INSPECTION RISK AND OPPORTUNITY IN MEDICAL DEVICE MANUFACTURING

Including Metrology Fixture Buying Guide

VERUS METROLOGY PARTNERS

Contents

Introduction

The global economy has seen a lot of volatility in 2022. Largely protected against the financial impact of the COVID-19 crisis due to the heightened dependence on medical technology, from personal protective equipment to diagnostics and lab equipment, the medical device manufacturing industry remained secure. In 2020, the US medical technology industry saw a growth of 6.3% to US$446 billion, according to EY's 2021 Pulse on the Industry[1]. However, the Russian and Ukrainian war, which has had a strong influence on the western and US market, has created more doubt and uncertainty in the greater economy.

With the increased need for signs of security and a reduction in risk, quality departments are under pressure to identify and work towards the ever-evolving, highest possible standards. In this whitepaper, we will discuss quality best practices and the connection to overall business health, as well as taking a deeper look into how the inspection process can support the wider business objectives.

Skilfully organised quality labs can increase revenue, strengthen access to a skilled workforce, and boost productivity and efficiency which will see benefits across your business and not just on regulatory reports.

In this paper, you will also find a guide to metrology fixture planning, so you and your team can have complete awareness of how to equip your metrology and inspection team with fixtures that will increase productivity, minimize risk, and reduce manual interaction.

Your quality department shouldn't just present problems, your quality department should be identifying opportunities.

[1]Ernst & Young LLP. (2022). Pulse of the industry medical technology report 2022. [Online]. EY. Available at: https://www.ey.com/en_us/life-sciences/pulse-of-the-industry [Accessed 13 January 2023].

Why Quality is Essential to Your Business

Quality is essential to your business due to the safety of your end patient, first and foremost. We operate in a high-stake industry, our commitment to quality must always be 100%. We are now aware that the quality department can also identify ways in which we can make our products better and our systems better. The McKinsey analysis[2] that came to this figure estimated that quality costs the medical device industry between 6.8 and 9.4 percent of annual sales. According to the estimated global market value of the industry in 2021 (USD$489 billion), the cost of quality in the medical device industry is between USD$33 billion and USD$46 billion.

The McKinsey analysis also broke down these costs:

Direct cost of ensuring good quality

2.0 - 2.5% of industry sales (up to approximately USD$12 billion in 2021)

Direct cost of poor quality

4.8 - 6.9% of industry sales (up to approximately USD$33 billion in 2021)

There are also indirect quality costs that can apply on top of the above. Examples of indirect costs include reductions in market capitalisation and lost revenue.

By doing this analysis, the McKinsey authors could also estimate the level of recoverable quality costs. In other words, how much could be saved by implementing quality best practices. The figure they came to was between 1.5 and 3.0 percent of annual sales. On an industry-wide basis, that equates to up to USD$15 billion.

In terms of your business, it is a potential cost saving of up to 3 percent of your annual revenues.

You can make those savings by implementing quality best practices. The main points to focus on are:

- Develop a quality culture in your organisation
- Move to a predictive approach to asset maintenance
- Ensure ongoing product and process optimisation

All three of the above quality best practice areas will be explored in more detail in the next section of this whitepaper.

[2]McKinsey & Company. (2017). Capturing the value of good quality in medical devices. [Online]. McKinsey & Company. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/capturing-the-value-of-good-quality-i [Accessed 13 January 2023].

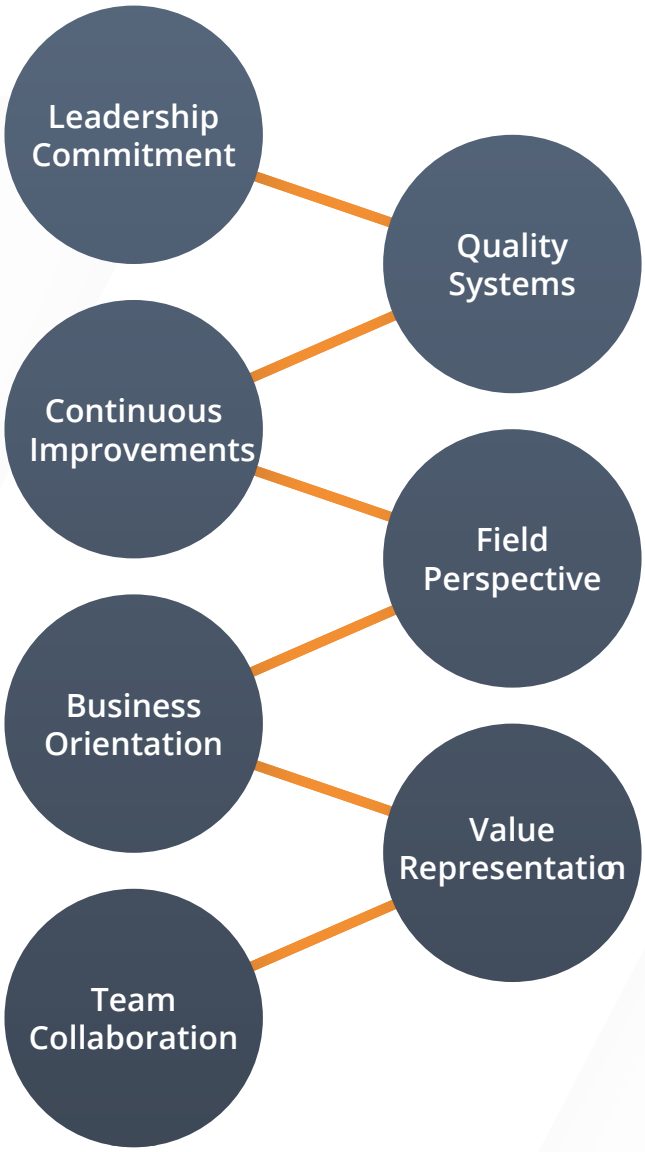
Quality Best Practices

Develop a Quality Culture

Quality cannot be the responsibility of the quality department alone, as quality doesn't begin or end with your quality team. Your quality team will play an essential role in delivering the improvements in quality that could lead to an increase in profits by up to 3 percent, but it can't do it by itself.

