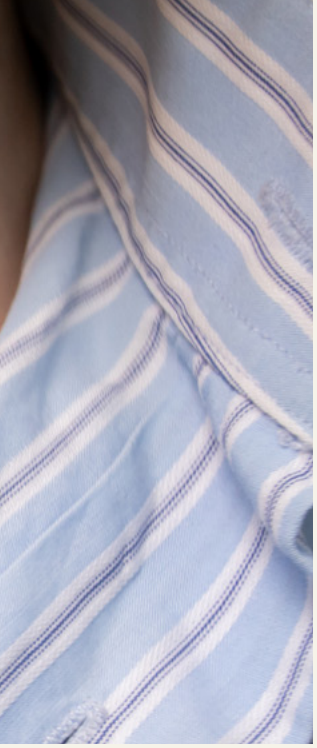
Rethinking regulatory compliance

How to turn regulatory demands in MedTech into development strengths

Regulation doesn’t slow development when it’s embedded early and applied proportionately.



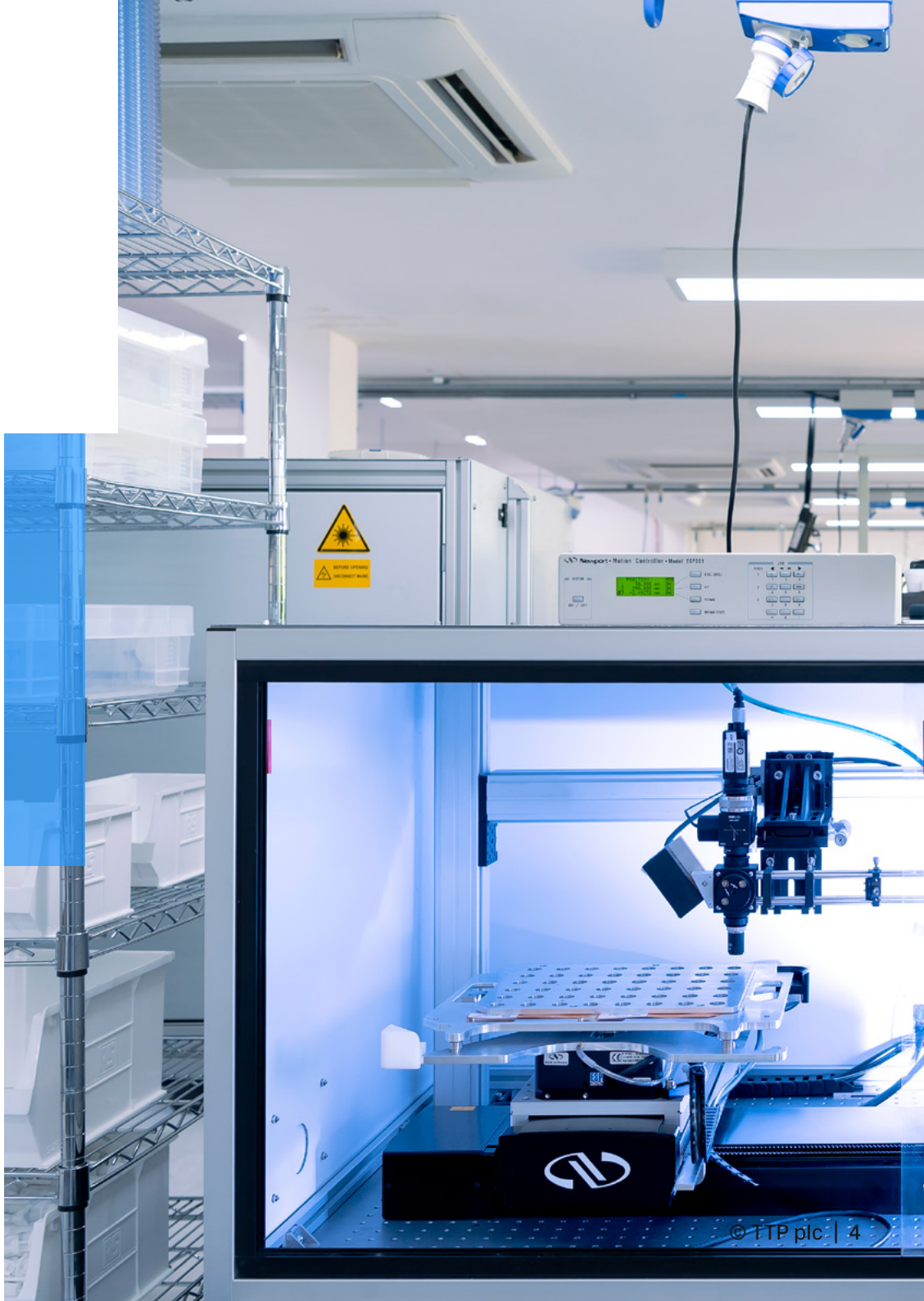
Contents

The compliance challenge

Bringing a medical device to market is not simply a matter of implementing a novel technology. It is an exercise in rigorous proof of the safety of the device and careful consideration of user, regulatory and technical requirements. Every requirement a device is expected to meet must be formally verified, and regulators will demand evidence in the form of a traceability matrix that maps from requirements through to tests.

For complex devices, such as those that inform clinical decision-making, or active implantable devices, this can mean adherence to dozens of standards, hundreds of individual requirements and the completion of associated, carefully documented tests. The scale of this effort can seem formidable.

But when regulatory requirements are discovered too late, or addressed as an afterthought, costly redesigns and additional uncertainty about regulatory outcomes are often the consequence.



In this e-book, we set out how integration of regulatory processes from the earliest stages of a development can act as a strategic enabler, contributing to a roadmap for technical development with credible project milestones, timelines, and budgets. By grounding requirements in a robust risk management process, and creating a clear record of design decisions, developers not only ensure safety and faster regulatory approval, but also create clarity of purpose, sharpen design priorities, and streamline the path to market. We give examples of how we at TTP structure early development activities, and supporting systems, to support both technical and regulatory success, without compromising on the speed of development.

Planning for success: turning regulatory complexity into clarity

The most common pitfall in medical device development is not technology – it's surprise. Late-stage discoveries of overlooked standards and unexpected requirements can push projects over time and budget. The solution is to seek expert guidance early and clearly define your regulatory goals from day one.

This requires addressing the following strategic, engineering-focused questions early in development.

1. What is clinical risk and device classification?

The level of clinical risk and device classification defines the depth of design controls, verification workload, and documentation required. Recognising these implications early enables teams to communicate credible development plans to stakeholders and investors, and allocate funding and resources realistically.

For example, a team developing a wearable biosensor may initially plan for a Class II classification and structure their development activities around that assumption. However, if the device also provides diagnostic or decision-support functions, it could be reclassified as a higher-risk device, triggering the need for more stringent software lifecycle controls, additional failure-mode redundancies, and significantly expanded verification activities.

Similarly, a company developing a biosensor may decide to expand the device's functionality or broaden its intended user population; for example, from Type 1 to both Type 1 and Type 2 diabetic patients for a continuous glucose monitoring (CGM) system. While these enhancements may seem incremental, they can introduce new clinical hazards and lead to a higher regulatory classification.

Such scope changes may result in a large shift in compliance requirements, which can easily overburden a development if not considered strategically. Understanding the consequences of these decisions can allow developers to focus on what matters most and keep the compliance effort lean.

Identifying these regulatory implications early allows teams to plan accordingly, build realistic timelines, and maintain development momentum. With clear compliance objectives established from the start, programmes stay focused on measurable outcomes and progress with confidence.

