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Change Management in Pharmaceutical Quality Control Laboratories

Three pharma experts explain the motivations and challenges of change management within a pharmaceutical quality control (QC) laboratory and share best practices on effectively steering the course of change when introducing new technology, software, or procedures.

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INTRODUCTION

Adaptability to change provides significant benefits by providing a foundation for success in today's dynamic and fast-changing business environment. In this white paper, three pharmaceutical professionals delve into the intricacies of change management in a QC laboratory by discussing the various motivations and challenges that come with implementing new technology, software, or procedures. They also offer insights into best practices for effectively navigating the course of change in this environment.

The pharmaceutical industry serves a unique role in society through its contributions to improved quality of life and increased life expectancies for people around the world, through life-saving treatments, vaccines, pain management solutions, and more. Yet the present conditions in the manufacturing sector are arduous — encompassing escalating costs, (such as raw materials), and a volatile economic outlook that necessitate a compelling justification for investing capital. At the same time, these challenges must always be weighed against the imperative to advance, optimize business processes, and boost efficacy while trimming expenses.

For pharma contract development and manufacturing organizations (CDMOs), the market has become increasingly crowded, with more companies entering the space and established players expanding their capabilities. This has led to increased competition for contracts and pricing pressure. As a result, CDMOs need to stay up to date with the latest technologies to remain competitive, which requires significant investment in research and development, as well as the ability to integrate new technologies into existing manufacturing processes.

From the point of view of change, pharmaceutical manufacturing requires constant reevaluation and modification, not just in terms of new drug discovery and design, but also with regards to all aspects of the production and quality control of existing and legacy drugs. External pressures such as competition, market trends, and regulatory requirements can motivate change. However, pharmaceutical companies operate in a controlled and regulated environment that can make managing change more difficult, so developing a strategy for change management helps a company identify potential risks and ensure that appropriate measures are taken to either preempt or mitigate any risks associated with a given change.[1] Change will happen, and it's continuous. Ensuring changes are aligned with the strategic direction of the company is imperative.

MOTIVATIONS FOR CHANGE

Planning, implementing, and controlling change in pharmaceutical QC laboratories encompasses products, processes, systems, and people. Numerous motivations drive pharmaceutical manufacturers to ensure that changes are implemented in a smooth and efficient manner, while also minimizing any negative impacts on the organization and its stakeholders. These changes are often made as part of a continual improvement process to optimize laboratory operations, increase efficiency, or address issues identified through internal audits or customer feedback.[2]

Eric Hill of Boston Analytical believes continuously improving processes, products, and services is essential for life science companies to remain competitive and provide value to customers, particularly in contract research, testing, and manufacturing organizations. These companies focus on providing services that will benefit their customers in the long run. That requires managing change to future-proof their organizations — for example, making investments in laboratory equipment that will be able to maintain the course for some time. He explains, "New drug development will always require investments in new technology, because customers are interested in starting their data trending using the latest instrumentation. So, at the end of that program, whether it's 2 years, 5 years, or 10 years down the road, that data trending is still in the prime of its life."

Eric describes his firsthand experience on how technology changes can affect processes in the QC laboratory, "Around 10 years ago we added Waters Empower™ Software to our laboratory. When we made that change, it wasn't only an investment, it was also a process change. It may slow things down for a short period, but once you get over that, you start to see huge improvements and see the ROI benefit. That applies today with other tools like informatics and data collection software as they become further integrated into faster and less error-prone laboratory processes."

There are a number of benefits that come from embracing change:

- Manufacturers continually work to increase productivity and reduce costs. Adaptable companies are better prepared to face future challenges and uncertainties that affect the financial aspects of manufacturing, such as technological disruptions, regulatory changes, or market demand.
- Meeting regulatory requirements and guidance is essential to ensure compliance and maintain the reputation of the organization. Those requirements include ensuring data integrity, system security, and disaster recovery to safeguard critical information and prevent potential breaches.
- Remaining competitive in the industry is a crucial motivation for change. Companies that can quickly adapt to changes in the market, industry, or economy are better positioned to take advantage of new opportunities and navigate challenges.