Instead, everybody in the organisation needs to be involved in, and take responsibility for, product quality. For this to happen, there needs to be a quality culture in your organisation, and that has to come from the top. Quality must have C-suite attention and it should be factored into every decision that is made.

It is then important to nurture the quality culture in your organisation, just as you would with any other similar cultural focus. Examples like a learning culture or a customer service culture require continual work to develop and improve. That same applies to a quality culture.



Organisational Culture **includes and impacts** Quality Culture

What does a quality culture look like? A good starting point is to ensure sufficient priority and emphasis is placed on all four essential quality functions:

- Monitoring – to prevent non-conforming products from entering the market
- Process optimisation – continual efforts to improve manufacturing and inspection processes to enhance product quality
- Prevention – optimising the maintenance of production assets to ensure manufacturing consistency
- Remediation – efficiently and effectively investigating quality issues to identify the source

How to Develop a Quality Culture

- Quality should be driven by the CEO and other members of the C-suite
- Quality should permeate every level and function of the organisation
- Quality should be considered in every C-suite decision
- Finance and procurement teams should look at spending on quality as an investment
- With quality viewed as an investment, there should be an emphasis on calculating the impact of quality spending in areas such as recruitment, staff retention, training, equipment acquisition, and process optimisation
- Spending on quality should go beyond the quality department, where investments in quality are also made in manufacturing, engineering, supply chain management, and design
- The success of quality spending should be measured on a return-on-investment basis rather than a simple regulatory box tick
- There should be regular messaging on quality, with an emphasis on responsibility throughout the organisation
- Key personnel in non-quality roles should also be given direct responsibility for quality improvements, in addition to the responsibilities taken on by the quality team

Some key examples of sharing quality responsibility

Product design teams should consider quality in the early stages of the product development process, with an emphasis on manufacturability and ease of inspection

- Manufacturing and engineering teams should be involved in process optimisation to improve quality consistency
- Procurement, finance, engineering, manufacturing, and quality teams should work together to introduce systems and solutions that can identify conformity deviations as soon as possible, allowing remedial action before acceptable tolerances are breached

Manufacturing Asset Maintenance

There are many factors that can have an impact on product quality, but some of the most influential are the machines and equipment used to manufacture your product. Despite this, many medical device manufacturing facilities continue to operate a reactive or schedule-based approach to maintenance.

With reactive or schedule-based maintenance procedures, equipment failures are inevitable. This has a knock-on and expensive impact on the business, as products cannot be produced during periods of maintenance downtime.

Equipment failures also have a substantial impact on quality. However, these negative impacts on quality are often overlooked as the focus is to return the failed equipment to an operational state.

Just as importantly, the impact the quality function can have on preventing equipment failures is also overlooked.

The aim should be to move to a predictive maintenance model, where assets are monitored in real-time to identify impending failures before they occur. This allows planned maintenance rather than unplanned downtime.

There are multiple technologies that can help move medical device manufacturing facilities to a predictive maintenance approach, including digital twin technologies. Quality and inspection technologies can also help.

The process of inspecting manufactured products can be an early indicator of a problem with equipment on the manufacturing line. With a predictive maintenance approach, deviations from the norm during quality inspections can trigger an investigation that can help engineers and technicians identify maintenance requirements.

Crucially, this can take place before products start to fail inspections, significantly reducing (and potentially eliminating) the production of non-conforming product batches.

Product and Process Optimisation

Product and process optimisation should be an ongoing focus and priority in medical device manufacturing environments.

Products should be designed using DFM (design for manufacturing), DFA (design for assembly), and DFI (design for inspection) principles. In other words, going beyond designing a product to instead designing a product that is as easy as possible to consistently manufacture, assemble, and inspect.

Manufacturing processes should also be regularly reviewed to identify opportunities for improvements. The same applies to inspection processes. The aim in both situations should be to automate as much as possible while minimising the number of steps it takes to complete the process.

We are now going to explore one element of product and process optimisation in more detail – optimising the inspection process. We'll look at why inspection process optimisation is important in improving quality in your organisation, as well as practical steps that you can take.

Why Inspection Process Optimisation is Essential to Your Business

The real benefits of inspection processes are greatly underestimated. There are many reasons for this, including the view that inspection is simply a go/no-go function of a production environment.

Whatever the reason, underestimating the benefits of post-production or in-line product inspection can be costly. It can also lead to unnecessary delays and inefficiencies.

Many of the worst-case scenarios in this regard are when inspection is a forgotten element in a project. This inevitably leads to a frantic rush for a solution as inspection backlogs start impacting production line output, customer orders, supply chains, and the financial performance of the business.

This is even before you consider the regulatory impact of inadequate inspection processes. Resolving situations similar to these results in unnecessary costs and avoidable delays.

