Achiever medical

YOUR 5-STEP GUIDE TO SUCCESSFUL LABORATORY SAMPLE MANAGEMENT COMPLIANCE

Interactive software
ACHIEVER SOLUTIONS

Introduction

Whether you are a laboratory, biobank or biorepository, compliance with some form of legislative requirement or internal standard operating procedure will be high on your list of priorities. After all, if you fail to comply with the appropriate legislative requirements, your operations could be put into remedial measures which damage your reputation and could result in the end of your operations. Or worse, the responsible individuals could end up in prison.

Many organisations view compliance as something extra that they must do in addition to their day-to-day operations.

If you are constantly trying to impress, and second guess what the inspectors and auditors are looking for, then the burden of compliance will become ever heavier and unsustainable. For compliance to work in tandem with your business, you need to return to basics and understand the basis for these processes and checks in the first instance.

The main reason why these legislations and processes were created was to instil quality.

Quality matters

Quality comes in many guises, depending on your business and your outputs. Your business and how you operate are unique. This is what gives you your competitive advantage. Therefore, when, where and how you manage and monitor quality in your lab is also individual to your business.

Careful consideration of how your lab operates, your processes and where these quality control checks and measures should be introduced is where you need to start; rather than just looking at the compliance requirement in isolation.

Understanding how these quality controls and measures can positively impact and benefit your organisation is key to successfully implementing compliance measures. This approach allows compliance to become integrated into your day-to-day operations and not simply a box-ticking exercise. In addition, by incorporating quality and compliance into your standard operating procedures, your scientists can spend more time on research and less time on administration.

> ***Leeds Teaching Hospitals Trust passed our HTA inspections in 2013 and 2017. It was commented in the final report that the Achiever Medical System enables good practice for tissue tracking. Removing manual audit tasks and the automation of repetitive data entry in Achiever Medical, has created time for both clinicians and laboratory workers. This allows for more research and less concern about legislative compliance."***
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> **- Chris Chambers, IT Systems Officer**

The challenges of compliance

There are some common misconceptions and challenges when considering compliance and how to ensure you meet the legislative and industry requirements.

1. Compliance is a necessary burden

Compliance is often seen as something to be endured; taking your time and efforts away from research and stopping you from carrying out your daily operations. However, by focusing on how compliance can help you improve quality and efficiency you can see and measure tangible benefits rather than just counting the cost.

2. Choosing what to comply with

Firstly, there are some legislative requirements that you must adhere to, depending on the types of biosamples you are collecting and processing. In the UK these include the Human Tissue Act (HTA), Medicines and Healthcare products Regulatory Agency (MHRA) and General Data Protection Regulation (GDPR).
In addition, in every industry, there are many bodies with best-practice guidelines and it is impossible to comply with them all. When considering which optional best-practice accreditation to achieve, select the one that will provide you with the most benefits. For example, choose one that will help you deliver operational improvements and increase your reputation with your customers and suppliers.

3. Difficulties identifying standards and processes

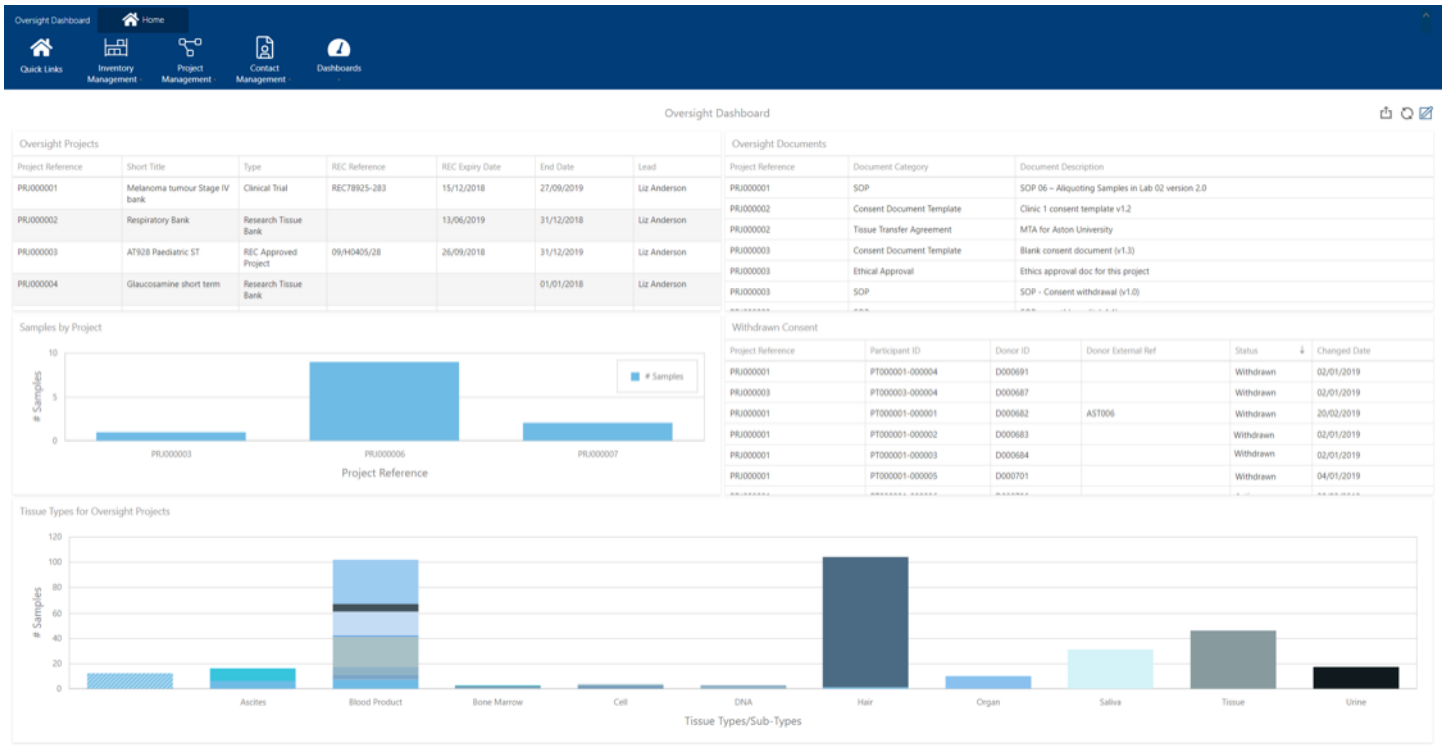
It can be tempting to automate and standardise every process. Over-automating and over-standardising can be as detrimental to a business as not enforcing any processes at all. It can often have the opposite result to that required, by decreasing efficiency and, in some instances, your team may end up working around the processes.
Identify the most critical processes and outputs in your business and review these. You can always include more processes at a later date if required.

