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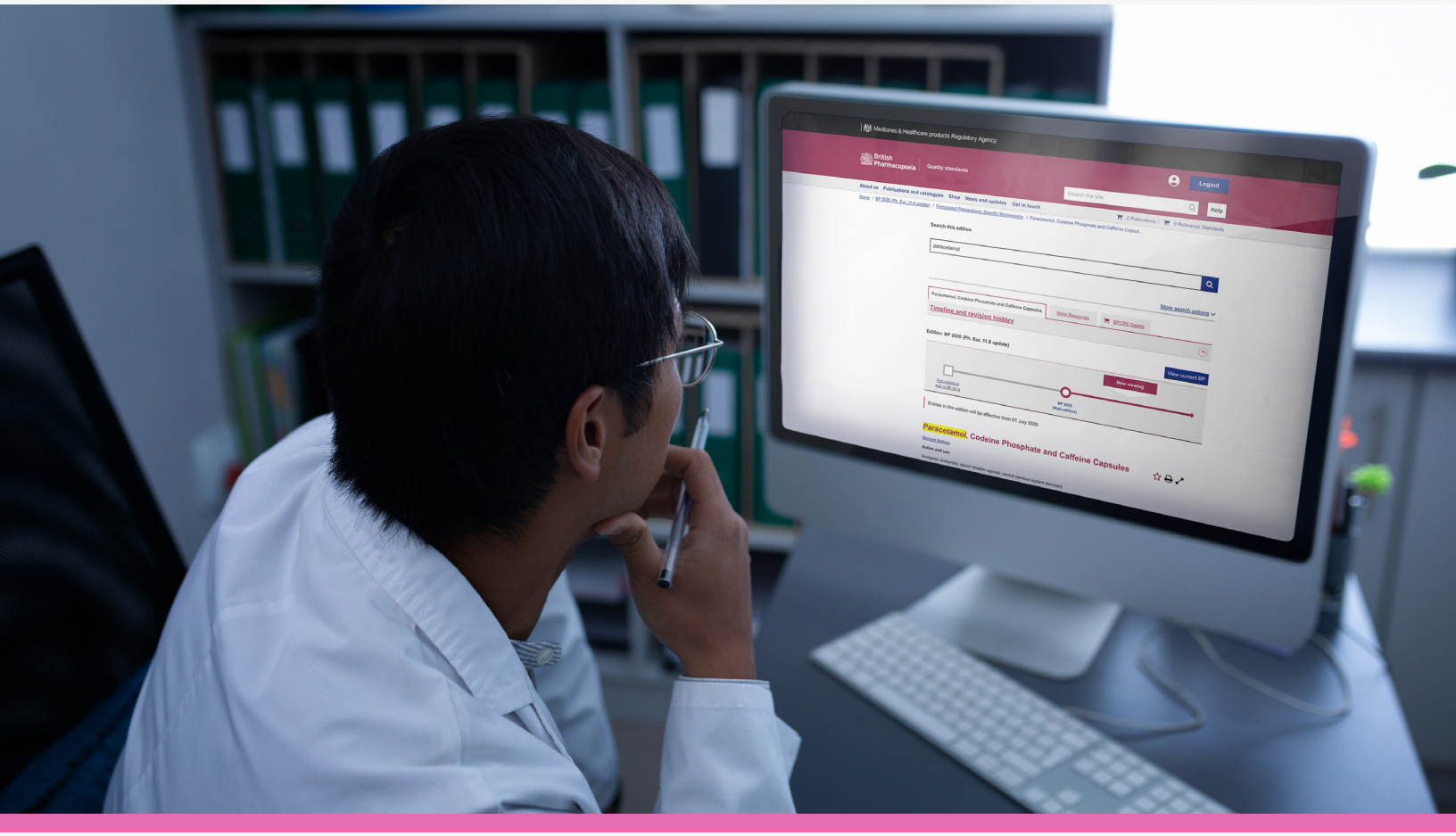
# The British Pharmacopoeia: Setting standards that are trusted worldwide

Meredith Landry, Citeline | OCTOBER 2025

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# The British Pharmacopoeia: Setting standards that are trusted worldwide

With the release of the 2026 edition, the British Pharmacopoeia is demonstrating regulatory confidence, greener science, and global relevance in healthcare.