The Placement of Quality in Business

What about the benefits of operating a best-in-class inspection process in your facility? Those benefits include:

- Maintain project timescales and milestones
- Optimise your inspection equipment (particularly if you are investing in new equipment in addition to new fixtures) to ensure it delivers on your objectives and you have the right machine for the job
- Minimise the cost of the new fixture
- Ensure inspection processes are repeatable and reproduceable, including if the product or component is delicate, intricate, and/or very small
- Eliminate human variance and reduce operator error
- Reduce waste and improve production line productivity and throughput by identifying measurement deviations before they fall outside acceptable tolerances
- Optimise productivity in your quality function through the semi-automation of inspection processes
- Enhance the service you offer to customers, including in areas like product quality, traceability, and availability
- Improve regulatory compliance and quality assurance processes by, for example, improving your ability to achieve a justifiable sampling rate (i.e., the percentage of products that need to be inspected to give you a high enough level of confidence that a sufficient number of manufactured parts in a batch will pass inspection).
- Enhances safety
- Improves quality throughout the entire product lifecycle, improving the competitiveness of your product and business
- Enhance and guide product design and R&D processes through, for example, proving a design can be efficiently and effectively inspected before it is finalised
- Enhance the design transfer stage through processes such as First Article Inspections (FAIs) to get production lines up and running faster while minimising New Product Introduction (NPI) delays.
- Improve decision-making with accurate and reliable data
- Make progress on achieving the goal of becoming a more automated, connected, and smart manufacturing facility

Avoiding Business & Financial Risks in Your Quality and Inspection Processes

Operating best-in-class inspection processes in your facility can help mitigate a number of risks, including operational, business, and financial risks.

Patient safety risks

Ineffective and inefficient post-production or in-line product inspection processes increase the risk of defective and unsafe products being sold in the market. This puts patients at risk and, potentially, physicians. From a business perspective, selling unsafe and defective products into any market can have knock-on regulatory, legal, financial, and reputational impacts. According to Sedgwick's State of the Nation Recall Index report, medical device recalls went up by 40% in 2021 from 2,061 in 2020[3].

Reputational, financial, legal, and regulatory risks

Operating substandard quality and inspection procedures can result in FDA warning letters that will require corrective action. FDA warning letters can also impact your reputation in the market.

Reputational, financial, legal, and regulatory risks increase considerably if defective products enter the market, particularly if those products result in adverse incidents or recalls. In both cases, the legal and regulatory implications can be substantial, plus there will be direct costs involved to resolve the situation. The reputation of both the business and product will also take a hit.

Manufacturing process risks

The majority of medical device manufacturing facilities operate at high speed to produce high volumes of products. Any interruption in the normal operation of the manufacturing process, including because of ineffective, inaccurate, and/or inefficient inspection processes, can have a significant and potentially costly impact.

Quality function risks

Inefficiencies in the quality function of your medical device manufacturing facility will have a direct impact on output, waste, productivity, and your ability to deliver on customer requirements.

[3]Sedgwick. (2022). European product recalls spiked by over 25% in 2021, rising ahead of pre-pandemic levels. [Online]. Sedgwick. Last Updated: Sedgwick. Available at: https://www.sedgwick.com/news/2022/european-product-recalls-spiked-by-over-25-in-2021-rising-ahead-o [Accessed 13 January 2023].

Drive Value, Performance, and Innovation

Post-production or in-line product inspection processes can achieve much more than verifying that a component or medical device product has been (or is being) manufactured according to its design and specification, and that the dimensions are within the required tolerance ranges.

Below are some examples using metrology fixtures that demonstrate how inspection processes can drive business value, performance, and innovation.

It is worth noting that these examples only scratch the surface of how metrology can benefit wider business operations and strategies. Cutting-edge inspection solutions, out-of-the-box thinking (within compliance parameters), and the latest Quality 4.0 technologies make it possible for metrology and inspection processes to do more and achieve more with fewer people, errors, or interruptions.

Multi-station fixtures

Multi-station fixtures make it possible to inspect multiple components or products in a single set-up. This significantly speeds up the inspection process. It also reduces the involvement of operators and improves the accuracy of your inspection data, as well as making it possible to inspect products at a faster rate.

The overall impact is an inspection process that can reliably keep up with manufacturing output with minimal resources.

Auto-rotational fixtures

Auto-rotational fixtures take fixturing technology to another level, particularly if your parts or products need to be inspected in multiple dimensions.

In a manual inspection process, it is up to the operator to rotate the part being inspected. Auto-rotational fixtures rotate parts more accurately, faster, and with multiple components at the same time. This positively impacts not only quality processes, but manufacturing performance and output.

In-process inspection

In-process and fully automated inspection is the ultimate goal of the Quality 4.0 concept. Quality 4.0 involves using technologies and metrology best practices to automate and digitalise quality and inspection processes.

With in-process metrology solutions, inspections take place on the production line to ensure seamless alignment between metrology processes and production output. You can also inspect a higher number of products in a batch, improving overall product quality, and you can identify measurement deviations in real time. The latter allows operators to take corrective action before downtime occurs.

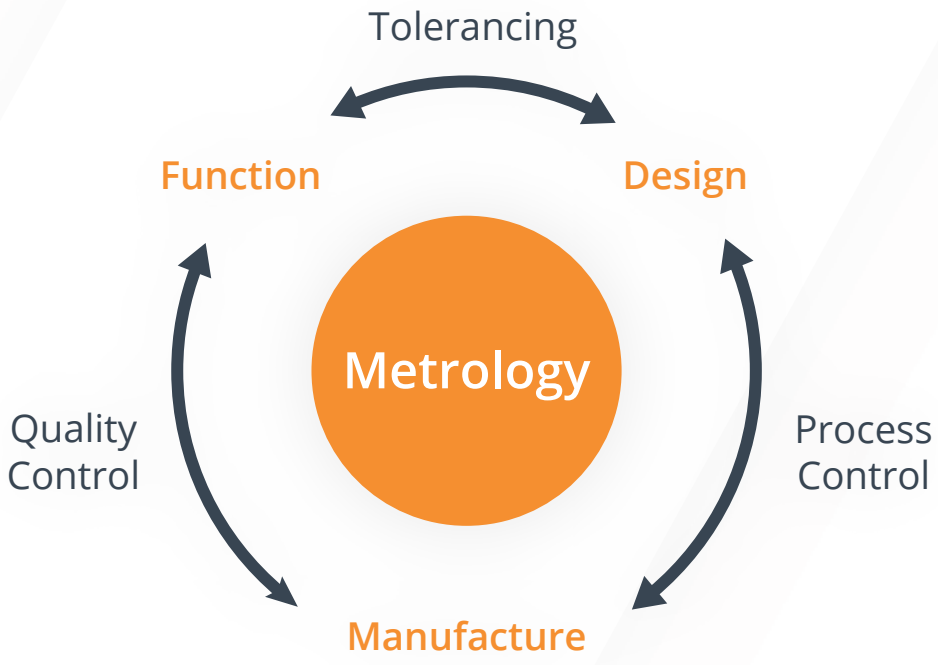
Plus, with full automation, you can reduce the resource requirements for inspection processes to close to zero.