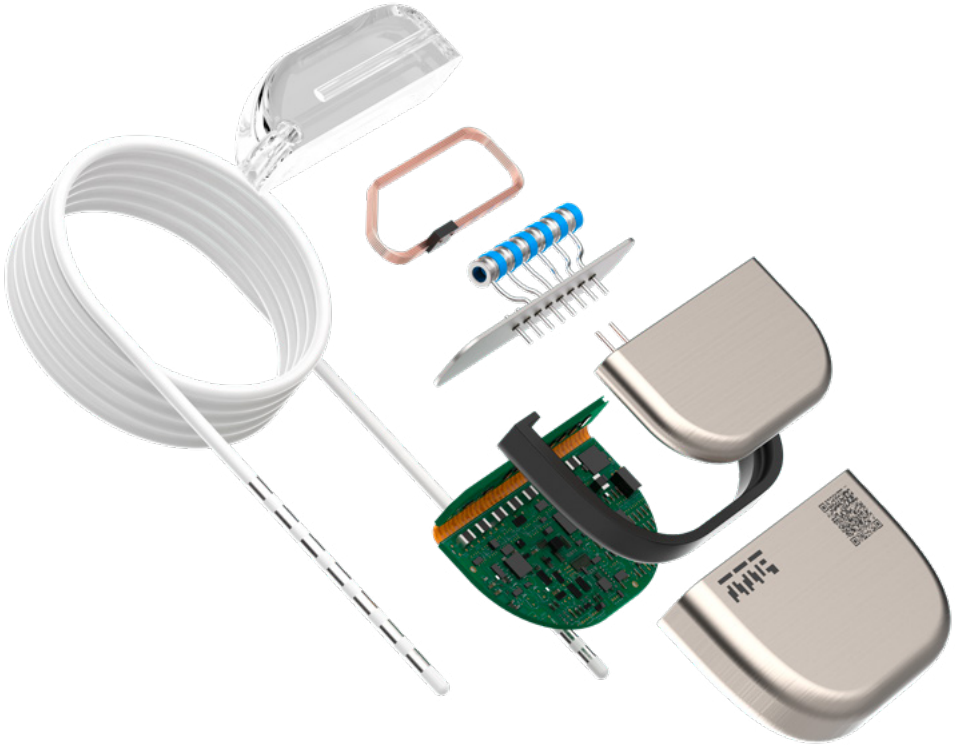
2. What is the regulatory pathway for similar devices?

The FDA Devices and De Novo databases are publicly available resources that offer invaluable insight into comparable regulatory strategies and verification approaches for similar medical devices. Together, these databases contain all 510(k) and PMA submissions since 1976, and all De Novo classifications since 2012. These databases provide real-world examples for the devices and associated test data that has been previously accepted by the regulator, to help inform a robust regulatory and testing strategy.

FDA submissions typically include the device description, the device classification (Class I, II or III) and the standards applied by the manufacturer. These details can help identify which regulations and classifications are likely to apply to a new device. Submissions also frequently outline additional verification tests beyond the core standards, that have been deemed necessary to verify a design requirement or to mitigate a safety risk, as well as indications and contraindications for use, and potential hazards that may arise from using the device. This information provides practical insights into the safety risks identified by seasoned manufacturers of similar devices and can highlight design controls that may need to be planned for and implemented.

FDA submissions also describe the clinical studies conducted for design validation, including the number of patients enrolled and devices tested. These data points provide evidence of the scale and scope of manufacturing activities needed to support future clinical studies. When accounting for all devices required for both design verification and clinical validation, the total quantity can easily reach the thousands. Any robust product development plan should include a clear strategy for manufacturing at the necessary scale to enable those studies.

For developers, leveraging FDA submission data early allows teams to refine their regulatory strategy, anticipate testing requirements, and plan for future manufacturing capacity with confidence. By learning from the pathways of comparable devices, it becomes possible to avoid unexpected testing demands, minimise costly rework, and to be more confident in the success of a chosen regulatory approach.



3. What are the applicable standards?

In addition to the FDA databases, engaging regulatory advisors and technology experts with market-focused experience can help developers identify the key standards relevant to their device. Understanding these early can reduce the overall development effort and increase the likelihood of success when ultimately submitting design evidence to a regulatory body.

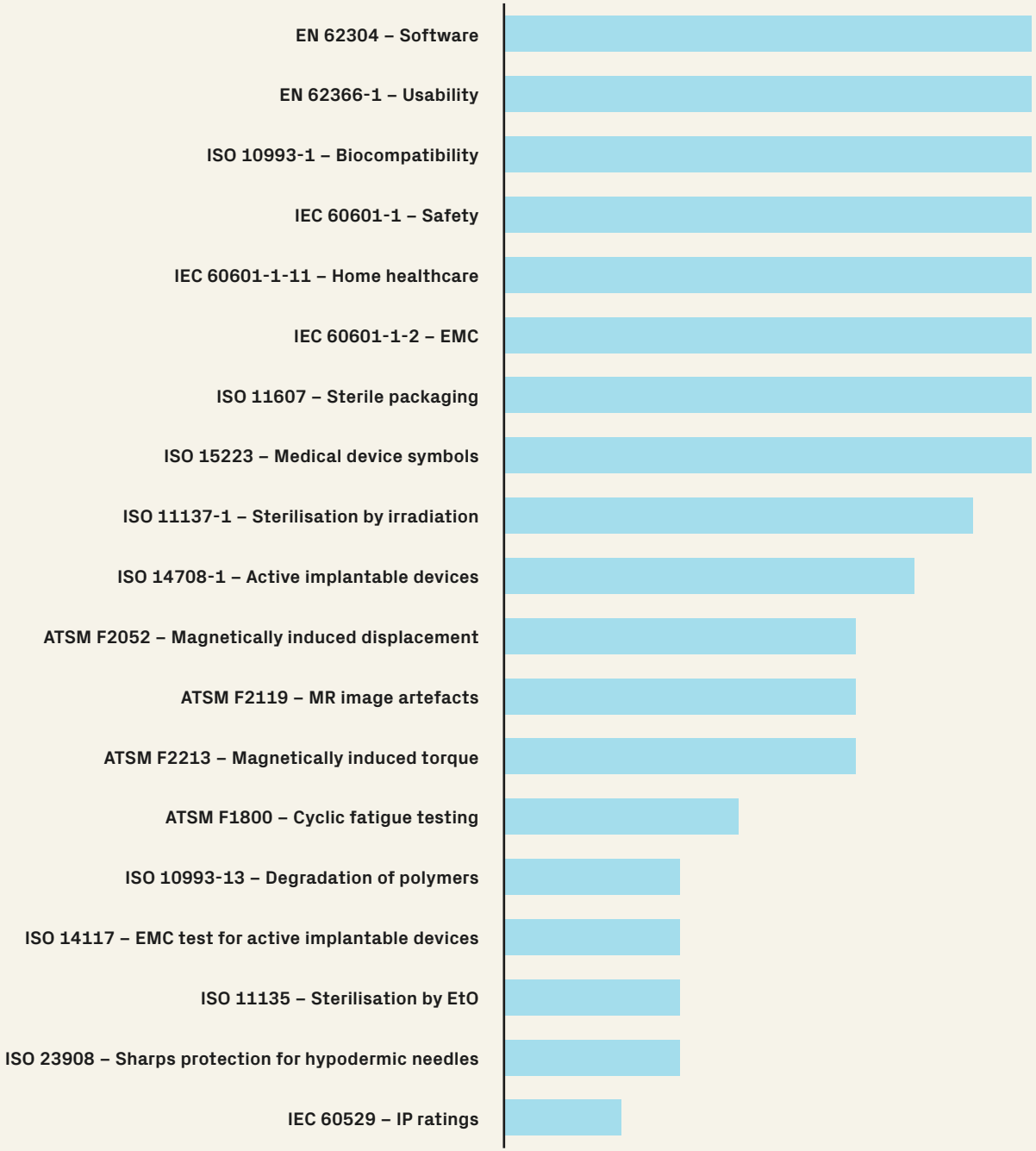
For example, an electronic engineer familiar with ISO 14708 will recognise the requirement to manage heat generated by power dissipation in implantable medical devices to prevent tissue damage. Identifying this requirement early on allows teams to plan for and evaluate the thermal performance of the first prototypes in a considered way and avoids a costly redesign later when verification testing exposes a gap.

