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Balancing safety and testing

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A recent Deloitte report[1] focussing on a cohort of 14 of the world's largest pharmaceutical organisations suggested that peak sales per asset will decline to half of what they were a decade ago ($816m)[2] whilst the cost of bringing a drug to market has almost doubled over the same period (now $2,168m)[3] meaning the incentives to drive efficiencies are obvious.

Equally, as organisatns seek to become ever more customer centric in approach, there is also a drive in the pharmaceutical industry to further build trust and confidence with patients and regulators through enhanced safety and compliance measures.

For those working in the pharmaceutical industry safety has always been paramount, but with advances in technology there is an option to go further. Compliance with regulations such as the European Union's Good Manufacturing Practice (GMP) guidelines is not easy and for many organisations can represent a significant management headache. Operating within the rules is essential though and there are undoubtedly many examples of best practice throughout the industry.

But how do organisations deliver best practice while keeping costs down, increasing trust with customers and ensuring the safety of both its people and products? Deloitte[4] suggests that "companies should look beyond their traditional partnership groups to increase trust". Working with experts who specialise in pharmaceutical safety and testing, with established trusted global reputations and expertise would be a common-sense next-step.

Together, VWR, Part of Avantor and 3M, work with organisations to help surpass the expectations of customers and regulatory bodies, to find efficiencies and to begin to drive innovation. This strong partnership, helps organisations to navigate the difficult path of meeting all these demands by finding the right balance between safety and testing.
And this is how...

Lean-lab approach

Adopted from lean manufacturing thinking in the 90's, the lean-lab approach is now less of a process and more of a mindset. Pioneered by Toyota Motor Company, there is an underlying principle which supports the approach: the 5S system. These principles include Sort (seiri), Set in order (seiton), Shine (seiso), Standardise (seiketsu), and Sustain (shitsuke).[5] Taking inspiration from other industries, we have now adapted this and innovated within it.

Understanding, familiarity and intimate knowledge of the environment and process is vital to the application of testing procedures. The importance of understanding the air and water quality, the age of equipment or people flow can't be undervalued. It's this familiarity that can, when applying the principles, drive efficiencies in productivity, testing and costs.

In some ways it is the cumulative effect of small gains that can make a significant difference. For example, improving productivity within the QC lab can reduce the lead times for delivery to the customer and reduce the cost of processes. Enhancing first-time quality in this area can also reduce rework and investigations. Through effective test management and controls we can establish and ensure high quality results, sustaining a consistency across the entire process.

Standardisation within the lean lab will not only drive efficiencies, but also be key to the business's ability to adopt a more agile approach. Developing a standard, yet flexible and holistic lab design will go a long way to deliver this. These practices can then be replicated across the global network with partners who not only understand the local complexities and regulatory requirements, but also have the experience of standardised global roll-out and understand the inherent issues within it.

One of those issues is resistance to change within organisations, however, the only way to overcome it is to prove change works with robust evidence. Experienced partners understand this and practical modern information systems make this possible. Not only can these systems benefit the proof of success it can also monitor compliance with procedure and process, capture and analyse data to produce useful information, and enable better decisions in real time.

Continuous improvement and innovation

The mindset extends to building a culture of continuous improvements. This allows all employees to focus on fresh and innovative ideas that can improve the operation of the lab. Continuous improvement also brings sustainable benefits to the business, the team and the customer.

Establishing a culture of continuous improvement and innovation is key. The combination of external expert support and internal expert innovation, underpinned by a company-wide determination to improve, always delivers positive results.

To achieve and maximise the opportunity of improvement, knowing the details of how a lab works is vital. Whether we're looking at and analysing individual processes and product use to physical environments and movement, we can determine if there are too many working steps in testing or whether waiting times for measurement results render the lab unproductive.