Best in Class Metrology Fixtures – the Essential Ingredient

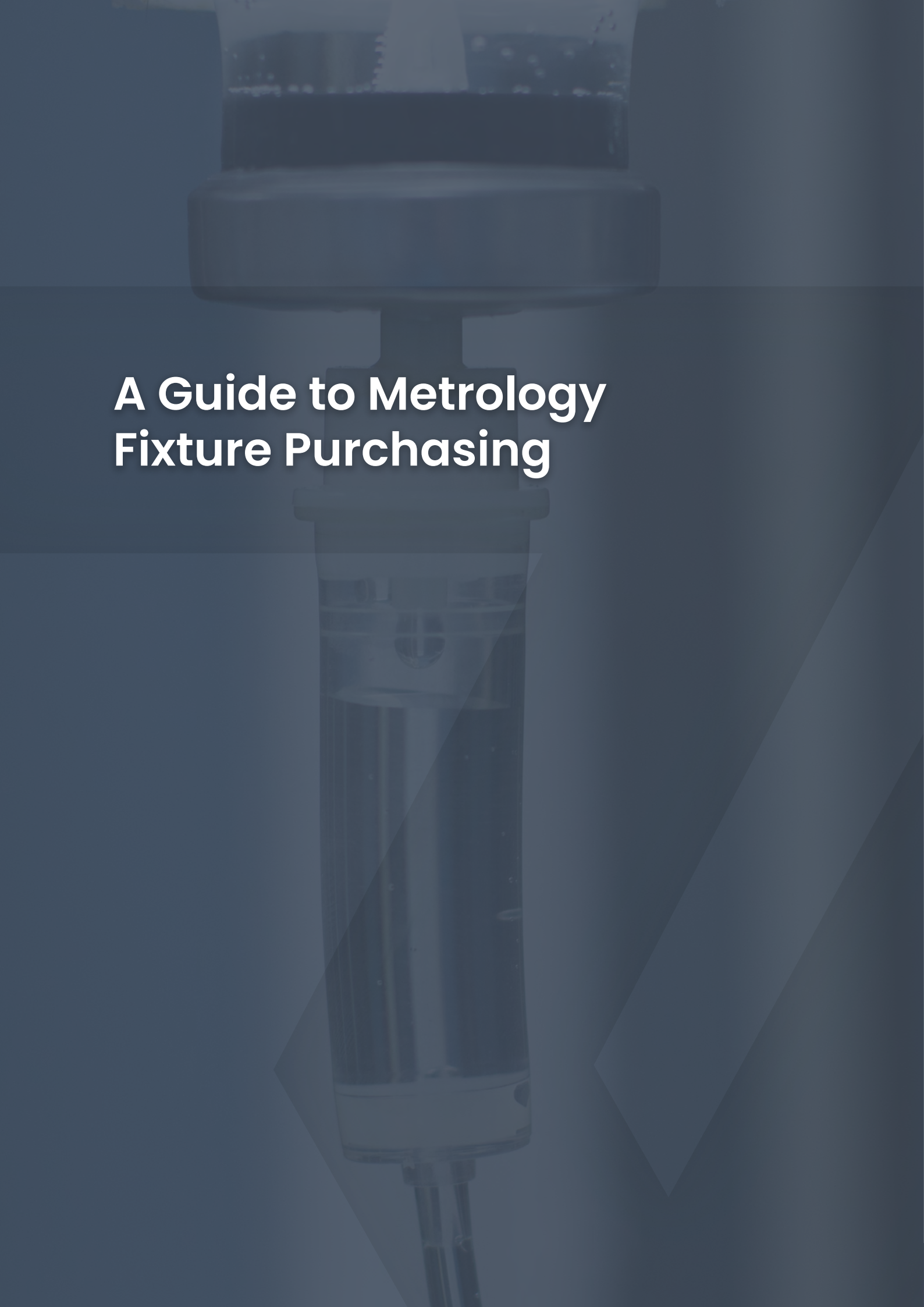
In this section, this whitepaper has covered metrology processes, the concept of Quality 4.0, and the latest inspection best practices and technologies. All are essential to transform metrology and inspection processes from being data gathering, go/no-go tasks to also contributing to continuous operational and business improvement.

Best-in-class metrology fixtures are central to the ability of inspection processes to drive business performance in areas like productivity, product quality, supply chain management, and customer service.

The remaining sections of this whitepaper will guide you through the process of buying a new, best-in-class metrology fixture, starting with the things you should be aware of before you begin.



The central role of metrology controlling design, manufacture and function



A Guide to Metrology Fixture Purchasing

Buying a new metrology fixture is not a regular occurrence in most medical device manufacturing facilities. Therefore, it is important to address incorrect assumptions and to get an understanding of the options available before you begin the process. Here are the key things that you need to know.