Based on 15+ years of experience at TTP in implantable devices, the core standards to consider for a development are shown to the right.

Key to device applications:

- **Essential to all medical devices**
- **Most devices**
- **Some devices**
- **Specific devices**
- — **Not commonly applicable**

		Device type		
Standard	**Description**	Wearable	Breaching	Implantable
ISO 13485	Quality Management	■	■	■
ISO 14971	Risk Management	■	■	■
EN 62366-1	Usability	■	■	■
IEC 62304	Software	■	■	■
AAMI TIR57	Cybersecurity	■	■	■
IEC 60601-1	Safety and essential performance for medical electrical equipment	■	■	■
IEC 60601-1-2	Electromagnetic disturbances	■	■	■
IEC 60601-1-8	Alarm systems	■	■	■
IEC 60601-1-11	Home healthcare, including portable devices	■	■	■
IEC 60601-1-X	Collateral standards covering other functions	■	■	■
IEC 60601-2-X	Particular standards covering specific device types	■	■	■
ISO 14708-1 or EN 45502-1	Active implantable devices	—	■	■
ISO 10993-1	Biocompatibility evaluation	■	■	■
ISO 10993-3	Tests for genotoxicity, carcinogenicity, reproductive toxicity	—	■	■
ISO 10993-4	Tests for haemotoxicity	—	—	■
ISO 10993-5	Tests for cytotoxicity	■	■	■
ISO 10993-6	Tests for local effects after implantation	—	■	■
ISO 10993-10	Tests for skin sensitisation	■	■	—
ISO 10993-11	Test for systemic toxicity	—	■	■
ISO 10993-23	Tests for irritation	■	■	■
ISO 10993-18	Chemical characterisation of medical devices	■	■	■
ISO 11135-1 / ISO 11137-1	Sterilisation	—	■	■
ISO 11607-1	Sterile packaging systems	—	■	■
ISO 15223-1	Medical devices symbols	■	■	■
ISO 20417	Medical devices, information provided by manufacturer	■	■	■
ISO 14155	Good clinical practice	■	■	■



Compliance patterns in predicate devices

TTP conducted an analysis of FDA submissions from multiple implantable medical devices, spanning neurostimulators, CGMs, Pacemakers and Smart Orthopaedics, to identify the standards that are referenced with the highest frequency.

Building safety and compliance into product concepts and architectures

Even at the earliest stages of development, compliance considerations can and should influence concept selection and system architectures. However, rigorous review of standards and clauses can burden an early development with growing costs and pull focus away from achieving early technology milestones.

Instead, a light-touch hazard analysis, inspired by ISO 14971, can be a useful tool to identify key risks for a device at the product concept stage, and to highlight areas of development that require early de-risking. Identifying patient risks effectively means that these can be mitigated directly into the system architecture.

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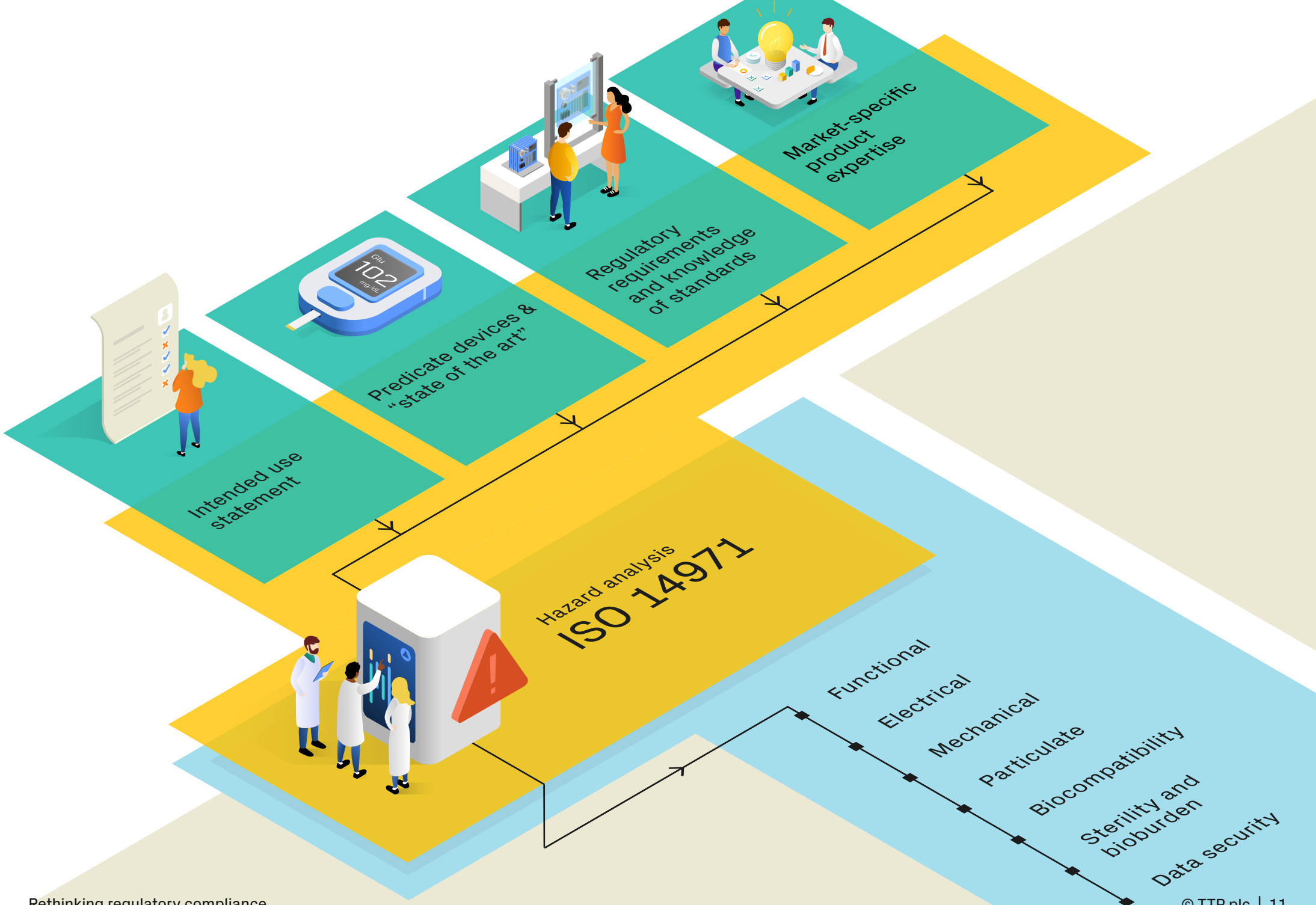

Market-specific product expertise
Regulatory requirements and knowledge of standards
Predicate devices & "state of the art"
Intended use statement
Hazard analysis
ISO 14971
Functional
Electrical
Mechanical
Particulate
Biocompatibility
Sterility and bioburden
Data security

Common implantable and wearable biosensor hazards

Sensor accuracy

Sensor accuracy is a critical requirement if it is used to inform a clinical measurement, for example a CGM that is used to inform the administration of insulin. Sources of measurement interference can include temperature, medications (e.g., paracetamol) or patient physiology, and can lead to hazardous situations and potential harm. Considering these early can identify the need for additional compensating sensors or outline key tests that need to be conducted in the early feasibility stage to demonstrate sensor specificity.

