Medical Devices Regulatory Support, Testing & Validation Services

2025

IPN
INSTITUTO PEDRO NUNES

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The Instituto Pedro Nunes (IPN), through the Laboratory for Automation and Systems (LAS), is able to support companies and institutions in the process of testing, validation and certification of medical devices. Based on the identified needs, IPN supports the companies/ institutions through personalized service.

What is LAS?

The Laboratory for Automatics and Systems (LAS) develops R&D and technology transfer activities in partnership with companies in Medical Device development, testing, validation, and regulatory support. The LAS team is composed of specialists in different areas to provide global support to clients even if they have recently entered the world of health products.

Services Description

LAS provides services aimed at supporting companies and facilitating the process of testing, validation, and certification of their medical devices taking into account global regulations, from several markets (European Union and US). The Specialized consultancy support for medical devices include:

CE Mark Regulation
EU 2017/745 (Medical Device Regulation)

Support in the Medical Devices CE Marking Process

Supports manufacturers, distributors, and importers of Medical Devices (MDs), in the CE marking process taking into account Article 20 of Regulation EU 2017/745 (Medical Device Regulation - MDR). In this sense, IPN supports the implementation and review of the Quality Management System (QMS), preferably according to ISO 13485, together with the elaboration or revision of the Technical Documentation (TD) of the device (under Annex II and Annex III of MDR). CE marking comprises, among others, risk management and clinical and biological evaluation. IPN also assists in obtaining the UDI and registration within EUDAMED and, depending on the device classification, submission of the certification request to a notified body. If an authorized representative is required, IPN also refers possible entities to the company.

Support in Registering on the EUDAMED Database

The European database on medical devices (EUDAMED) improves transparency and coordination of information regarding medical devices available in the European market.

The database consists of 6 modules, and IPN can assist organizations in using the modules already available, that is, in the registration of manufacturers, importers, and authorized representatives in the "Actor Registration Module" with the issue of the "Single Registration Number" (SRN), and in the device registration in the "UDI/Device Registration Module".

Clinical Evaluation

Compliance with MDR requires a robust Clinical Evaluation to demonstrate the safety, performance, and clinical benefits of a medical device. This process involves a systematic assessment of clinical data related to the device.

In the context of Clinical Evaluation, IPN services include:

- Development of a Clinical Evaluation Plan (CEP): Defining the scope, methodology, and objectives of the evaluation, tailored to the device and its intended use.
- Identification and Appraisal of Clinical Data: Systematic collection, appraisal, and analysis of clinical data from existing literature, clinical investigations, and post-market sources.
- Elaboration of the Clinical Evaluation Report (CER): Compilation of all findings into a detailed CER aligned with MDR requirements to support regulatory submissions.
- Gap Analysis: Evaluation of existing clinical data to identify gaps and strategies to address deficiencies, ensuring compliance with regulatory standards.

This service ensures a systematic and compliant approach to clinical evaluation, supporting regulatory approval and lifecycle management of medical devices.

Support in Submitting the Process for Certification by a Notified Body

IPN team is able to bridge the gap between companies and the Notified Bodies. More specifically, the team supports the management of communication with the Notified Bodies during the certification submission process. This support includes guidance and support for the Notified Body selection according to the applicable product codes, assistance in requesting quotes, filling in the form, Gap analysis of the TD prior to submission and support in responses to Notified Bodies' requests for additional information about submissions.

Person Responsible for Regulatory Compliance

According to Article 15 of the MDR, the manufacturer of medical devices is required to have, within its organization (or an external person for small companies), a person who is responsible for regulatory compliance and with the explicit responsibility to ensure that all 'Manufacturer's Obligations' are met (Article 10). Our team includes competent and experienced people to play the role of Person Responsible for Regulatory Compliance, ensuring:

- The verification of the conformity of medical devices according to the QMS (Article 10(9), MDR);
- Maintenance and updating of technical documentation (Article 10(4) and (6), MDR);
- Compliance with market surveillance obligations (Article 10(10), MDR);
- Fulfilling incident reporting obligations (Article 10(13), MDR).

Elaboration or Revision of PMSR and PSUR Reports

The placing of a medical device on the market is preceded by an evaluation of the residual risks related to quality, safety and performance. However, this evaluation shall continue throughout the entire lifecycle of the device, including the post-market period.

