INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

PMS & PMCF WITH MDR COMPLIANCE WARRANTY

We believe that even in a highly regulated environment like medical devices things can be solved in a simple way.

That is why we are offering specific solutions to one of the most complex areas in the field of medical devices.

Are you suffering from an increasing number of post-market requirements in the European market? You don't know how to handle all of this in the future? We have a solution for you. Our experience shows that PMS & PMCF activities can be analysed, remediated or outsourced in a easy and effective way.

That is why we developed multiple solutions with a focus on class I up to class IIb devices. All are tailored to your needs, giving you the most value out of your post market data.

WHAT WE PROVIDE

Audit: Gap-Analysis and Feedback

- Review of processes, plans, templates and records relevant for your PMS
  - ➔ If you need to know your level of compliance, choose the PMS Audit Package.

Remediation: Gap-Analysis and Update

- Includes the analyses from the Audit Package
- Remediation of processes, plans, templates and records relevant for your PMS
  - ➔ If you need to update your PMS System, choose the PMS Remediation Package.

Outsourcing: Gap-Analysis, Update and Maintenance

- Your PMS file is taken care of by a specialized team with vast experience in PMS & PMCF and the opinions of notified bodies and their reviewers.
- Value-oriented collection, processing and documentation of PMS & PMCF data
- Periodic updates of your PMS report or PSUR, RMF and CER
- Full MDR compliance guarantee
  - ➔ If you do not want to bother with PMS, choose the PMS Outsourcing Package.

Customer statement

"Outsourcing saves us a lot of internal work and costs and guarantees us a compliant PMS. We are very satisfied with the solution. Thanks to this close cooperation, HCI Solutions AG can meet the legal requirements without having to build up its own resources."

Neslihan Umeri-Sali,
Product Manager HCI Solutions AG
ISS customer since 2015

WHY ISS

We know how

By focusing on product risk management, analyzing and assessing post-market data as well as writing clinical evaluation reports for years, we have gathered experience and knowledge. This know how allows us to provide you with this integrated solution with clearly defined interfaces to outsource your PMS and PMCF processes, so you don't have to care about it anymore.

Services tailored to your needs

Your benefit is the focus of our service. This is why we are offering different packages with different outsourcing levels, in order to make sure that you get exactly what you need. Therefore, we are happy to advise you personally to find the best solution for you.

We give you warranty on our work

Our PMS System is an integral part of our quality management system and thus subject to yearly audits and therefore guarantees the state of the art. Based on our experience, we are confident that our solutions lead to full MDR compliance. This is why we give you a full compliance guarantee for our service, meaning that we will rework every non-conformity free of charge.

Contact

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