Biocompatibility

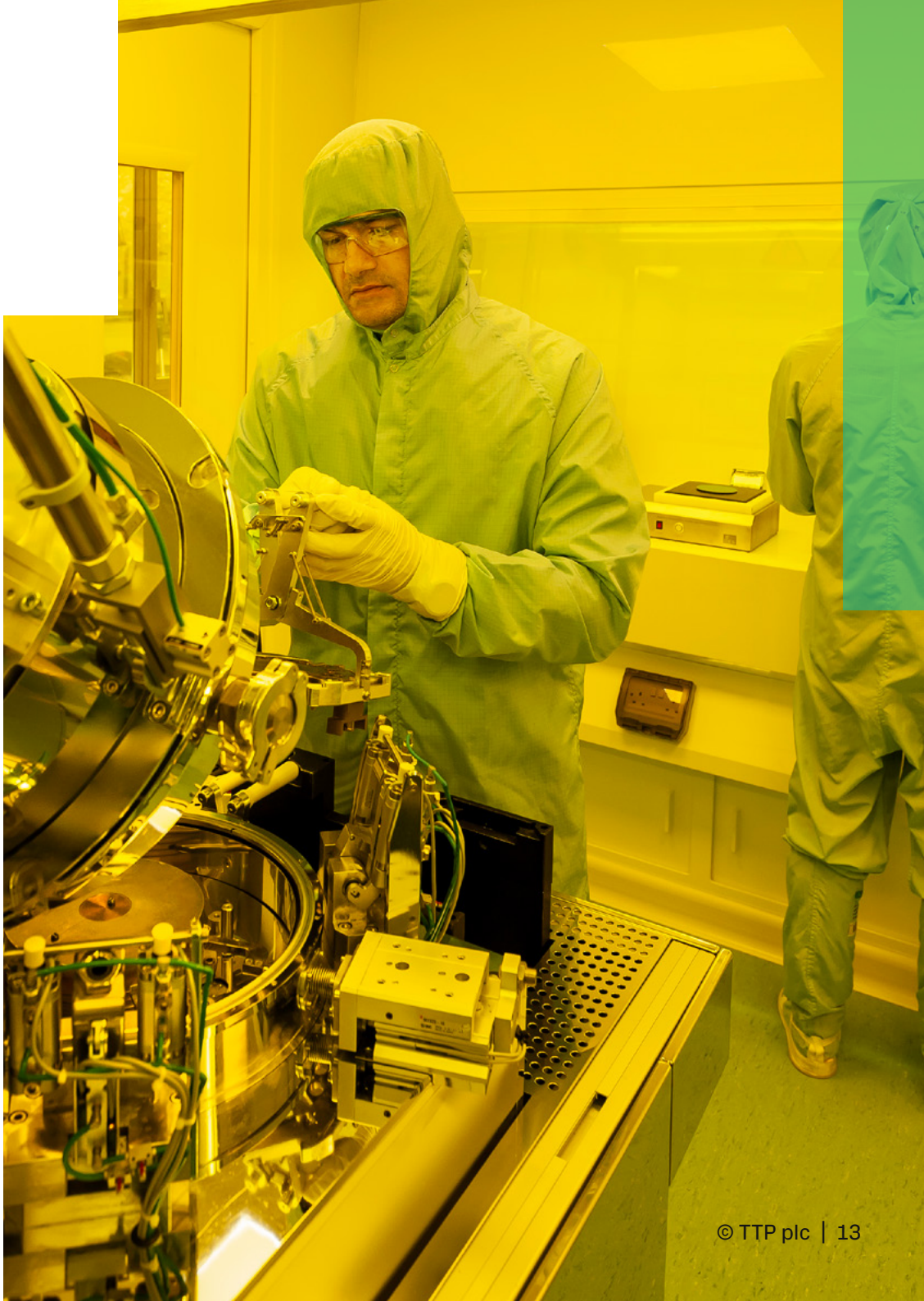
For implantable devices, many of the risks revolve around biocompatibility (ISO 10993). Assessing biocompatibility requirements early can guide material selection toward polymers or metals with a proven history of safe implantation, reducing biological validation risks and enabling more reliable prototype evaluation. When a device incorporates novel materials or surface treatments, early biocompatibility testing on material coupons or representative components can provide valuable data and build confidence in the safety of critical materials long before full-system testing begins.

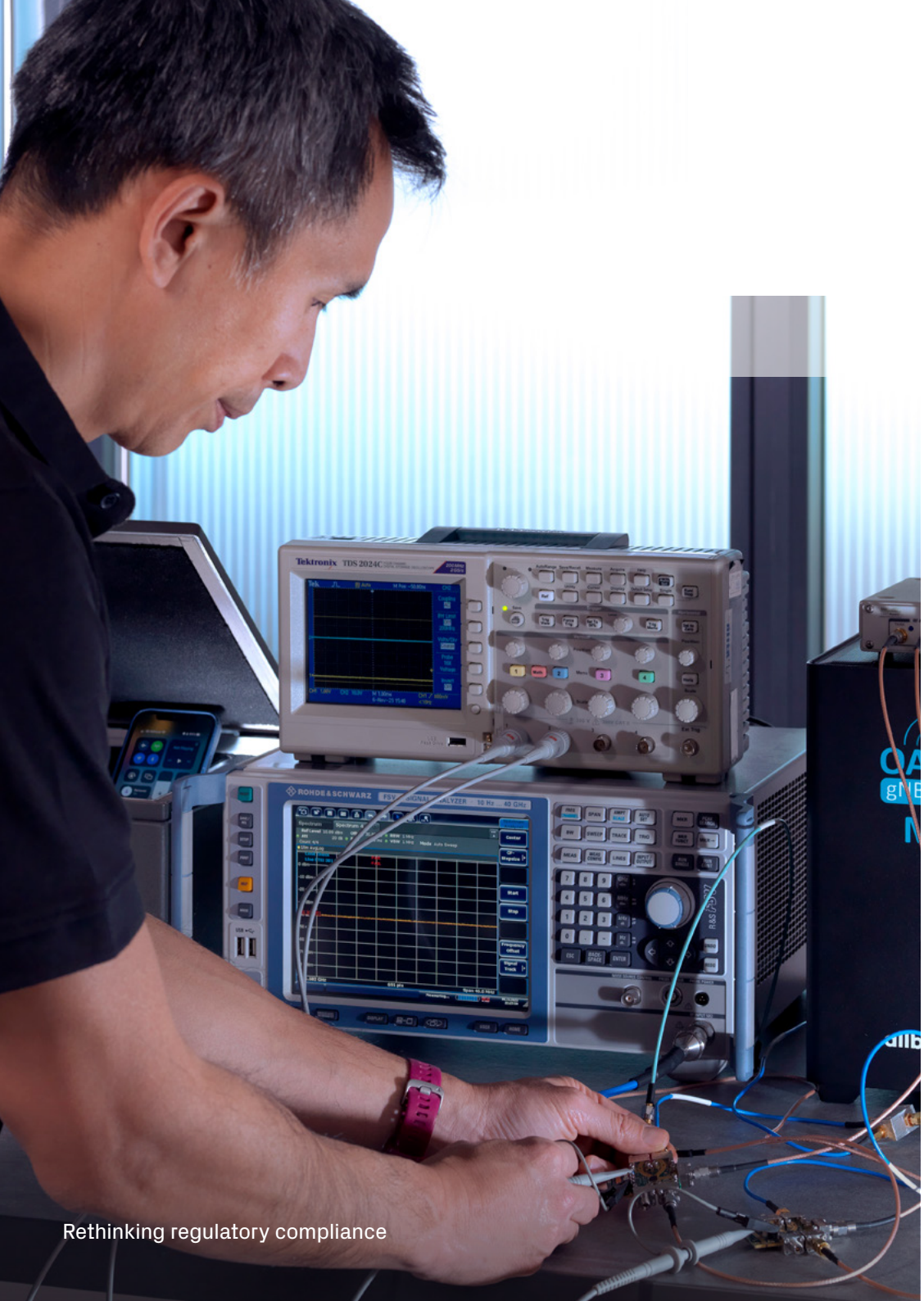
Sterilisation

Considering sterilisation strategies during concept design ensures compatibility with established methods (ISO 11135, ISO 11137) and avoids costly compromises or redesigns once the device architecture has matured. Implantable or wearable devices often contain integrated electronics, which are not commonly compatible with irradiative sterilisation methods. These limitations can be circumvented by designs that allow electronics and other components to be sterilised separately, or other considerations of the sterilisation and manufacturing workflow.