VALUE OF VENDOR SUPPORT WHEN MANAGING CHANGE

Much of the success in the contract testing industry depends on keeping laboratories operational and minimizing downtime.

When contract organization A&M STABTEST GmbH, based in Germany, invested in Waters BioAccord LC-MS System and waters_connect Lab Informatics Software to expand their service capabilities[3], it was the support that the company received from Waters during the installation that was a key element to successfully integrating both into the laboratory's workflows. Dr. Thomas Franz, STABTEST Study Director, explains:

"We received good support from Waters, including in-house training, which is important because it's better to train on your own system. After the training, the support from Waters was also very good. If we had questions, we got an immediate response."

- Sustainability goals, such as reducing waste and minimizing the company's carbon footprint, can drive changes within the laboratory. Making changes can lead to a more responsible and efficient laboratory operation, which can benefit both the company and the environment.
- By adopting new technology and staying up to date with the latest trends and advancements, pharmaceutical QC laboratories can reduce the likelihood of costly disruptions and minimize the company's exposure to risk.
- The introduction of new drugs into the pipeline often requires the adoption of new analytical techniques and approaches. Manufacturers that can adapt to change quickly can respond to market or industry changes by adjusting their operations, strategies, or resources.
- Companies that embrace change are more likely to be innovative and develop new products or services that meet the changing needs of their customers. Adapting to changes in customer preferences, behaviors, and expectations can also improve customer satisfaction and loyalty.
- Contract organizations need to offer new services in response to changing regulations or customer demands. Embracing change makes these companies more likely to be innovative and to meet evolving requirements or requests.
- Organizations that are adaptable to change are often more dynamic and engaging places to work, which can attract and retain employees with the right skill sets.

THE CHALLENGE OF CHANGE

Pharmaceutical QC laboratories play a vital role within the wider manufacturing process by ensuring the quality of production output. In the QC space, changes are often required to comply with updates to industry standards or regulations. Changes may also be made to improve the quality of the product or testing process, such as sampling procedures, acceptance criteria, or data analysis methods. Instrumentation and software advances can prompt changes in testing methods, equipment, or data analysis techniques.

New product formulations, ingredients, or manufacturing processes will require modifications in QC laboratories. Additionally, changes may be required to address the need to reduce costs or improve the safety of laboratory personnel or the environment.[4]

Eric describes the improvements in the capabilities of ultra-performance liquid chromatography (UPLC™), compared to traditional high-performance liquid chromatography (HPLC), that occurred in the 2000s, as a prime example of how technological advances spark the need for change. But he explains that change, while it offered significant benefits, wasn't a simple process, "Everyone had to look at their legacy HPLC methods. UPLC was clearly better, and no one would argue that it's not. But we can't just take hundreds or thousands of methods and just start running them on UPLC Systems. So that was a particular challenge that every pharma laboratory had to suddenly deal with."

In all cases, changes should be carefully evaluated to ensure that they do not compromise the accuracy, reliability, or validity of the testing process or the quality of the product. Any changes should be thoroughly documented, validated, and communicated to relevant stakeholders.[5] As Eric explains, "Being in the GMP space, everything we bring in is going to have to be qualified – it is an inevitable part of working in this sector. Every instrument must be qualified, and every method validated and documented. That's just the cost of doing business; it is the baseline."

Contract research, testing, and manufacturing organizations also need buy-in from customers who may be resistant to change. Eric explains why changes are sometimes met with resistance from customers that don't want to rock the boat when it comes to regulatory compliance, "When you're in a regulated environment, instrument qualification is just part of the process. We have hundreds of methods in our systems that are validated, some of which are tied directly to one customer, and some used by multiple customers. But they've been collecting data using these methods for years, and we need to continue to generate that data for trending purposes. So, it's not easy for them to go to a new instrument that, although it's better, disturbs that data trending. We need to be prepared to address those needs."

