Pharma IT

A ProductLifeGroup Company

PLG
ProductLifeGroup

Medical Device Consulting

Supporting you with a scientific approach to device development and a comprehensive understanding of the regulatory landscape

Pharmait.dk

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rafu@pharmait.dk

Medical devices and their enabling technologies are constantly evolving resulting in higher degrees of complexity and integration

This drives an ever-changing set of regulatory requirements to ensure device safety and performance. When you work with Pharma IT, you'll benefit from our team's years of experience and diverse industry exposure. We provide our customers with a unique understanding of both current and upcoming changes in the medical device landscape.

Rasmus Funk, BSc. Eng,
Director of Medical Devices

Benefit from an experienced team that meets your needs

With years of experience in the medical device industry, our consultants know the critical importance of managing stakeholders and aligning expectations to ensure a successful collaboration.

Our Medical Device consultants help customers design and develop compliant medical technologies and products

We can support you with a wide range of tasks to support your medical device development and quality management. We offer highly technical engineering and R&D support, as well as assistance with compliance tasks. Our consultants work in alignment with the best practices of implementing, or working within, a Quality Management System (QMS).

We support medical device companies with a scientific approach to device development and a comprehensive understanding of the regulatory landscape

Be it early phase concept development, European Union (EU) or Food and Drug Administration (FDA) approvals, or post-market activities, our experts are highly qualified to assist you throughout the product lifecycle.

We are happy to work together to create a tailored solution to meet your needs

We value assignments of all sizes and can work together with the broader Pharma IT team to provide you with support tailored to your needs.

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Selected Pharma IT Profiles for Medical Devices

Rasmus Funk, BSc. Eng

Medical Device Director Rasmus Funk holds more than 10 years' experience within medical device R&D working with product development, compliance and product lifecycle management. With a background in mechanical engineering Rasmus has a deep understanding of what it takes to bring a medical device to market and maintain and support it throughout its lifetime. Besides the technical aspects he has experience with navigating the defined processes of a customer's QMS as well as the regulatory constraints.

Rasmus Lund, BSc. Eng

Senior Pharma Consultant Rasmus Lund holds more than 6 years' experience in the medical device industry working with product development, regulatory/compliance projects and development models. DFX (Design For X) Through hearing device and accessory design, Rasmus has experience designing for various manufacturing methods and processes. A majority of the DFM has been focused on injection molded plastic parts characterized by high complexity and molded in engineering grade polymers needed to reach requirements to function, robustness and visual quality.

Marco Donolato, PhD Nanotechnology

Senior Diagnostic and Medical Device Consultant Marco Donolato holds more than 15 years' experience working in the industry, with a substantial portion of those years focused on in-vitro-diagnostics (IVD) development. His expertise encompasses the entire spectrum of designing, developing, and marketing Medical Devices and IVD tests. Marco has successfully coordinated complex development projects at the crossroads of biochemistry, plastic consumables, and electronics. He has consistently operated within the framework of ISO 13485 and associated guidelines, ensuring the highest standards of quality and compliance.

Kasper Bredkær Sidenius, Msc Human Psychology

Medical Device Consultant, Kasper, is an experienced systems engineer and design control specialist within R&D and lifecycle management. He brings a great regulatory overview and strong stakeholder skills to any team, and has broad project experience working with change control, risk management, deviations, medical writing, usability, and more. This experience makes Kasper easily adapt to new technologies and projects, where he will also bring insights on various international standards.

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Do you want to get in touch?

Call **Rasmus Funk** at **+45 31 44 28 02**

or write an email to **rafu*@pharmait.dk***

We look forward to hearing from you!

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