Particles and surface contamination

Implantable medical devices must meet stringent cleanliness requirements that define acceptable limits for surface particulates (ISO 14708). During concept development, it's important to assess how different materials or metals may degrade over the lifespan of the device to produce particulates. In addition, potential manufacturing processes, such as machining, bonding, or coating, might generate debris or residues that exceed safe limits. Considering cleanliness at this stage enables developers to select materials, processes and surface treatments that minimise contamination and simplify downstream cleanliness validation.





Electronic and mechanical safety

The same logic applies to electronics and system safety; wearable and implantable medical devices have strict electrical and mechanical safety requirements that developers must adhere to (ISO 14708). Familiarity with these requirements and an intuitive understanding of “high integrity characteristics” (IEC 60601-1) enables developers to make informed design choices that incorporate appropriate fail-safes from the outset. Designing these protections early ensures that critical functions remain secure under both normal and single-fault conditions, reducing the likelihood of costly redesigns later in development and shortening the overall path to compliance.

Cyber security and data integrity

For devices that wirelessly communicate sensitive information (such as blood glucose measurements), cyber security and the potential for data corruption are key safety risks that must be considered early, and these areas are increasingly “hot topics” for medical device regulators.

Defining the appropriate software classification, interfaces and components from the outset supports adherence to IEC 62304 and emerging cybersecurity guidance. A common pitfall for wearable and implantable devices is to select small and low-power microcontrollers that meet space constraints and battery requirements but lack the functionality to meet full cyber security requirements. Considering this upfront creates development efficiency and can avoid the need to retroactively update designs and develop software resilience during late stages of development.

Foreseeable misuse

Human Factors Engineering (IEC 62366) should also be considered from the earliest stages of development. Familiarity of user workflows and safety-critical use scenarios should inform concept selection, and evaluating these through low-resolution handling models provides valuable insights while design changes remain practical and cost-effective. IEC 62366 places particular emphasis on assessing foreseeable misuse, recognising that misuse can introduce risks that span multiple engineering disciplines and may not be immediately apparent.

For instance, a device that could accidentally be worn or implanted in an incorrect location, or used beyond its intended duration, may involve additional biocompatibility or safety requirements. Likewise, protection against foreseeable misuse can influence hardware and firmware design, prompting the inclusion of alarms, alerts, or specific user interface features to prevent or mitigate hazardous situations. These considerations are especially critical for portable and wearable devices, which must operate safely across a wide range of user demographics, environments, and levels of user experience.

Design development: building confidence in successful compliance

Once technical feasibility has been demonstrated, medical device development enters a critical phase: transforming concepts into defined product requirements and proving that the design can reliably meet them. Developers need to build confidence in the safety of their device, ensure that design decisions are effectively implemented, and progressively build the evidence to support this.

For highly integrated wearable and implantable devices, regulatory and technical requirements, and safety and performance risks must be understood across multiple disciplines and be reconciled into a coherent, verifiable set of system-level requirements. Without a cross-disciplinary perspective, teams may introduce inconsistencies, overlook risks, or miss opportunities to improve design robustness. Structuring projects around multi-disciplinary collaboration helps avoid such pitfalls. By bringing together experts from different domains to explore trade-offs and balance competing requirements, teams can make informed, collective decisions that maintain both safety and compliance without sacrificing rigour.

Building confidence through progressive testing

The design development phase also aims to build confidence that the device will eventually pass the necessary verification tests for each of the captured requirements. TTP's approach is to gain early insight into whether key components, materials, or subsystems are fit for purpose by conducting targeted in-house evaluations or by working with external test houses to conduct pre-compliance testing against regulatory requirements.

Examples can include an early biocompatibility assessment of material samples long before they are integrated into a prototype (ISO 10993), computational simulations and mechanical testing of implant encapsulations against vibration and shock (IEC 60601-1) or electromagnetic compatibility testing of RF antenna designs (IEC 60601-1-2). This iterative testing allows design changes to be made when they are still relatively easy to implement, and greatly improves the chances of regulatory and clinical success whilst still allowing developments to remain flexible and agile.

CASE STUDY

Rapid manufacture ventilator for COVID-19 patients

Rigour does not need to mean slow. With the right processes in place, it is possible to balance regulatory demands with rapid development, even for systems where reliability is critical to life. In just 5 weeks, TTP was able to develop the CoVent Ventilator – the UK's response to the Covid Ventilator Crisis – from a clean sheet to a technical file ready for regulatory approval. This was achieved by understanding the largest programme risks, and running design, prototyping, regulatory, and manufacturing work in parallel. None of this was possible without clear communication and close collaboration, which allowed multidisciplinary team to make rapid, informed decisions.