Post-market surveillance allows manufacturers to collect and analyze experiences of the actual use of medical devices. Based on the outcome of this analysis, further actions such as incident reporting to competent authorities, field safety corrective actions or safety warnings to users may be required.

Post-market surveillance activities are planned in the Post-market Surveillance Plan and the data is compiled in the Post-marketing Monitoring Report (for class I medical devices) or the Periodic Safety Update Report (for class IIa, IIb and III medical devices).

Our unit assists in the elaboration of the PMS Plan with the definition of actions and also the elaboration of PMSR or PSUR.

FDA Clearance

Support in the US FDA Market Access

IPN can assist companies with US market access through the FDA, a service that begins with the regulatory path assessment. IPN team can then help with the product code and regulation number determination, device classification (classes I, II and III), as well as in the identification of applicable standards and guidance documents. IPN also assists in the confirmation or identification of potential predicate devices, and in the identification and evaluation of performance data needed in premarket submissions.

IPN is able to prepare or review the following types of submissions:

- Q-submission,
- Pre-Request for Designation (Pre-RFD)
- 510(k) Premarket Notification
- De Novo Classification requests
- Premarket Approval (PMA) Applications
- Emergency Use Authorizations (EUA)

IPN can also aid with FDA's Investigational Device Exemption (IDE) and other clinical studies requirements, as well as support and guidance regarding US post-market requirements.

CE Mark Regulation
EU 2017/745 (Medical Device Regulation) and
FDA Clearance

Regulatory Roadmap/ Technical Documentation Gap Analysis

IPN performs gap analysis, in order to assist the success of medical device development projects, with the ultimate goal of making the devices available in the intended markets. This analysis identifies data gaps in projects, procedures, and product portfolios, considering the regulatory requirements.

The regulatory/market assessment gap analysis consists, among others, of the following steps: map out current policies and procedures; outline the regulatory and normative framework and determine which requirements the organization and/or project needs to meet; identify and analyze the gaps; establish concrete recommendations on how to resolve the gaps.

Support in the UDI (Unique Device Identification) Assignation Process

IPN provides services related to the Unique Device Identification (UDI) system (Article 27 of MDR), which ensures proper traceability of the devices throughout the distribution chain and by the user.

IPN assists in the registration of organizations within an accredited UDI issuing agency, in the creation and correct use of UDI codes (UDI-DI, UDI-PI and basic UDI), ensuring that UDI data is formatted correctly for submission to EUDAMED and/or Global Unique Device Identification Database (GUDID – FDA). IPN also provides support in the maintenance of data related to the UDI.

Biological Evaluation

Biological evaluation is a critical process in the development of medical devices, aimed at assessing their safety and biocompatibility when interacting with biological systems. This evaluation ensures that the materials used do not cause adverse biological responses, and is guided by the ISO 10993 family of standards. To systematically address these requirements, it is essential to develop a Biological Evaluation Plan (BEP), detailing the specific tests and assessments needed based on the device's intended use, material composition, and duration of contact with the body. The findings from this process are compiled into a Biological Evaluation Report (BER), which summarizes the results, demonstrates compliance with ISO 10993, and ensures the device's safety and regulatory approval.

Identification of Pre-clinical Testing Requirements and Accredited Labs

We provide expert guidance in identifying the applicable pre-clinical tests required for medical devices, ensuring alignment with regulatory standards and facilitating a seamless pathway to market. The focus is on determining the specific tests based on the unique characteristics of the device, such as whether it is sterile, active, implantable, or software-based. Examples of pre-clinical tests include electrical safety and electromagnetic compatibility (EMC) evaluations, biocompatibility assessments (e.g., cytotoxicity, sensitization, and irritation testing), cybersecurity analysis, sterilization and cleaning validation, microbiological tests (e.g., bioburden and sterility), and stability or shelf-life studies. Additionally, we assist in identifying accredited laboratories with proven expertise to conduct these tests, guaranteeing reliable and regulatory-compliant results. With our support, navigating the complexities of pre-clinical testing requirements becomes efficient and straightforward.

Vigilance of the Market

Vigilance means to be watchful of the possible danger or difficulties. The medical device Vigilance System is designed to collect information on post-market incidents or adverse events related to medical devices and, where appropriate, distribute or disseminate such information to prevent adverse events from recurring. This indicates that medical device manufacturers must have a dedicated system in place for the management of vigilance activities.