It is important to include your team in this exercise

Begin by highlighting the results you are looking for from each process, including any qualitative as well as quantitative measures. Then complete a ‘current state’ review of the process identifying gaps and issues. Follow this with a required ‘future state’ for each process detailing any actions and including any measures and check points to track progress.

4. Difficulties enforcing and monitoring standards

Implementing compliance standards as part of your standard operating procedures and not as an additional piece of work, reinforces the importance of quality to your team. It also makes it easier to include in their day-to-day workload.
In addition, incorporating these processes into a Laboratory Information Management System or Sample Tracking software can help automate repetitive tasks as well as prompt users for information at key stages in the process. Dashboards and reports can be used to display key measures and progress, and some systems have automated email alerts to highlight non-compliance. These systems can ensure processes are followed correctly and any issues can be promptly addressed.



Achiever Medical's Interactive Oversight Officer Dashboard

5. Lack of time and/or team to carry out the additional compliance tasks

If you change your approach to compliance and build quality measures into your standard processes, then this becomes part of your daily operations. This means that come the day of the audit or inspection you can print off reports using data captured during the process rather than spending time collating information after the fact.

Benefits of compliance and accreditation

You may be wondering, with all these challenges with becoming accredited or compliant, why bother with any optional accreditations? When chosen for the right reason - that being to improve your quality and daily operations - the benefits gained by being accredited can be significant. These can include:

1. Reputational benefits

That accreditation logo signifies that you are committed to quality and you are following industry-standard best-practices. For customers, partners and suppliers this can speak volumes and give a very clear indication of your professionalism.

2. Support for funding bids

When choosing which companies to award grants to, funders are looking for well-organised organisations capable of delivering repeatable, measurable outcomes. Funders want to ensure that their money will be used as efficiently as possible. Demonstrating that you have processes in place to ensure that your team is consistently working to a high standard will help elevate your business and alleviate perceived risks around managing and measuring outcomes.

3. Improved efficiency

Focusing on quality and outcomes for your key processes allows you to identify and address inefficiencies. This can lead to increased production and reduced costs whilst improving quality.

4. Increased team morale

When implemented correctly, and in conjunction with your team members, your team can spend more time on the job they are there to do and enjoy - research - and less time on administration.

5. Improved biosample and product quality

When your processes are operating effectively this can mean fewer bottlenecks. This could be the difference between your biosamples being processed immediately rather than waiting hours. In addition, by tracking the process, any bottlenecks can be accurately pinpointed, and issues addressed.

> ***Leeds Teaching Hospitals Trust chose to implement Achiever Medical to facilitate the safe and secure storage and management of human tissues used for research. It has enabled multiple teams to move away from Excel-based record keeping to a robust system, which in turn reduces potential for human error and loss of data.***
>
> **- Chris Chambers, IT Systems Officer**

Your 5-Steps to successful compliance

STEP 1: IDENTIFY AND UNDERSTAND YOUR PROCESSES, OBJECTIVES AND MEASURES

You need to know your business inside out including its critical success factors and business objectives. Understanding the driving force behind your business and its key outputs will help you assess where quality control, compliance and measures need to be implemented. This will help to check progress and make sure that everything is on track. You need to know what you are trying to measure and improve before you can evaluate the accreditations on offer.