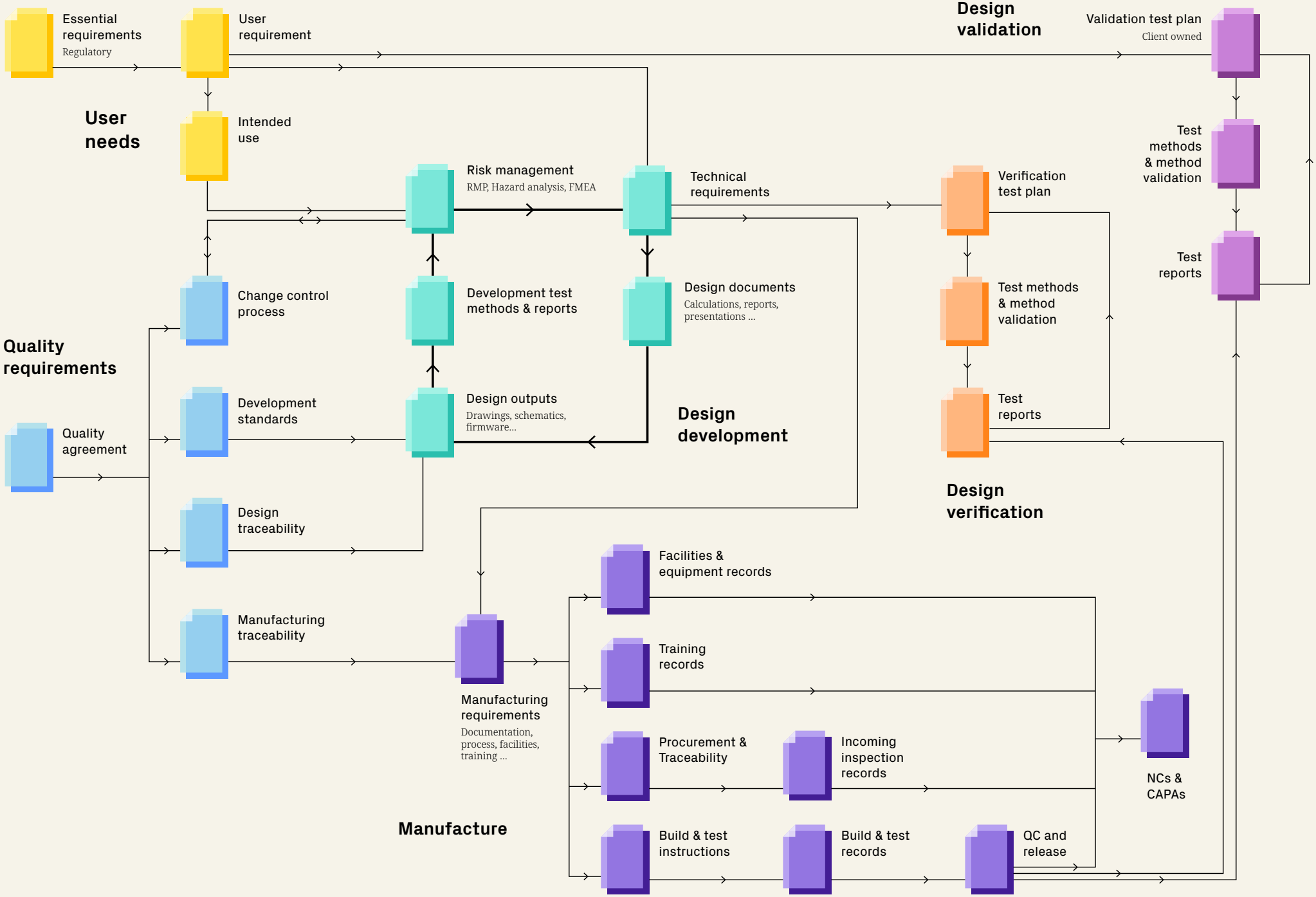
Read the full case study ↗

Generating documentation and the Design History File

Throughout these activities, the Design History File (DHF) begins to take shape to capture the traceability from design inputs, such as user and technical requirements, through to verification and test outputs. It is both a record and a roadmap, demonstrating to regulators that the device is not just functional, but safe, effective, and compliant.

Process-orientated standards such as ISO 14971 (risk-management), IEC 62304 (software lifecycles) and IEC 62366 (usability) require developers to follow defined processes and produce specific documents to evidence this. Familiarity with the specific documentation requirements for each standard can avoid uncertainty and significantly streamline this process, and avoid the scenario where documents need to be hastily written towards the end of a development – and long after design decisions have been made.

At TTP, we streamline the development and documentation process using structured DHF templates and a deliberately lightweight yet fully ISO 13485-compliant Quality Management System (QMS). Our QMS and processes have been designed to accelerate development and can readily deployed, enabling teams to move quickly while ensuring compliance and rigor. Alternatively, processes and outputs can be tailored to integrate seamlessly with a client's existing QMS and avoid the need for complex document translation or duplication. To ensure every DHF is complete and "audit ready", TTP routinely conducts internal audits and reviews, and engages with external regulatory specialists to confirm alignment with the latest regulatory expectations.


Essential requirements
Regulatory
User requirement
User needs
Intended use
Design validation
Validation test plan
Client owned
Test methods & method validation
Test reports
Risk management
RMP, Hazard analysis, FMEA
Technical requirements
Verification test plan
Test methods & method validation
Test reports
Change control process
Development test methods & reports
Design documents
Calculations, reports, presentations ...
Quality requirements
Development standards
Design outputs
Drawings, schematics, firmware...
Design development
Quality agreement
Design traceability
Manufacturing traceability
Design verification
Facilities & equipment records
Training records
Manufacturing requirements
Documentation, process, facilities, training ...
Procurement & Traceability
Incoming inspection records
NCs & CAPAs
Manufacture
Build & test instructions
Build & test records
QC and release

Balancing risk in early clinical feasibility studies

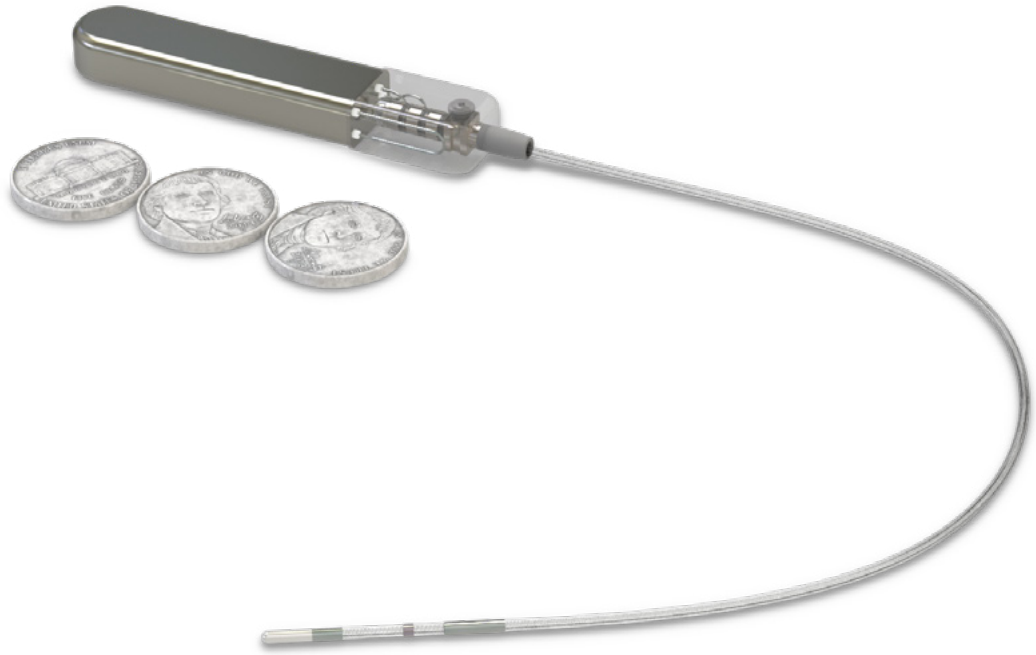
When a medical device enters its first clinical study, the regulatory landscape looks very different from the one it will face at commercial launch. Devices in early feasibility trials often serve a narrower purpose; they are tested in fewer patients, under closer supervision, and clinical functions (e.g., CGM measurements) may be either blinded or verified against gold-standard comparators. Because of this context, the risks associated with using a clinical trial device can, paradoxically, be lower than those of a finished market product.

Balance verification and risks for early clinical studies

Regulators still expect developers to show that risks are understood, managed, and controlled. This is where ISO 14971 risk management becomes essential. By systematically reviewing hazards and risks, developers can separate the critical-to-safety requirements from those that can be addressed in later design iterations. The result is a leaner set of requirements that captures what matters most and a “minimum-viable” device design that focuses on achieving early clinical feasibility. In other words, the level of compliance and design maturity can be adapted to be appropriate to the study stage, giving developers and regulators confidence that the device is safe without over complicating early developments.

Manufacturing for clinical studies

Manufacturing for clinical studies also raises its own set of trade-offs. It is not realistic to build early feasibility devices using highly automated or validated processes when the design is still evolving and manufacturing processes are likely to change. Instead, devices are often assembled in tightly controlled environments where risks are managed through intelligent process design and thorough inspection. The goal is not to “over-develop” manufacturing at this stage, but to find a balance that ensures patient safety while maintaining flexibility for iteration and improvement.