The British Pharmacopoeia (BP) has been a cornerstone of pharmaceutical quality and regulatory confidence in the UK since its inception in 1864. With its integration into the Medicines and Healthcare products Regulatory Agency (MHRA) and global partnerships, the BP plays a vital role in setting scientifically robust standards, supporting innovation, improving access, and embedding sustainability across the life sciences. As the BP releases the latest 2026 edition, its leadership is focused on ensuring the organization evolves with scientific and regulatory change.

## A Unique Position Of Influence

One of the BP's greatest strengths lies in its integration with the UK regulator, the MHRA. This alignment ensures that the standards published by the BP are not just scientifically rigorous but also directly reflect regulatory expectations. For manufacturers, aligning with BP standards streamlines the process of achieving UK market authorization.

"Our relationship with the MHRA is one of the BP's key strengths," says Peter Crowley, Secretary and Scientific Director of the BP Commission. "If you're following BP standards, you can be assured they have been developed in close collaboration with the UK regulator."

This close connection to a globally respected regulatory body gives the BP influence that extends well beyond national borders.

"MHRA experts sit on several International Council for Harmonization (ICH) groups and help shape global regulatory acceptance," Crowley says.

## Evolving To Support The Full Product Lifecycle

The BP's strategy in recent years has shifted toward a more proactive role in supporting the full product lifecycle—from early development through to post-market quality assurance. One area under consideration is the early publication of monographs for products likely to become generics. While not yet a


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formal commitment, this approach is under feasibility assessment.

“If we can get in early and develop a monograph before generics enter the market, it helps build standardization from the outset,” Crowley says. “But it’s difficult to get innovators to share data early on because it can be seen as giving competitors a head start.”

Crowley still believes there is value in creating early-stage tools that support both innovators and generic developers, particularly in terms of analytical techniques that demonstrate equivalence and quality.

## Driving Sustainable Standards

Sustainability is now a core priority within the BP’s operations. The 2026 edition introduces greener chromatographic methods in several monographs, including a significant update to the ibuprofen family. These revised methods are designed to reduce solvent use, shorten testing times, and decrease energy consumption—all without compromising scientific integrity.

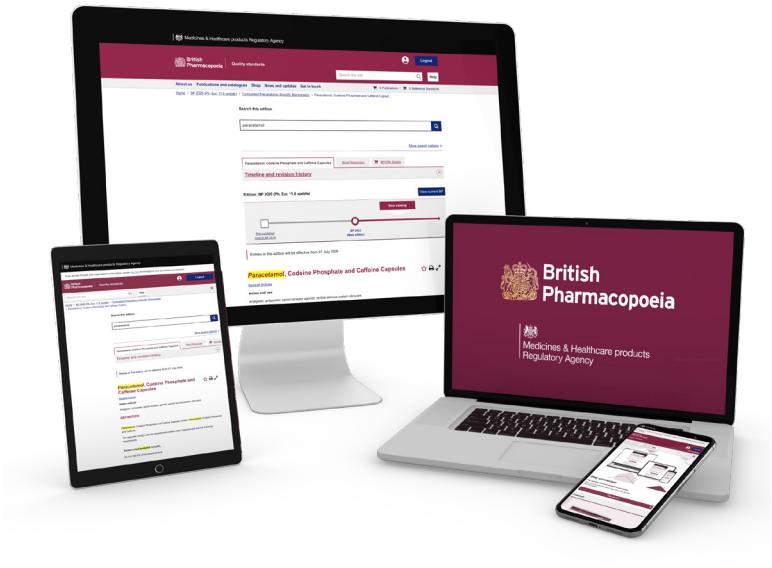
“We’ve released a new sustainability information pack with case studies, encouraging industry to adopt greener practices,” Crowley says. “We’re also updating chromatographic methods and related parameters to reduce solvent use—thus reducing environmental impact.”

There are broader implications to this effort, of course.

“If we can publish sustainable methods that work across multiple pharmacopoeias, we help the industry reduce duplication and cost,” he says. “One method accepted by the world’s major pharmacopoeias, including the US, European, Japanese, and British, means one less hurdle for global manufacturers.”

Thus far, feedback on these sustainability efforts has been positive. User research over the past year has shown that greener methods are being noticed and appreciated by industry stakeholders. Crowley emphasizes that sustainability is no longer a side project, but it is now a permanent part of how the BP designs its standards.

> “Traditionally, pharmaceutical standards were developed behind closed doors—an image the BP is actively working to change.”