Your New Metrology Fixture Should Deliver a Return on Investment

The first point is to highlight the importance of not only treating your new metrology fixture as an investment, but also to think about how you will calculate and measure return on investment. Some points you should consider include:

- Time and resource savings in the completion of inspection processes
- Productivity gains in your quality function
- Savings in time and resources due to enhanced inspection accuracy and fewer errors
- Improvements in manufacturing performance metrics as a result of optimised inspection processes
- Reductions in product waste and the related costs of producing products that can't then be sold
- Commercial benefits from improvements in product quality and distribution reliability
- The financial benefits that come from eliminating inspection delays in NPI projects

Not all of the above will apply in every situation, but they will help you get a truer understanding of the financial returns and operational benefits of your new metrology fixture.

There is No Such Thing as Off the Shelf Fixtures

One of the most common misconceptions is that there are cheap, off-the-shelf metrology fixtures available that are suitable for medical device applications.

This isn't the case.

When it comes to medical device manufacturing operations, there simply is no such thing as off-the-shelf fixtures.

The reality is that every medical device is different, every manufacturing process is different, and every quality team has its own unique workflows. As a result, custom metrology fixtures are the only solution.

A custom metrology fixture will be fully optimised for the product or component it is designed to inspect. It will also be optimised for your inspection equipment, sampling rate, and throughput objectives, as well as the wider objectives of your business.

For example, one of your objectives could be to increase automation in your quality function to improve productivity and alleviate the impact of skills shortages. In this example, you could opt for a fully tailored auto-rotational multi-station fixture to help you achieve this objective.

A final point in this section – one of the reasons why there is a misconception about off-the-shelf fixtures could be because of the existence of modular fixturing solutions. Modular fixturing solutions feature multiple off-the-shelf products that you use together to create a fixturing solution.

Modular fixtures are useful in some industries and situations. However, the nature of the medical device industry, particularly in relation to compliance, quality, and patient safety, means modular fixtures have very limited practical applications. This is because they add too much variation and room for error in the inspection process. The documentation requirements are also more laborious as each individual set-up and combination of modular components needs to be documented.

In summary, there are too many ways and opportunities for mistakes to occur if you use modular fixturing solutions in a medical device environment.

So, in summary, off-the-shelf fixtures don't exist, and modular fixtures have limited applications in the medical device industry. The best choice for your fixturing needs is a custom fixture. More on that in an upcoming section. First, let's look at the importance of independent advice.

The Importance of Independent Fixture and Equipment Advice

There are many different design approaches that can be taken when developing a new metrology fixture. Furthermore, technologies, best practices, and material considerations constantly evolve. Therefore, it is important to get expert advice when purchasing a new metrology fixture.

It is also crucial to take this several steps further. In addition to getting expert advice on your metrology fixture, you should also:

- Ensure the advice you get is independent, particularly in relation to the manufacturer of your CMM, vision system, or other inspection equipment.
- Where possible, seek independent advice before you buy either a fixture or inspection equipment.

Inspection equipment vendors will adapt the advice they give you based on the capabilities and limitations of the machines they produce. Independent advice, on the other hand, will be completely focused on your requirements.

Whether you are purchasing a fixture on its own or both inspection equipment and a fixture, getting fully independent and expert advice from a team like us at Verus Metrology Partners is the best approach.

The Benefits of Customised Metrology Fixtures

- The fixture will be fully optimised for your product, inspection workflows, and inspection equipment.
- The fixture will be able to do its core job, i.e., holding the part or component securely in place to enable accurate measurements.
- The design of the fixture will take into account future requirements. For example, you might be planning further iterations of your product. The potential updated version of your product can be factored into the fixture's design.
- The inspection workflows for your product or component can be optimised through automation or semi-automation, and by ensuring the maximum number of products can be inspected with every set-up.
- Engineers designing your metrology fixture will also optimise the set-up process to minimise CMM downtime between inspections.
- Maximising the efficiency of your inspection equipment with multi-station fixtures and fast set-up routines.
- Easy and fast set-up routines make it possible for any operator to load and measure parts, alleviating pressures on your quality resources.
- Customised metrology fixtures can help with regulatory processes such as, for example, ensuring the inspection of a sufficient number of products in each batch.
- New fixtures should be fully gage R&R tested, further contributing to your compliance efforts while also giving you peace of mind that inspections using the fixture are repeatable and reproduceable.

Understanding the Different Types of Metrology Fixtures

Auto-Rotational Fixtures

Metrology fixtures that auto-rotate during the inspection routine to allow measurements to be taken in multiple orientations.

