



PHARMA

Streamlining Pharmaceutical Quality Control with Bruker Benchtop NMR Technology

Innovation with Integrity

Pharmaceutical manufacturing is a rapidly evolving landscape as Industry 4.0 concepts are adopted. New regulatory guidelines are emphasizing a focus on better understanding of analytical procedures in a risk-based life-cycle management to ensure robustness and consistent product quality. Following these guidelines requires pharmaceutical manufacturers to embrace the benefits offered by new technologies—technologies such as benchtop-scale Nuclear Magnetic Resonance (NMR).

The pharmaceutical industry's need for higher quality and more consistent products is being driven by several key regulatory guidelines. Recent revisions to the ICH Q2 and the new USP-NF <1220> and ICH Q14 guideline advocate for a systematic approach to quality control that includes risk management, life-cycle management and sound science-based control strategies. These guidelines emphasize the principles of Analytical Quality by Design (AQbD), focusing on the development of robust and reliable analytical procedures that can withstand the complexities of pharmaceutical manufacturing.

Adopting these guidelines principles requires a shift from traditional quality control (QC) procedures to more advanced, technology- and data-driven approaches, with an emphasis on integrating robust analytical techniques that provide detailed data on critical quality attributes (COAs).

This is where NMR technology gains a renewed interest.

The Role of NMR in Quality Control

Building on the need for a science-driven approach with a deep understanding of the underlying variables and their interdependencies to quality control, NMR can significantly enhance QC processes across the pharmaceutical industry. Unlike other analytical methods, NMR does not require identical reference materials, which simplifies workflows and reduces the burden on quality control laboratories. In addition, because it is built on universal, well-established physical principles, NMR is one of the few analytical technologies that can leverage the modern concept of platform procedures, allowing for more efficient and effective operations. By streamlining QC processes, NMR technology can thus help pharmaceutical companies reducing turnaround time and operational expenses while meeting stringent regulatory standards.

Historically, however, NMR technology has not been widely adopted in the QC processes of pharmaceutical manufacturing due to challenges relating to cost and convenience. Traditional high-field NMR spectrometers are

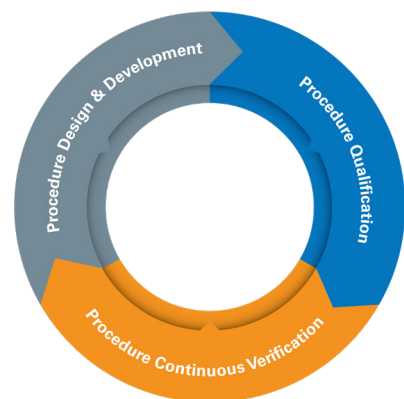


Figure 1: Analytical procedure lifecycle in the AQbD framework

expensive to purchase, install, and maintain. They also typically require dedicated infrastructure, including specialized rooms to house the equipment and environmental controls to manage the cryogenic liquids used to maintain superconducting magnets.

As regulations have advanced, however, so has technology, and the development of benchtop-scale NMR systems has vastly increased the practicality and affordability of such instruments.

The Benefits of Benchtop NMR

Benchtop NMR systems such as Bruker's Fourier 80 offer several advantages over traditional setups, making them particularly appealing for use in QC applications. The key benefits include:

Small footprint

As the name implies, benchtop NMR systems are significantly smaller than traditional floor-standing NMR spectrometers. The compact size of benchtop systems allows them to be easily integrated into existing lab setups or even placed in manufacturing environments.

Affordability

Benchtop NMR systems are less expensive to purchase and install compared to traditional high-field NMR systems. The elimination of the need for cryogenics also leads to significant savings in operational costs and maintenance. This affordability lowers the financial barrier, enabling more laboratories to adopt advanced NMR technology and improve their QC processes.

Fully automatic workflows

Designed with user-friendly interfaces and support for fully automated analytical workflow, Bruker's benchtop NMR system requires minimal training and oversight to operate effectively. This ease-of-use means that even laboratories without specialized NMR expertise can quickly adopt and benefit from the technology. Simplified maintenance and operation reduce downtime and the risk of non-compliance due to user error.

Support for full regulatory compliance

Bruker's benchtop NMR system is designed to meet the stringent regulatory requirements of the pharmaceutical industry. With built-in support for GMP and GLP, Bruker offers a unique solution for data integrity and regulatory compliance of NMR procedures that align with the standards established by traditional QC technologies.

Embrace the Future of QC with Benchtop NMR

By integrating benchtop NMR systems into their QC processes, pharmaceutical manufacturers can achieve greater efficiency, flexibility and adherence to the modern principles of AQBd. The small footprint of these systems makes them ideal for a variety of settings, from traditional laboratories to production lines. Their affordability and ease-of-use lower the barriers to adoption, allowing more laboratories to leverage the powerful capabilities of NMR technology.

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