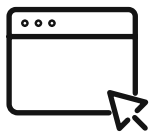


CASE STUDY

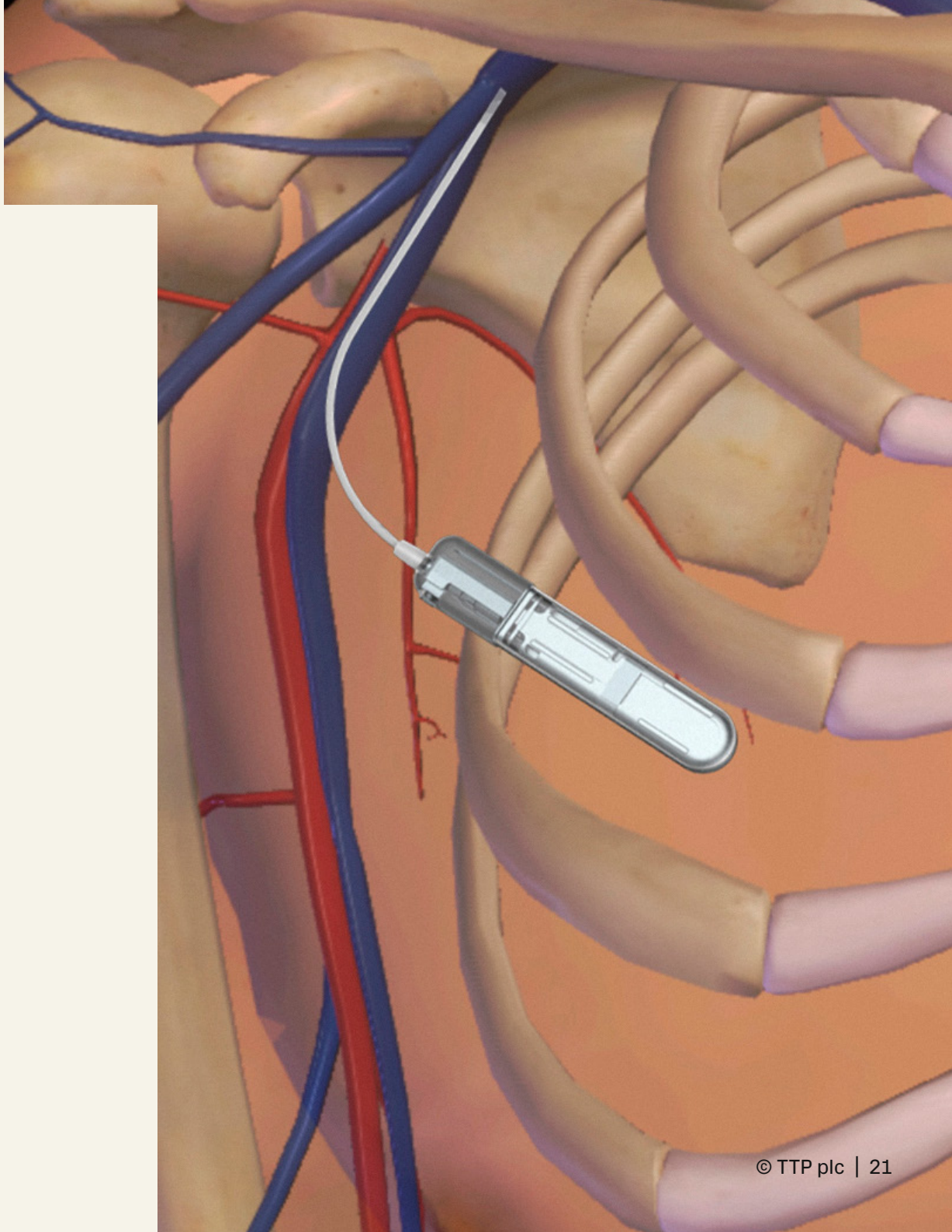
Implantable blood glucose monitor

At TTP, this principle is built into our practice. Our ISO 13485-accredited manufacturing process allows us to work with full product traceability from supplier to finished parts for clinical studies, whilst still retaining flexibility to our clients' evolving needs. Our manufacturing facilities include validated cleanrooms which can be used for implantable device manufacture, with strict controls to minimise the risk of particulates and contaminants (a requirement in ISO 14708). Crucially, our manufacturing engineers often work side-by-side with the technical experts who have designed the device.

This was the case for the development and manufacture of Glucotrack's long-term implantable electrochemical sensor. TTP was closely involved in the development of the sensor coating design, in which the specific materials and thicknesses combine in a highly complex system to control the balance of glucose, oxygen and hydrogen peroxide required for the glucose oxidase reaction. When undertaking sensor manufacture for Glucotrack, this experience allowed TTP to identify and control key process parameters, and to predict the impact of process changes on the device's sensing performance. This proximity between development and manufacturing teams meant that manufacturing decisions could be made quickly and efficiently, and risks which could impact performance or patient safety were identified and addressed.



Read the full case study ↗



Streamlining verification and traceability

In the design verification stage, the foundation of regulatory compliance is traceability; the ability to demonstrate clear links between design requirements, verification test protocols, and test reports. This ensures that every technical requirement is systematically verified and documented in a way that meets the expectations of regulators and notified bodies.

Planning for verification

At TTP, we've learnt that efficient verification begins long before any test is run. The value of well-structured requirements and early risk analysis becomes most apparent during verification, where clarity and foresight translate directly into efficiency. By defining requirements that are specific, testable, and risk-informed from the outset, teams can ensure that verification activities remain focused on what truly matters.

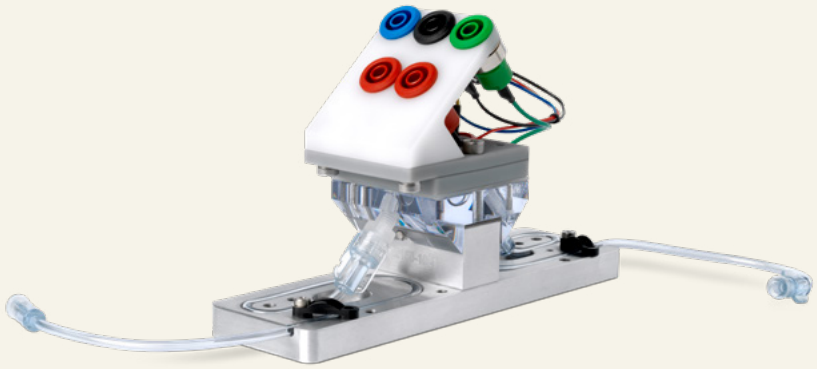
Planning for verification also means thinking beyond what will be tested to how and when testing will occur. An optimised verification plan minimises duplication, reduces sample usage, and helps prevent workloads from escalating as system complexity grows. Test automation can greatly improve consistency and throughput when large volumes of repeated testing are required, but it must be applied strategically where the return on investment and verification value are clear.