Manual Rotator Fixtures

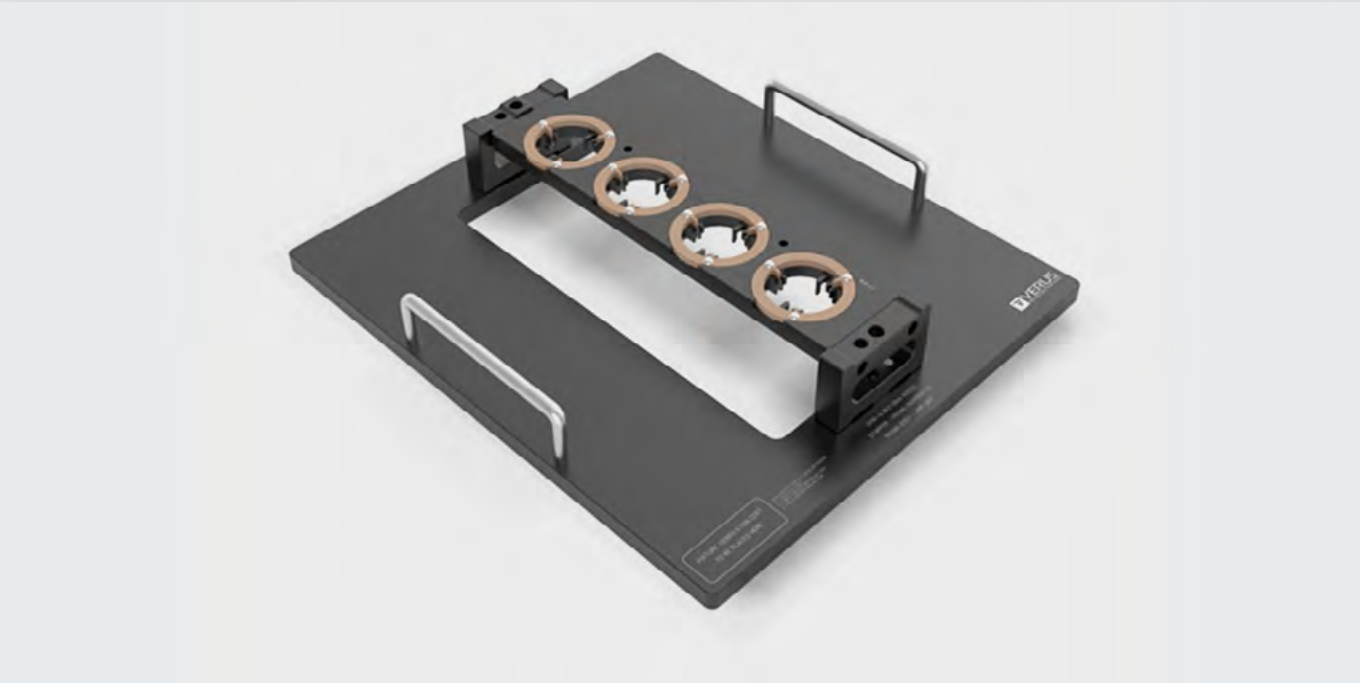
Similar to auto-rotational fixtures, except the operator uses a mechanism on the fixture to manually rotate the components or products.

Multi-Station Fixtures

Fixtures that hold multiple components or products at the same time, speeding up inspection processes.

Proof of Principle Multi-Station Prototype Fixtures

When designing a multi-station fixture, it is often necessary to create a proof of principle version, usually for verification and validation. At Verus Metrology, we produce single-station versions of multi-station fixtures for POP applications. All our POP prototype fixtures come with a complete gage R&R study, so are compliance, validation, and verification ready.

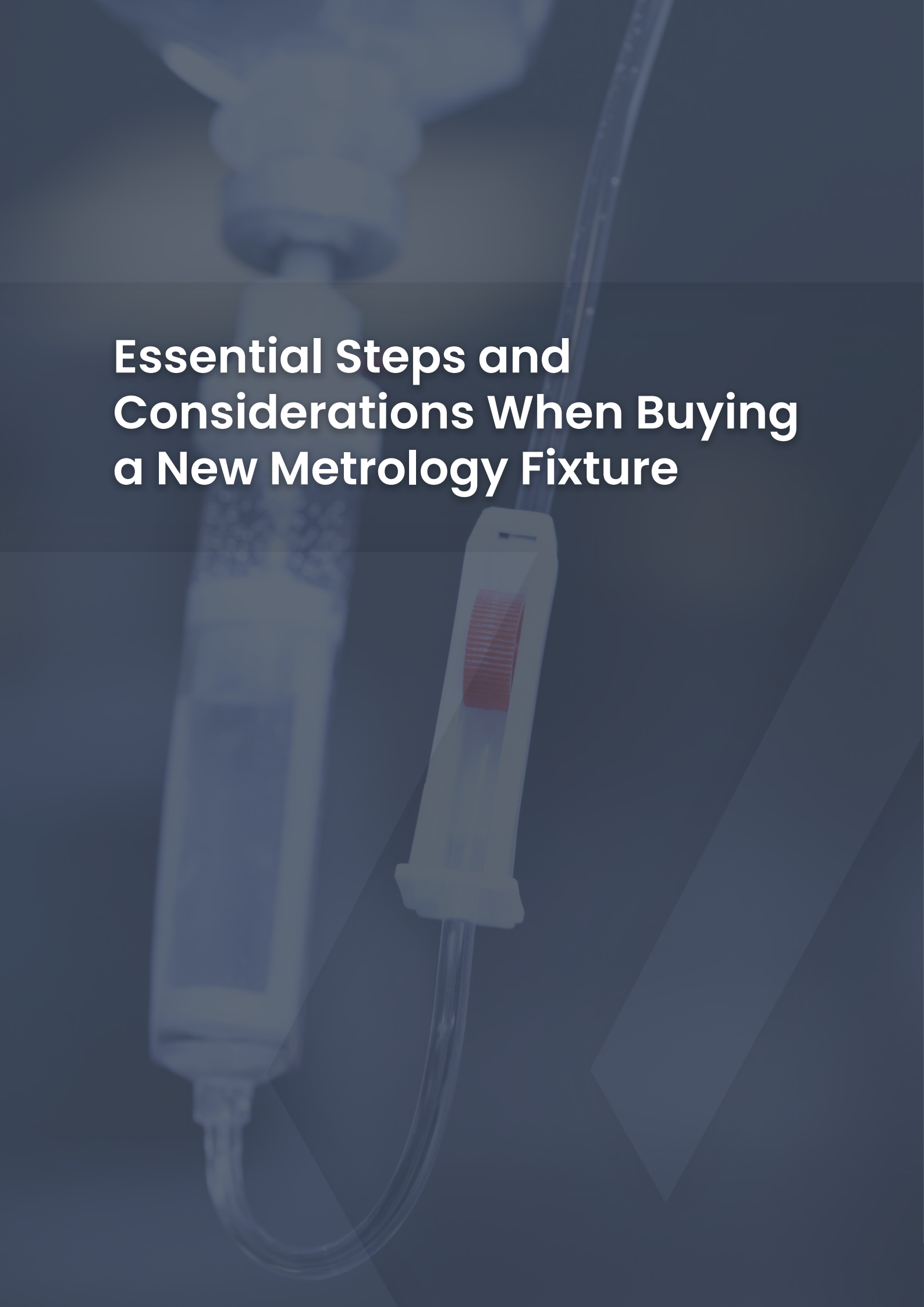


Vision System Solutions

Fixturing systems designed and optimised for vision systems and other non-tactile CMM inspection equipment.