## A Modern Platform For A Global Audience

With more than 2,000 daily active users worldwide, the BP has invested significantly in modernizing its online platform. Improvements include streamlined navigation, a cleaner interface, and tools like a change tracker and timeline to support user compliance.

Crowley points to recent user research, which gathered nearly 300 responses: “The feedback was overwhelmingly positive, with several improvements noted. Quick and efficient access to the BP Online remains central to positive perceptions, while more frequent updates to content and monographs, alongside useful communications, contribute to a stronger sense of the BP as an evolving and progressing resource.”

A new user guide has also been developed to help both new and experienced users understand and interpret monographs more effectively. Crowley sees this as a vital step in ensuring the BP remains accessible, practical, and easy to use.

## Transparency And Inclusion

Traditionally, pharmaceutical standards were developed behind closed doors—an image the BP is actively working to change.

“We’re opening up our meetings to observers, hosting webinars, and modernizing how we recruit to our advisory groups,” Crowley says.

Historically, recruitment for these groups happened every four years. Moving forward, the BP is transitioning to a rolling recruitment model allowing for broader and more continuous engagement.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"We want more people to see what we do and feel like they can be part of it—even if they're not appointed right away," Crowley says.

Diversity and inclusion are central to this approach, as the BP looks to bring in a wider range of voices and expertise.

## Supporting Cell & Gene Therapy

The BP is also exploring how to support cutting-edge fields such as cell and gene therapy. Given the pace of innovation and the lack of consensus in this area, traditional standards often aren't feasible. Instead, the BP is focusing on developing early-stage guidance.

"We've been working with the Cell and Gene Therapy Catapult, who are part of the Innovate UK Catapult Network, to build convergence in areas where standards don't yet exist," Crowley says. "Rather than setting fixed rules, we're creating a shared understanding of quality expectations."

These guidance documents, such as those on replication competent virus assays, are freely available and designed to be used throughout the product development lifecycle.

"They give researchers something they can rely on from early development through to authorization," he says.

> "In a bid to better understand its own effectiveness, the BP has introduced a framework for evaluating the patient impact of its work."

## Patient Impact

In a bid to better understand its own effectiveness, the BP has introduced a framework for evaluating the patient impact of its work. While still in early stages, the initiative moves away from traditional volume-based metrics and toward more meaningful indicators of public health value.

"We're looking at coverage of UK medicines, how our guidance is used, and the support our labs provide to the regulator," Crowley says. "We'll be publishing the first round of data in our 2025 annual report."

The goal is not just accountability but also improvement: By understanding how its standards are used and perceived, the BP can make smarter decisions about future content and priorities.

## What Comes Next?

As the scientific and regulatory landscape continues to evolve, the BP is preparing for the future by engaging




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with broader MHRA initiatives, including the Centres of Excellence for Regulatory Science and Innovation.

“We’re watching digital health, AI in manufacturing, and other emerging areas very closely,” Crowley says. “Our question is always: Where does the BP fit into this? Can we provide the standards that make new technologies trustworthy and scalable?”

He also points to the biologics space as an ongoing priority.

“We’ve had a strategy in place for advanced therapies, and we’re looking at applying that other product classes in the biologics space,” he says. “It’s about making sure the UK’s expertise is backed by reliable, recognized standards.”

### A Trusted Voice For Science And Industry

At its core, the BP serves as a bridge between science, regulation, and industry. Crowley believes this position is not only relevant but increasingly essential.

“We deliver robust, practical standards that manufacturers follow and regulators can trust,” he says. “That reduces uncertainty, especially for small and mid-sized companies, and helps accelerate access to high-quality medicines.”

Through digital transformation, strategic partnerships, and a commitment to sustainability and inclusion, the BP is setting the foundation for a future where medicines are not only safe and effective but also accessible, affordable, and environmentally responsible.

“We can only meet the needs of stakeholders by engaging with them directly,” Crowley says. “Transparency, dialogue, and trust—that’s how the BP will stay relevant in a rapidly changing world.”

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**To learn more about the British Pharmacopoeia 2026 edition or to get involved with its advisory groups and user research, visit the BP’s official site or register for the upcoming October webinar.**

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British Pharmacopoeia

The BP has been providing official standards for medicines since 1864, and provides the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products, including all the monographs and texts of the European Pharmacopoeia (Ph. Eur.).

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