Furthermore, on the subject of compliance, Heather Longden explains why change can be an expensive and multi-faceted process for pharmaceutical manufacturers, "Pharma companies aren't just going to one regulator and updating a submission. They need to go to all the regulators in every country where the product is sold. The costs are significant, which is why bigger companies with more resources can react faster. They are better situated to deal with change compared to others that are content with their current quality systems until some critical requirement forces them to change."

Indeed, implementing change within a QC laboratory can be particularly challenging for a variety of reasons.

The regulated nature of the QC lab adds an additional layer of complexity to the process of making changes. Regulatory bodies have strict requirements for QC labs to ensure compliance with industry standards, and any changes must be carefully considered and documented to ensure that they do not negatively impact product quality or safety.

There may be reluctance to change established ways of working due to the need to document change, especially if those changes need to be reflected in other laboratories. This can be a time-consuming and resource-intensive process, further complicating efforts to implement change.

Disruptions to processes and downtime due to new installations and requalification are also significant challenges. These disruptions can impact the productivity of the laboratory and may result in delays that can be costly in terms of both time and money.

A lack of resources, including time, money, and personnel, can also be a significant obstacle to change. Without sufficient resources, it may be difficult to implement and sustain innovative change.

Finally, tight deadlines that are characteristic of the pharmaceutical industry can make change particularly challenging. Companies often do not have spare time to devote to managing change initiatives, which must be completed while still meeting all the laboratory's ongoing obligations.

LEADING THE REGULATORS OR BEING LED BY THE REGULATORS?

Despite the barriers to making changes within a highly regulated industry, the influence of regulatory agencies can work both ways, explains Heather. While regulators add complexity because they are a stakeholder, it can also be an advantage because the pharmaceutical industry needs to move at the same pace. She explains, "Doing just what the regulator says is a major issue in the industry, which can be very risk adverse. Regulators will issue regulations and guidelines that companies must follow. But the industry can also push agencies and guide them to make a new regulation that embraces innovation."

One such example is the recently issued draft guidance from the U.S. FDA CDRH that provides recommendations on risk-based assurance activities for computers and automated data processing systems used to support the manufacture of medical devices. The intent of the guidance is to describe computer software assurance (CSA) as a risk-based approach to establish confidence in the automation used for production or quality systems, as well as to identify where additional rigor may be appropriate. However, Heather believes that when the guidance was released, it didn't drastically change things for the industry.

REALIZING COMPETITIVE ADVANTAGES AS A RESULT OF PROACTIVE CHANGE

The product testing team at Eurofins BioPharma Product Testing Lancaster[6] recently worked closely with Waters to test the Waters ACQUITY™ Premier System's capabilities to overcome challenges with sensitivity in peptide and oligonucleotide analysis. Ms. Heather Bridwell, Director of Pharmaceutical Product Testing at Eurofins BioPharma, explains the motivation behind the technological upgrade:

"In our world, time is directly related to costs for our clients. If you can minimize challenges with the routine use of a method, then you have assurance that it's going to perform consistently without issue. From that perspective, it gives our laboratories an advantage over a competitor that may continue to struggle with onboarding and execution challenges for similar methods. The potential savings in time, headaches and hassle were significant. If we could take an onboarding situation where it took 3–6 weeks to resolve these issues, and then reduce it to 2–3 weeks, that would be a success."

"Companies were waiting on tenterhooks for this new guidance to come out. But they were already adopting these approaches and demonstrating that it was worthwhile long before the guidance came out. So, everyone was surprised that the guidance reflected what the industry was doing anyway. It is a good example of proactivity though – making innovations without waiting for the blessing from the regulators helps the regulators to see the best solutions to include in guidance."

