitable for use in process analysis. However, gas streams going in and out of a bioreactor can be connected to a process mass spectrometer for off-gas analysis, allowing for real-time measurement of a key indicator: Real-time specific oxygen consumption rate.

Analysis of the gas phase is often undervalued as a PAT that is solvent drying data to optimize the drying process. By capturing data continuously rather than retrospectively, process MS enables decisions earlier in the production cycle, where they have the greatest impact. In studies that depend on cell metabolism, the technique can provide real-time off-gas monitoring that generates insightful data about metabolic processes. Process gas analysis technologies deliver lab-quality, magnetic-sector precision in online gas composition analysis and help maximize product yield and profitability.

An example of the smarter control enabled by process mass spectrometry comes from the basic, fundamental step in solvent-based chemistry: drying the product. Historically, the drying process has been governed by two forces, tradition and safety margin. However, these are not reliable parameters for mid-process adjustments. As the pharmaceutical industry faces accelerating demands for speed, traceability, and control,

SIDEBAR (CONTINUED)

applicable in a bioreactor. Many more measurable variables in the liquid phase are available for analysis, so it seems like off-gas analysis might be less attractive. But, when gas streams going in and out of the bioreactor were connected to a Thermo Scientific™ Prima BT Mass Spectrometer for off-gas analysis, a correlation between viable cell concentration and oxygen concentration of the inlet gas into the bioreactor was found—meaning that the measure of incoming O2 could be used as a proxy for VCC. With the rapid feedback provided from the advanced analytical technique of process MS, the researchers were able to keep a real-time check on the viability of mammalian cell cultures in their experiment.



RESEARCH PAPER

Applications of Off-gas Mass Spectrometry in Fed-batch Mammalian Cell Culture

the limitations of outdated drying strategies are being exposed. Methods like near-infrared spectroscopy (NIR) looked promising for monitoring the drying process, but the shortcomings of sampling probes that were vulnerable to coating or damage, and offered only spot-level data, were too great to overcome. Mass spectrometry on the other hand, rather than probing the solid or liquid phase, analyzes the gas-phase composition above the product or at the dryer outlet. This is where solvent vapor concentration reveals how much drying is truly left to go; changes in the content of the headspace can indicate the actual endpoint. Through analyzing this vapor at regular, frequent intervals—and delivering immediate feedback about it—process MS can help manufacturers eliminate unnecessary drying effort, saving them time and money.

Another study, undertaken at the National Institute of Bioprocessing Research & Training (NIBRT), demonstrated how widely applicable process mass spectrometry can be. The researchers at NIBRT utilized process MS as a process analytical technology for fermentation and cell culture. The use of the advanced analytical technique was aimed at gaining insights into the influence of various Critical Process Parameters

(CPPs) on product titer and quality. They used process MS as an on-line solution because it was ideal for implementing PAT principles, as process data were acquired in real time. Typical off-line measurements and slower forms of on-line monitoring would not facilitate the development of understandings rapidly enough to yield robust and reproducible processes. The key differences between traditional and advanced analytical methods can be summarized this way:

- Conventional off-line and at-line analyses are characterized by discontinuous sample preparation, measurement, and evaluation. The turnaround time for information from such methods is too long to provide trustworthy process control.
- On-line measurement techniques divert a sample stream, but in the case of off-gas mass spectrometry this is done externally and does not interfere with the bioreactor or pose contamination risk.
- On-line measurements, like those performed by process MS, are obtained by external sampling of inlet and outlet gas streams rather than in-situ probes. This approach provides real-time feedback, with analysis frequent enough to generate truly representative results.

Continuous solvent drying insight with mass spectrometry

When cycle time and product quality matter, real-time gas analysis brings clarity to drying runs

Solvent drying is often a bottleneck in pharmaceutical manufacturing. Traditional approaches rely on end-of-run checks such as loss-on-drying or offline GC, which can extend cycle times or lead to over-drying.

Real-time mass spectrometry changes that by giving teams continuous insight into solvent removal.

By sampling the vapor above the product or at the dryer outlet, the Thermo Scientific™ Prima™ PRO Process Mass Spectrometer provides stable, quantitative measurements throughout the entire drying curve. Its magnetic-sector analyzer delivers high precision — often several-fold better than quadrupole systems — while resisting drift and contamination.

A variable-pressure inlet maintains constant internal pressure, ensuring data quality even as the process transitions from atmospheric pressure levels to deep vacuum. For development and manufacturing groups, this means earlier endpoint detection, fewer re-runs, and more predictable drying performance.

Real-time data that shortens drying time

2–10×	**Better analytical precision than quadrupole MS** more stable, more repeatable endpoint detection
99.9%	**Pressure stability from atmosphere to deep vacuum** consistent readings even as dryer pressure swings
30+	**Solvents measurable in a single run** simplifies complex multi-solvent drying profiles

Real-time mass spectrometry shows the true drying endpoint as it happens — reducing wait time, rework, and variability.

Read the full study

Questions? Ask a specialist

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The Data-driven Future of Pharmaceutical Development

Quality-by-Design principles, digitalization, and advanced analytical technologies are converging to reshape drug development into a fully data-driven discipline that rewards transparency, collaboration, and scientific insight across the entire lifecycle.