WHITEPAPER

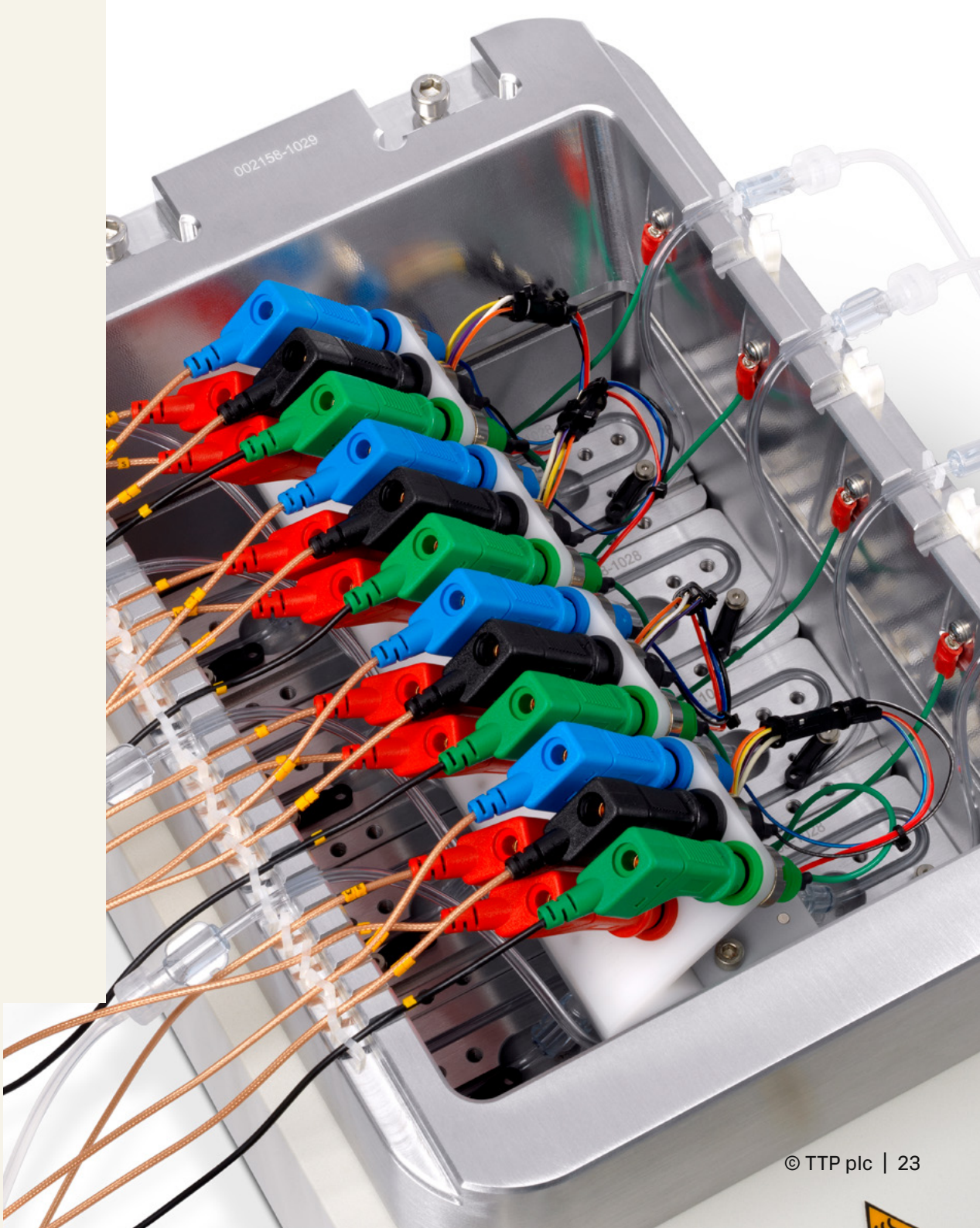
Automated biosensor testing

For biosensors that require repetitive or high-throughput testing, TTP has developed an automated test rig designed with compliance in mind. Our automated CGM test system tightly controls parameters that may impact the result of verification testing, such as temperature, O2 concentrations and flow rate, and is designed to deliver glucose concentration profiles guided by requirements for integrated continuous monitoring systems (FDA 21CFR862.1355).

The automated fluidics and control system reduces the cost and resource burden of repetitive, and rigorous verification while ensuring complete traceability of experimental conditions. By embedding compliance into the design of our test infrastructure, we ensure that results are both scientifically robust and regulator ready.



Download the whitepaper ↗



Traceability tools

TTP routinely uses an Application Lifecycle Management (ALM) platform that automates verification traceability. This tool is configured to closely align with ISO 13485 quality and 14971 risk-management processes to generate compliance evidence that clear and consistent for regulators to understand.

ALM tools are frequently used by software development teams for IEC 62304 processes, and this approach creates synergy between hardware and software development lifecycles and enables multi-disciplinary teams to collaborate with full traceability of changes, risks, and decisions. By automating the tracking of requirements, tests, and issues, the platform increases development robustness and frees teams to focus on the highest-value activities, developing robust tests and making informed design decisions.

Leveraging existing knowledge

Many standards define specific test conditions and documentation requirements, and success depends on executing these tests in strict accordance with the standard. For well-defined cases – such as electrical safety (IEC 60601), biocompatibility (ISO 10993) or sterilisation validation (ISO 11135/11137) – specialist facilities, calibrated equipment, and accreditation are essential to generate data that regulators will accept.

Partnering with accredited external test houses provides access to this infrastructure and ensures that all testing is performed under controlled, validated conditions that meet the relevant quality and regulatory expectations. Beyond simply generating test data, these partners offer independent verification of development outputs, helping to identify potential nonconformances early and strengthen the overall evidence package.

How can we help you?

Regulatory compliance is an unavoidable part of every medical device development. At TTP, we understand not just how to achieve compliance, but that embedding the appropriate level of regulatory structure early delivers the greatest long-term value and development efficiency. By integrating compliance thinking from the outset, we help clients navigate the path to regulatory submission with clarity, speed, and confidence.

Our flexible, ISO 13485-compliant QMS is designed to accelerate development while maintaining full traceability and can be tailored to integrate seamlessly with a client's own systems, ensuring smooth transfer of documentation and decisions.

TTP designs with compliance in mind from concept feasibility through to verification and manufacture. Our multi-disciplinary teams combine engineering excellence with deep regulatory fluency, embedding safety and performance considerations at every stage of design. The result is a more robust product, reduced development risk, and a faster, more assured route to market — turning compliance from a regulatory requirement into a genuine source of competitive advantage.

About TTP's MedTech team

TTP's medical device team specialises in wearable and implantable technologies, including active implantable devices, bringing deep multidisciplinary expertise and regulatory familiarity to support end-to-end development.

With scientific and engineering rigour, combined with well-established quality and risk management processes, we anticipate and resolve risks early, ensuring robust and high-performance solutions.

By flexing around your internal team, we provide the bandwidth and specialist expertise needed to build confidence in your product and produce the evidence required to demonstrate performance and medical device safety. This approach delivers tailored results that meet the quality and regulatory requirements for your stage of development.

The result: compliance becomes an active enabler of product success – reducing uncertainty, accelerating development, and strengthening confidence in every regulatory submission.

How we can help you turn compliance into progress:

- **Integrated regulatory strategy** – early engagement with ISO 13485, ISO 14971, IEC 60601, ISO 14708, and other relevant frameworks ensures requirements are defined with verification in mind and proportionate to device risk.
- **Structured requirements management** – automated traceability tools link risks, requirements, and tests, giving complete visibility across the design lifecycle and reducing verification burden.
- **Evidence-ready documentation** – Design History Files (DHFs) and Quality Management Systems (QMS) are configured to be both lightweight and audit-ready, streamlining regulatory submissions and inspections.
- **Early and iterative verification** – targeted pre-compliance testing and simulation identify potential failures and design gaps long before formal verification, saving time and cost later in development.
- **Collaborative manufacturing controls** – ISO 13485-accredited processes, validated cleanrooms, and close interaction between design and manufacturing engineers ensure that devices for clinical studies are produced safely, with full traceability.
- **Purpose-built test infrastructure** – automated verification systems for biosensors and other complex devices replicate regulatory test conditions precisely, ensuring data integrity and regulator-ready results.
- **Trusted partnerships** – collaboration with accredited test houses and regulatory specialists provides independent verification and confidence in compliance outcomes.

About the author

Sophie Meredith

Sophie is an experienced project leader in TTP's Biosensing team. She has a PhD in biophysics and has worked on a range of projects involving the development of optical systems and implantable devices for applications in biological sensing.

Sophie specialises in regulated developments and supporting our clients to navigate ISO 13485 Quality and ISO 14971 risk management processes and the regulatory framework. She leads projects from proof-of-concept through to controlled manufacture and design verification to enable first-in-human clinical trials.

Get in touch at ttp.com/medtech

TTP plc
TTP Campus, Cambridge Road,
SG8 6HQ
+44 1763 262626

ttp.com