It is the manufacturers or the European Authorized Representatives' obligation to notify the Competent Authority in case of any incident with their devices. In the regulatory unit, we help manufacturers to implement medical device Vigilance Systems in compliance with all legal and regulatory requirements and also support incident reporting as well as incident investigation and further actions implementation.

Risk Evaluation Gap Analysis

Risk evaluation gap analyses are designed to assess the potential risks and vulnerabilities associated with medical devices. The IPN team assists companies by conducting comprehensive gap analyses of current risk identification and evaluation processes for their devices, identifying any shortcomings in the existing risk management framework. Leveraging the principles outlined in ISO 14971, the team evaluates the adequacy of risk management practices and ensures compliance with international standards. Based on this initial evaluation, the team can also support the development of an action plan to mitigate or eliminate identified risks effectively.

Quality Management System

ISO 13485:2016

21 CFR Part 820

Support in QMS Implementation

The MDR states in Article 10 (9), the requirements for the Manufacturer's QMS. Despite not being specified, ISO 13485 is the most suitable quality management systems standard for medical devices companies. To effectively implement ISO 13485, manufacturers (and other economic operators) need to use documentation to control their internal processes.

IPN assists manufacturers identify/create the necessary processes and to develop/update the associated documentation to prove compliance with this standard. The documentation is not restrictive and is adapted to each organization. So, in order to meet the requirements and also operators' specific needs, IPN team work closely with each section or department representatives.

After designing an implementation plan, IPN team helps companies build their QMS in order to prepare them for a certification audit.

Internal Audits of the System and/or Product

An audit is a "systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled" (ISO 19011).

System Audit emphasis on the comprehensiveness and effectiveness of implemented procedures against specified management standards and customer-specific requirements to determine the quality capability of the QMS. Product audit goal is to check the compliance of the product with established specifications by assessing the quality characteristics of finished products or semi-finished products.

The auditors in our team conduct fully independent remote or on-site quality system audits either for companies with ISO 13485 certification already implemented or looking to prepare and get ready for the first ISO 13485 certification audit.

Clinical Investigation

ISO 14155:2020 - Pilot Studies

Coordination of Clinical Partnership

Through the established network with hospitals across Europe. In coordination with each hospital, IPN has Clinical Investigation Coordinators fully dedicated to managing clinical research. In this service, IPN identifies the requirements for testing and experimentation of the solution, presents the solution and the testing needs to partner hospitals that meet the requirements, and defines Clinical Research Teams and the Principal Investigator for future studies.

Support in Clinical Investigation Documentation

Annex XV of the MDR outlines the requirements for the documentation regarding the application for Clinical investigations to be conducted within the European Union. These requirements include the submission of necessary documentation to ethics committees and competent authorities.

LAS team is capable of supporting the preparation of the mandatory documents to achieve compliance with these requirements. Through an integrated approach, assistance is provided in:

- Structuring Clinical Investigation Plans (CIPs): Clear and detailed guidance is offered for creating CIPs that meet the requirements of Annex XV of MDR, ensuring all essential elements.
- Preparing Investigator's Brochure and Informed Consent Documents: Support is provided in developing Investigator's Brochures and informed consent forms, ensuring the protection of the rights, safety, and well-being of study participants while meeting MDR requirements.
- Developing Clinical Investigation Reports (CIRs) and Supporting Documentation: The team ensures that final CIRs and supplementary materials are meticulously prepared, accurately reflecting study results and aligning with regulatory expectations.
- Assistance with completing specific forms for local ethics committees and Competent Authorities in different countries is also provided.

By offering expertise and practical support in these areas, this unit facilitates the preparation and submission of essential documentation to ethics committees and competent authorities, ensuring that clinical investigations meet the rigorous standards set forth by the MDR framework.

Clinical Investigation Research Management

Supporting clinical researchers in managing patient recruitment, monitoring the research, and data collection according to ISO 14155:2020 - Clinical investigation of medical devices for human subjects — Good clinical practice.

Usability Testing

IEC 62366-1:2015

Formative Usability Testing Implementation (IEC 62366-1:2015)

Formative usability testing is not intended to evaluate the safety and performance of a device comprehensively. This service focus on an Iterative process where usability tests are carried out early and repeatedly during the development of the device. The goal of this service is to identify and correct any usability problems before the device is finalized, this means: Early identification of problems; Iteration and feedback; User involvement; Focus on improvement.