And just as change happens in the industry, it also happens in regulatory agencies. Not adapting to innovative change isn't always the safe bet, Heather clarifies.

"Just because something passed or you got a green light in a previous audit, it doesn't mean if you keep doing the same thing, you'll get a green light today. Regulators are growing and changing too. You might get an auditor or reviewer who has undergone updated training, resulting in a new understanding of processes and regulations, and they subsequently look at your processes differently."

PEOPLE ARE AT THE HEART OF CHANGE

Change happens at a personal level, and it can be hard for people to manage. Change may trigger reactions by employees, managers, and customers caused by fear of the unknown, loss of familiarity, resistance to new ideas, lack of control, uncertainty about the future, or disruption of routine. It is important to acknowledge these challenges and find ways to manage them effectively to navigate change successfully. In change management, it's important to put yourself in the shoes of each person who may be affected by the changes; explaining the changes being considered and understanding the potential impact and viewpoints of others.

Understanding the impact of change at a personal level is what helps people buy into the strategy. Encouraging collaboration and effective communication among stakeholders is vital to avoid misunderstandings, conflicts, and disputes. Over-communication is needed, and time for people to really understand the details of the change, what they need to do, and how it will affect what they will be doing tomorrow. Everyone has different questions, so communication is a huge part of the change management process.

Active change management processes are necessary to help pharmaceutical companies ensure modifications are compliant with regulations and quality assurance protocols. However, it can be challenging to know where to begin. Best practices for change management in pharmaceutical laboratories are designed to help companies achieve their goals and objectives by providing a set of proven strategies and techniques that have been tested and refined over time.[7] A structured approach encompassing the following steps can help successfully manage change successfully.

- **Identify the change:** Clearly identify what change needs to be made, whether that change is to processes, structures, technologies, or any other aspect of the organization.
- **Define the scope:** Determine which parts of the organization will be affected, who will be involved, and what the timeline will be.
- **Assess the impact:** Assess the potential impact on the organization, including how the change will affect employees, customers, suppliers, and other stakeholders.
- **Develop a plan:** Develop a plan for implementing the change with a detailed timeline, a communication plan, and a plan for managing any risks or obstacles that may arise.
- **Engage stakeholders:** Engage stakeholders throughout the process, including employees, managers, customers, suppliers, and any other groups that may be affected by the change.
- **Implement the change:** The implementation process should involve training employees, updating processes, and/or introducing new technologies.
- **Monitor and adjust:** Monitor the implementation of the change and adjust as needed to ensure that the change is successful and achieves the company's goals.

STAYING AHEAD OF THE GAME — PROACTIVE VS. REACTIVE CHANGE

A proactive approach to change helps pharmaceutical companies respond quickly and effectively to new challenges or opportunities. It can stimulate new ideas and encourage experimentation, leading to new products, services, or processes that can give companies a competitive advantage. Proactive change management can also help companies identify and mitigate potential risks before they become major problems, reducing the likelihood of costly mistakes or setbacks.

An example of such risks occurred in 2018, when unacceptable levels of nitrosamine impurities, which are classified as probable human carcinogens, were first discovered in the drug supply chain. The impurities were found in several medications that contained the active ingredient valsartan, which is used to treat high blood pressure and heart failure. Other drugs containing the same active ingredient or related compounds were also found to be contaminated, leading to recalls and supply chain disruptions.

The impurities were traced back to changes made by certain manufacturers in their manufacturing processes, which led to the formation of the impurities. Regulatory agencies around the world reacted to prevent the presence of nitrosamine impurities in drugs. Suddenly, companies had to risk-assess test where nitrosamines were likely to be present and reevaluate their manufacturing processes where needed.

Failure to act according to the regulatory requirements would have serious consequences, including regulatory penalties, product recalls, liability claims, and damage to company reputation, in addition to the potential risk to patient health and safety.

Where a risk assessment deems testing necessary, companies are responsible for introducing appropriate analytical technology and methodologies, or outsourcing testing.