Ultimately, it's about working smarter and not harder to deliver efficiencies and improvements. The cliche claxon may have just sounded, but it's a cliche for one reason: it's true. We can deliver quick solutions to deliver efficiencies in the short-term, but also consider improvements that could offer long-term efficiencies too. Whether that be automating regular error-prone tasks, simplifying tasks, developing processes and improving workflow or using more appropriate products that omit unnecessary working steps.

Preventative strategy

Part of the culture of innovation and improvement would be transitioning the business from a reactive strategy to a preventative strategy. The risks and costs with a reactive strategy are great: from the downtime and levels of over-testing alone it proves to be a costly approach. Adopting a preventative strategy will increase productivity and drive greater efficiency.

The value of a preventative strategy also goes beyond productivity and efficiency. The strategy will also inspire confidence and build trust into the entire system. Proactively preventing problems can be achieved through experienced and expert partners asking the right questions and getting a better understanding of the environment before working with internal experts to identify what could go wrong, where and when in the process. Taking this approach and working together we can then begin to consider the tests required.

The familiarity and expertise of the internal team coupled with the guidance of expert partners fuels efficiency because their knowledge is vital in terms of keeping greater control of the testing processes and also being able to identify where preventative measures can be best implemented. Depending on the needs, these tests could include sterilization process monitoring solutions such as biological indicators which are designed to allow positive release of sterilizer loads by demonstrating in real time they have been exposed to sterilizing conditions.

Using technology

Identifying and implementing a testing process workflow through transformational technology will drive efficiency, productivity and speed because of its simplicity of use. It will also prove to be more adaptable to the local needs of plants across a global network of internal labs. Not all technological solutions have to be complex. To facilitate implementation and limit the amount of required training, companies should turn to tech that is simple and easy to use.

No matter how good the technology there is not a 'one size fits all' approach that will work. Using a suite of compatible and complementary technology and science-devised solutions will drive better margins and greater efficiencies. Harmonisation will enable you to consolidate the number of products being purchased and driving scale right across your operation. The accuracy and reliability of a trusted provider's products will also further enhance confidence for customers and employees.

Maximising the brains on the ground

Identifying that technology may be problematic if the expertise on the ground is locked into work-load heavy schedules is essential. However, working with trusted partners who can deliver both local and global support would be key. Working together with you they will deliver joint innovation backed by the science-led business. Combined with the local knowledge they will identify and create solutions for the problem areas which consistently crop up across the operation.

For example, they will identify and advise on the most appropriate testing regime while maintaining safety and boosting your agility. The likely outcome being that the joint team would deliver results faster and more accurately.

The combined knowledge of the partners and your employees will also help identify leading products that are available globally and can be adapted to meet local compliance needs. This will enable them to take an efficient and consistent approach whilst maintaining accuracy. Equally, while utilising their increasing knowledge, they will be able to implement a minimal viable approach that keeps the standards high and will drive further efficiencies across purchasing.

The value of the joint partnerships also means that employees will benefit from the training provided around products and testing in general. While it is vital that the 'brains on the ground' are used to develop the preventative strategy, there is the added value of improving their knowledge and skill sets to drive further innovation and efficiencies. The expert and trusted partners will be key to building the momentum and supporting the cycles of development and innovation that follow.

[1,2,3,4] www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-ten-years-on-measuring-return-on-pharma-innovation-report-2019.pdf
[5] safetyculture.com/topics/5s-lean/

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Working with you

The way that organisations can get results from tests is getting faster, for example, with a modern biological indicator you can get your results in 24 minutes. This is a big shift from how it used to be when you would be waiting days. With these digital results, decisions can be made quicker, giving an increased chance of success as it is possible to understand if anything is not sterile earlier in the process and action as required. Any testing that is done must work with existing systems and as a strategic partner, we can work to identify the most suitable solutions to meet an organisations specific needs.

Get in touch

When managing the challenges of sterilization and monitoring, organisations around the world already depend on VWR, Part of Avantor and 3M for innovative products and creative solutions.

To learn more, please visit: **www.vwr.com/3M**

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