Docking Systems

Docking systems can be fixed to CMM machines to make the process of loading fixtures faster and easier. Docking systems are particularly beneficial for quality departments that use multiple fixtures or where it is important to maximise the inspection performance of the CMM.



Essential Steps and Considerations When Buying a New Metrology Fixture

Given the importance of metrology fixtures to your operation's quality control function, and the potential positive impact that effective inspection processes can have on the wider business, it is crucial to take time to make the right decisions.

When Should You Start

Ideal scenario

The best time to engage with a metrology fixture partner is during the product design stages. Starting as early as this enables Design for Inspection (DFI) principles to be factored into the design process. In other words, considering the impact of the product's design on future inspection and measurement processes.

In this ideal scenario, you would not yet have invested in a CMM. This makes it possible to develop the best solution without compromises or limitations, i.e., a solution that will include the best possible combination of CMM, metrology fixture, and inspection routine.

Good scenario

The ideal scenario described above is not always possible. For example, you might already have a CMM or other inspection equipment. In this situation, engaging with a metrology fixture partner during the design stage of your new or updated medical device product will still bring substantial benefits.

Similarly, you might already have finalised your product's design. In this situation, it is beneficial to engage a fixture partner before you decide on a CMM vendor or machine.

General advice

Whether any of these scenarios apply to your current circumstances or not, the best advice is to start the process of buying a metrology fixture as early as possible.

Each of the three scenarios above are centred around one key point – the earlier the better. Why is it beneficial to start the metrology fixture buying process early?

- You'll get a better fixture solution
- Metrology fixture costs will be lower
- Easier to meet project milestones and deadlines
- You can optimise your CMM investment to achieve maximum machine usage and ROI
- Inspection and quality workflows can be fully optimised
- You'll get a better product as quality assurance confidence levels can be optimised

Define Your Procurement Objectives

Defining your objectives is important when procuring any quality or engineering solution. From our experience at Verus Metrology Partners, we find it beneficial to define both procurement and engineering objectives.

The reason for this is that metrology fixture solutions have an obvious impact on operations, including quality control and manufacturing. However, as outlined earlier in this whitepaper, metrology fixtures can also positively influence the wider business. This makes it beneficial to consider how your decision aligns with wider business strategy, and to go deeper with your financial analysis and ROI calculations.

So, from a procurement perspective, it's helpful to define your financial, business strategy, and ROI objectives when purchasing a new metrology fixture.

Questions that are often relevant include:

- What impact will the new fixture have on staffing requirements in your quality team?
- Can you operate inspection processes with a lower headcount and/or with different skill levels?
- How will a reallocation of resources in your quality function impact productivity?
- How will the new fixture impact the performance of your CMM and the ROI you achieve from your inspection equipment?
- What regulatory compliance cost savings will the metrology fixture deliver?

There are also operational considerations:

- What reduction in waste can you expect from improved inspection processes made possible by an optimised metrology fixture?
- How will product quality improve and what impact will that have commercially and in terms of risk reduction?
- How will a metrology fixture that can identify deviations before tolerances are breached impact productivity on your production line?
- What are the general productivity gains that will result from inspection and quality control processes that are more aligned with manufacturing speed and output levels?

The above are just some of the questions that are relevant when considering the procurement objectives of a new metrology fixture investment.

Define Your Engineering Objectives

Clarifying your engineering objectives when buying a new metrology fixture involves looking at the practical aspects of developing, introducing, and using the fixture. The considerations you should take into account include the product or component the fixture is being designed to inspect, as well as the capabilities of your CMM.

Manufacturing considerations are also important. This includes how many products you manufacture in a batch and the batch sampling rate you need to achieve to ensure product quality and regulatory compliance.

The skills and capabilities of your quality team are also important considerations, as are the workflows and processes that apply to the members of staff who will be using the new fixture. Can those workflows and processes be automated or improved in other ways? How can the design of the new metrology fixture facilitate these improvements?

Future plans for your product, quality department, and overall manufacturing facility are also important. For example, are there existing products or components that also need to be inspected using your CMM, or are new products or components likely to be introduced in the future? If so, it might be beneficial to consider getting a docking station as well as metrology fixtures to make inspection batch changeovers as smooth and efficient as possible.

Another example of product considerations is whether the product is likely to go through further development stages in the future. If this is the first version of the product and it is likely to be expanded, changed, or upgraded, can the design of the fixture for the current iteration be aligned with those future plans?

Where you are in the process is another important factor when defining your engineering objectives. For example, is the product still going through the design process or have you reached the design transfer stage? Is the product already in production and you now want to improve your inspection and quality control processes? Are there any inspection challenges or bottlenecks that you want to improve?

By factoring in these considerations and defining your engineering objectives, the overall project will be smoother, and you will get the best possible solution for your requirements.

Engage an Experienced Partner

Working with an experienced partner is essential when buying a new metrology fixture.

Your partner should have expertise developing best-in-class metrology fixturing solutions for the medical device industry. After all, the components and products that are inspected in the medical device industry are very different from those inspected in other regulated industries, such as aerospace and automotive manufacturing.

When you select a metrology fixturing partner, you will need to supply information so the metrology engineers can design your new fixture. This includes the parts or products that will be inspected, although this isn't essential. For example, at Verus Metrology, we have extensive experience designing and developing medical device metrology fixtures using design drawings and CAD files.