The reaction time of companies to make the required changes has varied based on the available resources of the pharmaceutical organizations. Heather explains, "Introducing a technology like mass spectrometry that's needed for nitrosamine analysis is not trivial, and the deadlines from the regulators were very short. Some of the bigger companies were able to pivot because they already had access to advanced instrumentation, and they could fully assess the risk in the manufacturing process versus relying solely on final product testing. If an organization has a good portfolio of people, instruments, skills, and a network of external third parties if necessary to outsource, then you are more ready to adapt, irrespective of whether you've anticipated the change or not."

Manufacturers have had to remain vigilant through the evolving situation and adapt to changing regulations and emerging nitrosamines, including nitrosamine drug substance-related impurities (NDSRIs). Laboratories that are equipped with flexible technology and strong staff skillsets and are supported by instrument vendor applications expertise have been able to react more quickly and easily.

Stephanie Harden of Waters Corporation describes some of the challenges and implications for pharmaceutical companies.

"The prevalence of nitrosamine drug substance-related impurities (NDSRIs) has presented some significant sensitivity challenges where very low class-specific sensitivity thresholds are applied to mitigate for a lack of toxicity data. Companies that are used to being agile, with an effective change management process established will have found it less challenging to adopt different ways of working and establish new procedures or implement new instrumentation, but the nitrosamine crisis had such an impact that even the best prepared companies could not have anticipated the response needed."

Starting in 2018, the nitrosamine crisis related to small molecule nitrosamine impurities in drug product. The pharmaceutical Industry reacted and adapted to manage the situation, assessing risk and mitigating risk and/or testing for presence of small nitrosamines. At this time, manufacturers were challenged by the need to develop vast numbers of assays for their drug products, to test for nitrosamines.

"Method development takes time – there is no real generic approach – and each drug product required a specific method. Managing the changes required throughout the nitrosamine crisis has been a significant challenge."

Subsequently, NDSRIs were identified as an issue, leading to continuing recalls into 2023. Identifying NDSRIs in pharmaceuticals presents a complex challenge since a wide range of compounds are theoretically susceptible to forming NDSRIs, and they can form very easily. Companies invested heavily in new purpose-built facilities to cope with the testing needs.

"Even now, ensuring these impurities are within toxicologically defined acceptable limits is proving to be complicated and costly for companies. Thankfully, where testing is needed, the limits of quantitation are less demanding for many NDSRIs, than for low molecular weight N-nitrosamines."

Pharmaceutical companies have had to deal with a continuously evolving, extremely dynamic situation over recent years. Adapting to changing regulatory requirements, increasing testing capacity, adopting new technologies that can measure impurities in drug products to much lower levels, retraining staff, addressing inconsistent sample preparation, etc. The situation has settled somewhat but the crisis has necessitated new ways of thinking and there has been lasting change.

"Many of the larger pharmaceutical companies have introduced high sensitivity mass spectrometry (MS) into their QC testing facilities, something that was almost unheard of previously. And to address the challenge of transferring MS methods into QC, specific teams have been set up to manage the transfer process."

It's certainly the case that the stringent approach taken by regulators has led to the feeling that companies need to take proactive measures to be ready to deal with other potential low threshold contaminants that may arise in future.

Eric describes his philosophy regarding reactive versus proactive change, "A reactive approach will always put you in bad shape. The reality is, if we wanted to provide a new service and needed to buy five new instruments, whether they are brand new or more established, it could be weeks before a vendor could deliver them".