STEP 2: KNOW WHICH STANDARDS YOU WANT TO COMPLY WITH

Firstly, identify which standards you must comply with by law. This may be the Human Tissue Act (HTA) if you handle cellular human tissue or the Medicines & Healthcare product Regulatory Agency (MHRA) if your work is in relation to drugs or medical devices. In addition, depending on the type of data you are capturing, you may also need to comply with GDPR.

After this, review industry best-practice standards and bodies in conjunction with your processes and business objectives. Check out which standards your customers are looking for and also see which ones your competitors adhere to. However, do not slavishly follow these. Remember, you are implementing standards and achieving accreditations to improve the quality in **your** business, so they have to meet **your** needs.

ISO standards such as ISO 17025 (for testing and calibration labs), ISO 15189 (for medical diagnostic labs) or ISO 20387 (for general sample processing) or industry best practice guidelines, such as ISBER, all aim to help you to operate efficient, logical and audited processes to record and evidence your professionalism. There are many associated benefits in terms of efficiency, finance and reputation that should be carefully considered.

STEP 3: ASSIGN A TEAM AND GIVE THEM A NAME

This is two steps in one but essentially you need a team of people to help you achieve your compliance objectives. They need a compliance plan of action and time to implement. Assigning a team of people with clearly defined roles, responsibilities and objectives, and formally allocating them time to implement the compliance plan all means it will be prioritised and get done.

In addition, the team can help with communication, user adoption and gaining other users' buy-in.

It is all about change!

A key point to remember is that this is not just about introducing standards for accreditation and compliance but is also about changing the way you do things. Nothing is as unsettling to people as change. Even though these changes may make peoples' jobs easier and bring about untold benefits, the thought, and actions, of doing things differently to the norm, can be challenging for even the most brilliant team members.

STEP 4: IDENTIFY SYSTEMS

Your business systems should be designed to support your processes. If your team is 'working around' your software systems, this is costing you money and time. Many industry standard Laboratory Information Management System and Sample Tracking software have best-practice processes already built-in. This avoids you reinventing the wheel.

In addition, many of these systems already have automated audit trails recording key record creation and change dates. Further, some systems, such as Achiever Medical, have enhanced compliance and auditing capability allowing labs to carry out their own internal audits and monitor outcomes. Interactive dashboards and automated email alerts are used to monitor progress and highlight issues. This information can be provided to external auditors as evidence of quality management systems and compliance.

STEP 5: REGULARLY REVIEW AND ASSESS

This is not just about checking the performance and suitability of your processes and is also not a one-off exercise. Your business does not stand still, and to support this, your processes and systems need to adapt to meet changing requirements. Whenever changes are considered, they need to be reviewed in conjunction with your quality objective and measures for compliance. This is essential to maintain efficiency and quality as it could result in processes that were previously included in compliance being no longer required or vice versa.

In summary

When thinking about compliance you must first understand your legal obligations. Making sure you are compliant with any legal requirements is critical given their potential implications to your business, and to you personally.

Even when you are reviewing and determining how best to meet these, you should remember that their overriding purpose is to instil quality. Use this as an opportunity to incorporate standards and good working practices into your standard operating procedures. This will help ensure that you are gaining optimum benefits from compliance instead of it being purely a separate box-ticking exercise.

If you are contemplating optional industry-standard accreditations, do not just choose the ones that your competitors have adopted. Make sure that your chosen accreditation benefits your business and perhaps your customers and suppliers too.

Finally remember to include your team as part of this process. User buy-in is critical to success and gaining any type of accreditation invariably involves changes to your processes. Implementing and managing change can be incredibly tricky and ensuring the reasons and potential benefits are communicated and understood by your team will help ensure their successful adoption.

About Interactive Software & Achiever Medical

At Interactive Software, we have over 25 years' experience in helping our customers transform their lab processes and provide greater transparency and insight into their data using our innovative Laboratory Sample Management Software, Achiever Medical.

We understand how confusing and daunting compliance can be. We have attended a number of audit inspections with our customers to gain a better understanding of what is required. Based on our experience, we have designed Achiever Medical to help you manage and adhere to compliance requirements and help ease some of the pressure. Achiever Medical has inbuilt functionality to manage patient informed consent, track biological samples along with their chain of custody and movement history, and automatically capture details of when each record was created and changed. In addition, its interactive, real-time Oversight Officer dashboard quickly and easily highlights your compliance status and highlights any areas of non-conformance for attention. We also launched our enhanced auditing module that allows you to conduct and manage your own audits on your biological samples and storage locations to help you better prepare for inspections.

For more advice and guidance on how Achiever Medical can help you remove some of the burden and pressure of complying, please contact us.

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