Assess and Refine Your Measurement Processes

If the product or component is already in production, it is important to get a full understanding of the current inspection processes. This information will be highly beneficial when reviewing, updating, and refining your measurement processes.

The metrology engineers working on your new fixture will aim to create an inspection process where the maximum number of measurements can be taken in the minimum number of steps with as little operator involvement as possible.

Understand What You Need to Measure

A full analysis of what needs to be measured, how, and where, should be undertaken early in the metrology fixture design process. Your metrology fixture partner will take the lead, but your input is likely to be required. Examples of things to consider include:

- Characteristics of the part, including its size and shape, as well as the materials used in its production
- Methods of measurement
- Measurement equipment
- Dimensions
- Tolerances
- Datums
- Orientations
- Where the inspection will take place
- Inspection frequency
- Size and weight limitations of the fixture

Decide If You Need a Proof of Principle

Advanced metrology fixtures can be highly complex. It is also common for metrology fixtures to be designed before the first batch of products is manufactured. In both these situations as well as in other situations, it can be beneficial to produce a Proof of Principle (POP) metrology fixture before moving forward with the final fixture.

A POP fixture could, for example, be a single-station version of a multi-station fixture. This can be used to test the fixture's ability to properly hold the product in place. You can also test the inspection program created on your CMM, as well as the ability of your staff to set up the fixture.

POP fixtures can also be used for validation and verification purposes, with the results documented for future reference, regulatory audits, etc.

At Verus Metrology Partners, we also conduct full gauge R&R studies on the POP fixtures that we produce. Gauge R&R studies confirm the repeatability and reproducibility of your new fixture in conjunction with your CMM and inspection routine. The report you receive from the gauge R&R study will aid verification and validation processes, as well as regulatory compliance. It will also give you peace of mind that your new metrology fixture will deliver the level of performance that is expected.

How Necessary is a Gauge R&R Study?

Whether you are getting a complete fixture or a POP fixture, you should insist that a gauge R&R study is completed before the fixture is shipped. In fact, there are a number of elements an experienced metrology partner will provide you with:

- Your metrology fixture manufactured and finished to the highest standards
- Gauge R&R study and report
- Inspection routine written in your CMM's software language
- Instructions for use
- Details of aftersales support

The Importance of Programming and Creating Measurement Routines

As mentioned in the previous section, programming your CMM and creating measurement routines are crucial steps to getting up and running with your new fixture. Your metrology partner should look after the full process, providing you with a turnkey solution.

The main elements of a turnkey metrology fixturing solution include:

- Concept creation, development, and refinement
- Fixture manufacture
- Gauge R&R study
- Programming and creation of measurement routines

All four of these elements are crucial when buying a new metrology fixture for your medical device manufacturing facility.

Mitigate Risk with Installation and Training

When you partner with a high-quality metrology fixture provider, the relationship doesn't end with the production of your fixture and measurement routines. Your metrology partner should also look after the logistics of shipping the fixture to your facility, before installing the fixture and program, and testing that everything is running as it should be.

Your metrology partner should also provide training to ensure your team is fully comfortable with using both the fixture (especially in relation to the loading and unloading of components) and the software program.

At Verus Metrology Partners, we can complete new fixture installations and provide training in person or remotely. The remote installation and training solution that we offer is increasingly popular as it saves both money and time.

Conclusion: Quality Investments that Work for Medical Device Manufacturers

Let's recap the main points covered in this whitepaper:

- Implementing quality best practices throughout your organisation can add up to 3 percent to your bottom line every year
- It's important to develop a quality culture in the organisation, led from the top and filtered through to every element of the business, from engineering and technical to office-based roles and the C-suite.
- A crucial part of implementing quality best practices is optimising products and processes, with the latter including both manufacturing and inspection processes.
- A crucial component of optimising inspection processes is to invest in the right equipment, including metrology fixtures.
- Operational and procurement teams should be involved in metrology fixture buying processes in addition to engineering and quality teams
- Best-in-class metrology fixtures deliver inspection and quality control benefits as well as wider business benefits
- Getting an optimised metrology fixture from a reliable partner can help mitigate several quality, operational, and business-related risks
- Inspection and quality control processes can also be used to drive business value, performance, and innovation
- Your purchase of a new metrology fixture should deliver a tangible return on investment
- Fully custom metrology fixtures are the only way to proceed, particularly in the medical device industry
- It is highly beneficial to get advice on your fixtures and inspection processes – advice that is independent of CMM vendors
- There are different types of metrology fixtures available depending on your requirements, budget, and objectives
- It is best to start the process of buying a new metrology fixture as early as possible, including before the product's design has been finalised
- Defining your procurement/operational and engineering/quality objectives is an important part of the fixture buying process
- You should engage with an experienced metrology fixture partner with a proven track record in the medical device industry
- Alongside your metrology partner, you'll need to gather the required information, including existing inspection processes for products already in production, information relating to what you need to measure, and whether you need a POP fixture
- Make sure your metrology fixture partner offers a turnkey service that includes fixture design, fixture manufacture, CMM programming, gage R&R studies, shipping, installation, training, and ongoing support

Get in touch

At Verus Metrology Partners, we specialise in the delivery of metrology solutions specifically for the medical device industry. This includes the design and manufacture of custom metrology fixtures. To discuss your requirements or get further information on anything that is covered in this whitepaper, please get in touch with us today.

Unit 2 Cleveragh Industrial Estate
The Back Avenue
Hazelwood Demesne
Co. Sligo
F91 HRR3
Ireland

www.verusmetrology.com

info@verusmetrology.com

Tel Ireland	+353(0) 71 91 43506
Tel UK	+44(0) 115 967 7807
Tel USA	+1 781 214 6806