EXPERIENCE MEETS EFFICIENCY

REGULATORY SOLUTIONS

FOR SMES AND STARTUPS

HP MED CONSULTING

PARTNERSHIP, PROFESSIONALISM, RELIABILITY:

This is how we ensure quick and compliant market approval for your medical devices.

With over 40 years of experience in Regulatory Affairs across the medical technology, life sciences, and healthcare sectors, we are the ideal partner for the successful approval of your medical devices!

As your trusted experts, we see it as our mission to guide your innovation swiftly through the regulatory approval process.

Whether developing customized regulatory strategies, establishing effective quality management systems, or preparing and supporting your audits – you can count on us!

Efficient approval of medical devices ensures that patients gain fast and cost-effective access to safe treatments.

That is what we do!

According to your needs, we provide comprehensive guidance and support throughout the entire process and across all regulatory areas. We can also focus on specific aspects and assist your team with individual tasks.

Our offer to you:
Faster Approval + Proven Quality

HOW WE CAN ASSIST YOU

QUALITY

We specialize in building and maintaining effective quality management systems that comply with industry standards, including ISO 13485, 21 CFR 820, and AQAP-2110. We focus on balancing rigorous quality standards with streamlined process optimization.

REGULATORY

We guide you through the complex global regulatory requirements for medical devices. Together, we develop customized regulatory strategies to ensure a seamless market entry for your products.

TECHNICAL

We provide the essential technical documentation for your medical devices in full compliance with strict regulatory requirements (Regulation (EU) 2017/745, 21 CFR 800 ff.). Our commitment: manageable risks and precise documentation for an efficient approval process.

CLINICAL

Our expertise in Clinical Affairs includes precise clinical evaluations and comprehensive post-market surveillance. Our goal is to ensure the highest quality for your products throughout their entire lifecycle.

DIGITAL

With us by your side, you can rely on a seamless approval process for your software as a medical device. We support you from regulatory classification through standards-compliant development to ensuring information security and data protection.

WHAT SETS US APART

#1
We are medical device manufacturers ourselves!
We understand not only the regulatory requirements but also the complexities of processes and related business challenges.

#2
We treat your approval process as if it were our own.
That's why we build on what already exists,
rather than reinventing the wheel.

#3
We see ourselves as your support, not just consultants!
We stand by your side whenever you need us.

#4
Expertise, experience & cutting-edge technology:
Our team of Regulatory Affairs experts uses all its know-how and the latest technologies to ensure fast results and efficient processes.

ABOUT US

As an integral part of HP Medizintechnik GmbH, we have been actively involved in the approval and regulatory support of products in medical technology, life sciences, and healthcare since 1979.

This extensive experience allows us to provide tailored solutions without compromising on quality or efficiency.

HP Med Consulting: Over 40 years of experience, expertise and results!

Christoph Sing
Managing Director
HP Med Consulting GmbH

Sandro Schmalzl
Managing Partner of
HP Medizintechnik GmbH

LOST IN REGULATION?
NO PROBLEM.
WE ARE HERE TO HELP!

Book your initial consultation today.

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