metecon

the service company

We create market access for medical devices.

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TOP JOB
Arbeitgeber des Jahres 2018

Everything from a single source

Metecon is the strategic partner for medical device manufacturers throughout the entire product life cycle. We listen, think and develop individual solutions for the compliant international marketing of medical devices.

Documentation, verification, validation and market access: we will provide you with all the services you need from a single source. This approach brings substantial synergy benefits for your product. Development is where your expertise lies – and you can leave the rest to us.

Our expert engineers, scientists and computer technicians ensure that our work is always of a consistently high quality and your project will run smoothly in their hands. As an owner-operated company, our top priority since our foundation in 1999 has been creating long-term relationships of mutual trust with our clients.

We look forward to working with you!

Best regards from Mannheim

Alexander Fink
Managing Partner

"Our expertise in regulatory affairs AND verification makes us unique – fast, efficient and reliable."

Alexander Fink

Service across the entire product life cycle

DOCUMENTATION AND MARKET ACCESS

Technical documentation

Strategic consulting and active support in the creation and management of technical documentation

Clinical affairs

Clinical evaluation based on existing literature, clinical trials, clinical monitoring, PMS, PMCF

Regulatory affairs

Advice and support for country-specific marketing

Quality management

Quality management processes according to EN ISO 13485, GxP, audits

VERIFICATION AND VALIDATION

Verification

Verification planning, creating test specifications, implementing and documenting tests

Validation

Validation of measuring and testing stations including software, validation of medical devices including software, validation of sterile processes

Testing laboratory

Development of test equipment, flexible test automation with six-axis robots, performance of test series for customers, organisation and control of tests in accredited laboratories

Let's make a start!

TECHNICAL DOCUMENTATION

CLINICAL AFFAIRS

REGULATORY AFFAIRS

QUALITY MANAGEMENT

DOCUMENTATION AND MARKET ACCESS

Compliant with all requirements – and fast too

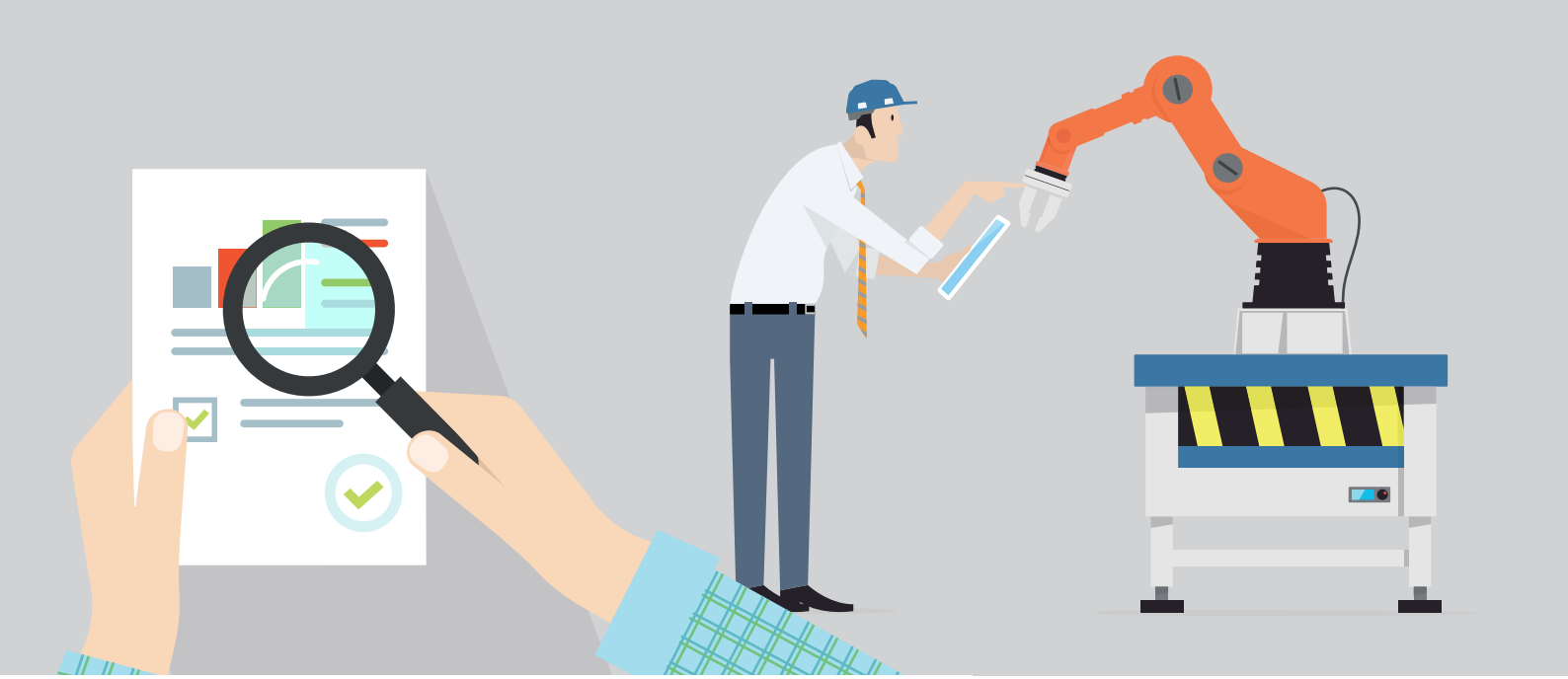
Are you experiencing delays at the start of your projects and capacity bottlenecks when developing your medical devices because you're stuck working through every last detail of the documentation? It doesn't have to be this way. Our specialists in the areas of technical documentation, clinical affairs and regulatory affairs are well-versed in these topics and can take care of the regulatory requirements at every stage of the development process.

Our team will provide you with efficient support in all the activities that accompany the development process, from creating and updating the technical documentation according to the Medical Device Directive and/or the MDR, through to the registration (in compliance with the German Ordinance on Clinical Trials with Medical Devices) and implementation of clinical trials, and across the whole spectrum of clinical evaluation right down to any and all issues surrounding market access for medical devices (CE and international).

REQUIREMENTS

DEVELOPMENT AND SPECIFICATION

VERIFICATION AND VALIDATION



VERIFICATION

VALIDATION

TESTING LABORATORY

VERIFICATION AND VALIDATION

Process-optimised and scalable

Your goal as a manufacturer is to implement accelerated development processes that shorten the time to market. By planning the design verification at an early stage, you will gain a decisive time advantage and reduce your development costs.

Whether you need to test electronics, characterise sensors or test the mechanical stability of your medical devices, we are on hand as your experienced partner. With a proactive approach to early planning and seamless integration of our measuring equipment and testing stations into your development workflows, you can boost efficiency at every stage of your development process. Together we will work to develop a verification strategy that enables your development process to reach its full potential.

CLINICAL EVALUATION

MARKET ACCESS

MARKET OBSERVATION

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