> "I don't want to be in a situation where a client needs to send samples tomorrow, but we're six weeks away from the starting point. We want to be prepared as things evolve."
>
> ERIC HILL
> *Senior Director of Chemistry Laboratories at Boston Analytical*

Proactive change requires careful planning and executing change initiatives that are fully aligned with the laboratory's overall goals and objectives. Start by carefully evaluating the following to determine the potential impact of any changes to products or processes:

- **Product safety and efficacy:** Changes should be thoroughly evaluated to ensure that they do not compromise the safety or effectiveness of the product, which should be the primary consideration.
- **Regulatory requirements:** Pharmaceutical manufacturers need to comply with strict regulatory requirements for the development, testing, and marketing of drugs.
- **Quality control:** Companies should ensure that they have adequate quality control measures in place to monitor and verify the quality of the product before and after changes are made.
- **Intellectual property:** Organizations need to consider intellectual property rights when making changes to products or processes to prevent infringement on existing patents or trademarks held by other companies.
- **Supply chain:** Manufacturers should evaluate the potential impact on suppliers, distributors, and customers before implementing any changes.
- **Cost:** Companies should carefully evaluate the costs and resources required for implementing changes, including potential costs associated with regulatory approvals and quality control measures.

MINIMIZING DISRUPTION TO OPERATIONS WITH COMPLIANCE-READY TOOLS

Eurofins BioPharma Product Testing Columbia[8] has used Waters Empower Software since 2007 to simplify the way the company collects, manages, and reports chromatography test results. Having compliance-ready tools for advanced data acquisition, management, processing, reporting, and distribution is vital for the contract testing organization's offerings of methodologies under GMP authorization, ISO 17025 accreditation, and ISO 9000 certification.

Mr. Mike Fields, Application Support Analyst for Eurofins BioPharma Product Testing Columbia, explains: "An Empower Software upgrade, or any upgrade in a lab, has the potential to be extremely disruptive to the business. My biggest concern is always downtime. An upgrade needed to be as minimally intrusive to operations as possible. Waters Empower Chromatography Data System (CDS) must be validated to be used in our laboratory, so we needed to find a way to set up the new system and get it validated while the current system was still in production. This required a lot of planning, test scripts, and other validation documentation beforehand. Plus, each acquisition server had to meet requirements set by Waters, and we needed to make sure testing was done on each type of instrument prior to making the change."

Whatever the type of change, Eric strongly emphasizes the "why" in a proactive approach. "I always start by looking at capacity and the needs of our customers when making recommendations and decisions, particularly for equipment purchases.

If I see requests for technology that customers may need, I can evaluate them to determine what laboratory equipment should be acquired and how large the demand is.

Then, of course, I look at ROI. It ultimately comes back to the customer. What does the customer need? What are they asking for? I can add all the newest tech because it sounds really fun. But if I don't have a customer need to service it, that equipment is just going to sit in the laboratory and collect dust. That's not good business."

It's important to remember that change management is an ongoing process, and organizations will need to continuously adapt to new challenges and opportunities.

One tool that pharmaceutical companies can use to work through obstacles is quality by design (QbD), Heather says. Analytical QbD (as described in ICH Q14), provides a better understanding of the overall analytical method capabilities and limitations, which can ensure a greater chance of success on implementation. It also can produce a significantly more robust and quality submission to regulatory authorities.

"You don't wait until the end until you find out something was wrong. If you're ahead of the game with QbD, you'll get the ROI faster than if you wait for the regulatory pressure. By then, your competitors who did get ahead are already getting the benefit of whatever that innovation could be."

HEATHER LONGDEN
Independent Regulatory Consultant

CONCLUSION

'THE ONLY CONSTANT IS CHANGE'

The ability to better anticipate and respond to the shifting needs and expectations of customers, employees, and stakeholders offers strategic advantages in the highly competitive pharmaceutical manufacturing industry. Companies that can adapt to change quickly often perform more effectively, as they can respond to constant modifications and fluctuations, and make necessary adjustments to their operations, strategies, or resources as needed. These manufacturers are also better prepared to face future challenges and uncertainties, such as technological disruptions, economic downturns, or unexpected crises. Beyond the business ramifications, however, the pharmaceutical industry is ultimately focused on patient safety, and changes should always be evaluated to ensure that they do not pose a risk to patient health. That includes any impact on the supply chain, which can affect patient access to medications.