Summative Usability Testing Implementation (IEC 62366-1:2015)

User interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated use errors „Medical devices – Part 1: Application of usability engineering to medical devices“: The purpose of the usability testing is to identify approaches to make a product more user friendly for its intended users. The usability testing focuses on the user experience with the device, including the device's graphical user interface (GUI), providing valuable insights into how users interact with the product and what improvements can be made to enhance their experience. The results of usability testing allow product developers, managers, and marketers to refine the product and ensure that it meets the needs and expectations of its users. By leveraging the insights obtained from usability testing, companies can develop a final product that is not only functional but also intuitive and enjoyable to use, leading to increased user satisfaction and loyalty. The service includes the design of the study, support on the definition of the clinical team, supporting clinical researchers in managing patient recruitment, monitoring the research, and data collection according to good clinical practices and reports.

EMC Pre-Compliance Testing

EN 55032:2015/A1:2020

EMC Pre-Compliance Testing:

How to ensure the device passes the EMC Radiated Emission test (EN 55032:2015/A11:2020)? A pre-compliance setup involving your team can be used to quickly isolate the "dominant noise source" and enable the design team to focus on a single component of the device. By fast comparative testing of that possible culprit with different options or small design adjustments, you can produce the necessary reassurance to quickly send the device back to the final EMC Radiated Emission test to put the device on the market.

Key-Opinion Leader (KOL) Validation

Along the innovative product/solution development pathway relevant go-no-go decisions should be taken into account. To ensure the suitability of the design and/or the product/solution market receptiveness, critical milestones should be checked in early phases to anticipate the health technology optimal launch.

By granting the product/solution a KOL validation, by clinical experts through a systematic assessment approach, in a timely manner, will reduce the risk of failing the next steps of the way.

IPN, in collaboration with Coimbra University Hospital – *Unidade de Saúde Local de Coimbra* (ULS-C) and the synergies settled through the *TEF-Health partnership*, counts on the expertise of high-tier health clinical professionals to provide new technologies assessment in a 3-step way,

1. Preliminary evaluation: the KOL self-assesses the product/solution provided information, to evaluate its medical purpose assumptions? If it answers an unmet medical need? competitor(s) in the market? Strengths/weaknesses of the technology? etc.

2. Short meeting: a 1:1 one-hour meeting, where the KOL is briefed with a 10-15 mins. demonstration of the product/solution, followed by a discussion of the concerning queries.

3. Expert assessment report: a report is issued addressing insight on the raised hot topics, including suitability strengths, weaknesses, opportunities and threats analysis (SWOT) analysis and useful recommendations/ suggestions to be considered.

Specialized Training

Specialized Professional Training

Our team also includes qualified trainers who provide specialized training in the area of medical device regulation, with our greatest experience being in Regulation (EU) 2017/745, Risk Management (according to ISO 14971), Quality Management Systems (according to ISO 13485) and Performance and Clinical Evaluation. All trainings are accredited and can be in a face to face or online mode, divided into asynchronous sessions and synchronous sessions. In addition to specialized training and mentoring services, we also offer free webinars on the topics mentioned above.

Customer Portfolio

Since 2020, the LAS has helped several companies achieve compliance for their devices.

More specifically, the lab has supported:

- More than **20 companies** implementing, for more than **50 devices**, the requirements of Regulation EU 2017/745 for devices already placed on the market under the scope of the previous Medical Devices Directive;
- More than **50 companies**, for more than **100 devices** (including MDSW, reusable medical devices, invasive medical devices, and active medical devices), obtaining CE marking for their devices including drafting or revision of the Technical Documentation, implementation/updating of ISO 13485, risk management, UDI assignation and EUDAMED registration, including:
    - The elaboration of BERs and CERs;
    - The implementation of vigilance systems, including the issuing of PMSR and PSUR;
    - The submission of several processes to Notified Bodies;
    - The submission of clinical investigations authorisation requests.

More than **20 companies** validate their quality management system and/or product through internal audits of the system and/or product;

Several small and medium companies subcontract collaborators from IPNlas as persons responsible for Regulatory Compliance;

Several FDA processes

Services for distributors/importers, including device registration;

More than **50 companies** address their specific training and competence needs through specialized professional training;

More than **15 courses** were completed, with more than **300 people trained**.

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