The development of new pharmaceuticals is a data-driven pursuit. From the moment a new molecule has been identified in the course of drug research, it must be extensively tested in ways that generate huge amounts of data. Starting in the preclinical stage and extending to the development of the final product and beyond, pharmaceutical researchers make use of a very robust analytic program to understand the molecule.

Early stages of drug development and analysis still rely heavily on tried-and-true methods for basic characterization, such as determination of melting point, boiling point, solubility, and crystallinity, but these alone can't deliver the speed or depth today's data-driven pipelines demand. The analytical methods for these properties are well-established—as tools like thermometers,

SIDE PANEL

The U.S. National Institutes of Health (NIH) describes Pharmaceutical QbD as a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and control based on sound science and quality risk management. These days, the U.S. Food & Drug Administration (FDA) and the European Medicines Evaluation Agency (EMEA) require quality-by-design studies to be performed to show robustness of the drug products that are developed prior to any pivotal studies or submissions or new drug applications. These QbD studies are applied at all Thermo Fisher Scientific drug product and drug substance sites, whether the focus is small molecules, large molecules, or drug product manufacturing.

Quality-by-design and the application thereof is a common practice throughout the global network of Thermo Fisher's Pharmaceutical Services Group sites. In the PSG's Drug Product Division, subject matter experts like Dr. Anil Kane's group support the discussions with our partners, as the company tries to determine how we can support any of the opportunities, starting discussions with clients as soon as a candidate drug substance has been selected for preclinical investigation.

calorimeters, gas chromatographs (GCs), even HPLCs (high-performance liquid chromatographs) have been around for decades. They still provide valuable information, but they take time to generate data and so are not capable of providing deep insight.

When more specialized information about a drug is needed, advanced analysis techniques now dominate. These advanced methods might reveal details about the molecular structure, or they could provide immediate data about the real-time release of new pharmaceutical in a biological setting. Techniques like near-infrared (NIR) spectroscopy, Raman spectroscopy and process mass spectroscopy allow today's researchers to study aspects like continuous processing and real-time release profiles in timely ways that other analytical methods cannot.

Having the right analytical techniques available is extremely important for upfront characterization and for designing a program that will suit the needs of the drug product development. This systematic approach to development is known as Quality by Design (QbD), and an essential aspect of QbD is advanced analysis. (**See side panel for more**.)

EXECUTIVE SUMMARY

Advancements in Drug Development and Formulation

BLOG
Innovations in Drug Discovery and Pharmaceutical Manufacturing for Novel and Orphan Diseases

Every phase of the pharmaceutical lifecycle requires comprehensive analytics. Thermo Fisher Scientific provides support at each step, from preclinical trials, to approval stages where products get inspected, audited and approved by regulatory agencies, and all the way until a drug reaches the patient and beyond. (Thermo Fisher supports commercial manufacturing as well, even after approval, throughout the life cycle of the product.) The research, development, and production processes are all data-driven, with each step in the journey based on the data generated. Today's sophisticated pharmaceutical and biopharmaceutical manufacturing require especially robust analytical data, like the type of information generated by process MS, Raman spectroscopy, and other advanced forms of analysis. Across that journey, advanced analytics bring decision-making closer to real time, reducing risk and accelerating the path from insight to impact.

Fast, confident identity testing for complex biologics

Accurate identification through packaging—without sample prep—helps teams release products faster and with greater confidence

Biologic drug products require precise identity and composition testing before release—but traditional workflows like peptide mapping or HPLC can take hours to perform, require specialized training, and use significant lab resources.

The Thermo Scientific™ DXR3 SmartRaman™+ Spectrometer gives teams a faster path. With high molecular specificity and the ability to measure through primary packaging, the DXR3 SmartRaman+ spectrometer can distinguish between drug products, verify identity, and track key formulation components in just minutes.

Using full-spectrum analysis and chemometric models, it supports multi-attribute testing without extraction or sample prep. For QC and manufacturing environments under pressure to move quickly and maintain compliance, the DXR3 SmartRaman+ spectrometer provides a dependable, streamlined approach to identity testing and release decisions.

Rapid ID testing that reduces release delays

1 minute typical scan time

→ speeds up decisions compared to HPLC or peptide mapping that takes hours

Through-container identity verification

→ reduces sample prep, handling errors, and contamination risk

→ eliminates sample waste and delivers significant cost savings

≥0.998 R^2 quantitative accuracy for key formulation components

→ supports multi-attribute testing aligned with RTRT principles

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By replacing slower, labor-intensive workflows, Raman analysis helps teams verify product identity sooner and release batches with greater confidence.

Read the full study

Questions? Ask a specialist

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CONCLUSION

Partnerships that Enable Data-driven Progress

Thermo Fisher Scientific aims to support our partners in generating robust analytical data to drive earlier insight and smarter decisions across development and manufacturing. This means providing tools for the basics, which should not be missed due to the important characterization data they provide, along with instrumentation and support for different advanced analytical techniques that will deliver insight into the challenges. We want to address those challenges of the molecule sooner rather than later to bring speed and efficiency into drug development.

Thermo Fisher Scientific partners with the pharmaceutical and biopharmaceutical industries across the entire value chain, from discovery through manufacturing and delivery, to turn scientific insight into life-changing therapies that reach patients faster.