Heather points to the nature of pharmaceutical products and their direct effect on human health and wellbeing as the reason that the industry has a moral responsibility to go above and beyond regulations and guidelines.

Heather summarizes, "In the long run, the company's responsibility is to not just follow a checklist or look at the financial benefits. Instead, pharma manufacturers need to really think about their responsibility to make the changes that are in the best interest of the people who use their products. It really doesn't matter what the regulators think if it affects patient safety at the end of the line."

The smart quality approach[9] being embraced by forward-thinking pharmaceutical organizations will allow them to significantly improve efficiency and productivity over coming years.

Instrument vendors are developing innovations that address the specific needs of QC laboratories.[10] New, intelligent designs will help reduce human error (preventing common mistakes and transcription errors), streamline staff training, improve testing efficiency, reduce risk associated with failed test runs, and help improve compliance.

To find out more, please watch this Waters webinar on The Role of Change Management in Regulated Pharma.

REFERENCES

1. Stephanie Harden and Heather Longden. "Empowering Pharmaceutical Quality Control Laboratories Through Strategic Change Management." Pharmaceutical Technology, 19 Nov. 2020.
2. Mike Wilson. "Mitigating Human Error and Supporting Compliance with Smart Technology." Pharmaceutical Technology, Quality and Regulatory Sourcebook, March 2023.
3. "A&M STABTEST Expands Service Offerings in Protein and Oligonucleotide Analysis with the Waters BioAccord LC-MS System." Waters Case Study, January 2022.
4. Phil Nethercote and Stephanie Harden. "Error Mitigation Tools to Support Quality Assurance and Control." Pharmaceutical Industry INSIGHTs, March 2021.
5. Stephanie Harden and Phil Nethercote. "Error Mitigation in Pharmaceutical Quality Assurance and Control." IPT Online, March 2021.
6. "Eurofins BioPharma Product Testing Lancaster Improves Analytical Sensitivity with Waters ACQUITY Premier System." Waters Case Study, March 2022.
7. Stephanie Harden and Heather Longden. "Change Management's Impact on Innovation in the Pharma QC Laboratory." Technology Networks, May 2021.
8. "Eurofins Streamlines Empower CDS Enterprise Upgrade with Waters Empower System Inventory Service." Waters Case Study, March 2022.
9. "Digitization, automation and online testing: Embracing smart quality control." McKinsey & Company, April 2021.
10. Mike Wilson. "The Role of Smart Technology in Mitigating the Risk of Human Error and Improving Productivity in Diagnostics." Technology Networks, April 2021.

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Eric Hill is the Senior Director of Chemistry Laboratories at Boston Analytical, a cGMP, FDA-registered contract testing and research organization. Boston Analytical supports pharmaceutical manufacturers and developers, from early conception and drug discovery through to routine QC chemistry support and release testing. In his current role, Eric is responsible for developing new service offerings in response to emerging business opportunities. One of his most recent projects included the establishment of extractables and leachables (E&L) testing services to assist customers in meeting the stringent FDA requirements for filings of drug products and devices.

Heather Longden is an Independent Regulatory Consultant with 30 years of experience at a major supplier to the life sciences industry, where one of her most recent roles was advising users on how to design standard operating procedures and configure the applications to take advantage of technical controls built into the software. Although enjoying her recent retirement from professional life, Heather continues to consult with leading companies on data integrity, specifically around the chromatographic analysis process.

Stephanie Harden is the manager of Waters global product marketing and applications teams, with 25 years of experience in product and segment marketing. She has a proven track record leading cross-functional teams, in B2B digital/omni-channel marketing and strategic program development and strategy execution. Specializing in quality by design and the analytical procedure lifecycle and process analytical technology, Stephanie is passionate about the modernization of pharmaceutical development and QC operations and has been instrumental in helping customers to transform the way their organizations operate.

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