RRR LIFESCIENCE

R&D
REGISTRATION
REALISATION

MANAGEMENT AND TECHNOLOGY ADVICE FOR:

MEDTECH COMPANIES

START-UPS

INVESTORS

OUR EXPERTISE IS YOUR SUCCESS

ABOUT US

3R LifeScience is a management and technology consulting firm based in Berlin, Germany. From starting up a venture, through periods of growth and change we support medical device companies and organisations within the healthcare sector.

Our track record of helping to achieve operational excellence and to deliver quality products in medical technology and healthcare demonstrates that innovative ideas and specialised knowledge alone are no guarantee for a successful product and a thriving business.

- We assess the product idea and realisation strategy and create with you the necessary infrastructure for a targeted product development, efficient and cost-sensitive production and successful market launch.
- We help you with process and facility certification, preparation of clinical trials, CE mark and market access.
- We prepare you to meet the challenges of the industry and support you through growth and change.

Our services include hands-on consulting and coaching projects. We also assist you through longer-term interim management and by taking on entire development projects.

OUR KNOW-HOW

Our consultants and partners have worked in the industry in various roles. We draw on many years of practical operational experience and therefore understand the challenges of the industry.

From Start-ups to established corporations we combine profound knowledge in medical and healthcare technology with proven management skills.

We have successfully spun-out and financed companies, brought innovative products to market and helped organisations to grow and change.

With our proven network of partners we address individual needs in our project work to get results and deliver sustainable and tailored improvements.

OUR SERVICES

01
Company, Technology and Product Assessment

02
Risk Analyses and Risk Management (DIN EN ISO 14971)

03
R&D Concepts and Product Development (MDD 93/42/EEC)

04
Conformity Assessment and CE Mark

05
Quality Management Systems (DIN EN ISO 13485)

06
Marketing and Market Entry

07
Company Change and Growth

08
Interim Management

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Dr. Michaela Hajek and Dr. Veit Otto

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

RRR LIFESCIENCE
R&D
REGISTRATION
REALISATION

Our expertise is your success

www.3r-lifescience.com

Company, Technology and Product Assessment

INVESTING WELL MEANS UNDERSTANDING RISKS, POTENTIALS AND TECHNOLOGIES.

We evaluate your investment project and help you make the best decision.

- PRODUCT ASSESSMENT
  On the basis of market requirements we assess your product idea and help you understand the potential turnover and market influencers.
- DEFINITION OF USP
  We evaluate your USP on the basis of market requirements, competition and defined objectives.
- RISK ASSESSMENTS
  We help you recognise, assess and manage projects and technology risks.
- BUSINESS PLANS AND DUE DILIGENCE
  We advise you on the quality and risks of your business plan and carry out comprehensive technical and commercial due diligence to support your investment decision.
- SEARCH FOR PROJECT AND FINANCIAL PARTNERS
  The search for a strategic or financial partner is difficult and time consuming. We help you define investor selection criteria and assist you in your worldwide search for the right partner.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

Risk Analyses and Risk Management (DIN EN ISO 14971)

MANAGING RISKS SUCCESSFULLY MEANS RECOGNISING THEM AND PUTTING IN PLACE APPROPRIATE MEASURES.

We carry out risk analyses for your medical device and develop R&D plans to minimise product risks.

- ANALYSIS AND REVIEW OF DEVELOPMENT AND REGISTRATION RISKS
  We help you define critical success factors and priorities and establish the framework for successful international product approvals.
- ANALYSIS AND REVIEW OF MARKET RISKS
  We analyse your market and likely market risks, for example, customer acceptance and compliance, and identify market access barriers.
- STRATEGY PLANNING AND REALISATION
  With you we define product development strategies and priorities for a successful realisation. In this process, we integrate existing capacities and competencies with timelines and requirements for quality and registration.
- PLANNING AND IMPLEMENTING TARGETED PROCESSES
  We minimise development risks by implementing target-oriented processes. We help you define measurable milestones and optimise review processes to focus your development effort on defined objectives.
- CERTIFICATION AND REGISTRATION PROCESSES
  According to legal requirements we combine development processes with DIN EN ISO 14971 risk management to efficiently take your product to CE marking and international product approvals.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

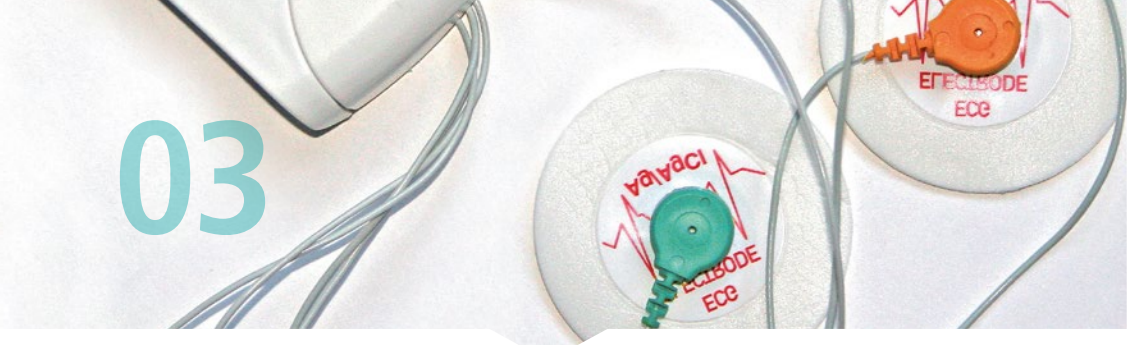
Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com



R&D Concepts and Product Development (MDD 93/42/EEC and MDR)

TARGETED DEVELOPMENT MEANS UNDERSTANDING MARKET REQUIREMENTS AND REGULATORY HURDLES.

With you we develop appropriate R&D concepts that are tailored to market requirements and successful registration and approval. Our focus is on providing and coordinating multidisciplinary teams and optimising interfaces.

- R&D CONCEPTS
  Based on risk classification of your medical device and existing QM processes we develop with you a route to targeted development and a successful CE conformity assessment.
- ANALYSIS AND MANAGEMENT OF DEVELOPMENT RISKS
  We identify success criteria, analyse structures and processes and define priorities to overcome operational bottlenecks, delays or quality problems.
- PLANNING AND IMPLEMENTING DEVELOPMENT PROCESSES
  Based on legal regulatory frameworks we support you with measures and processes to assure product safety, performance and reliability of your medical device. With you, we plan and implement new legal requirements.
- PLANNING CLINICAL TRIALS
  Together with medical experts we plan and coordinate clinical studies, as well as post-market product surveillance.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

04

Conformity Assessment and CE Mark

EFFICIENT CE MARKING MEANS COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS.

We understand the options of the conformity assessment route and apply them to your advantage. With us, CE marking is an achievable goal and not a hurdle on your way to market.

- CONFORMITY ASSESSMENT PROCEDURE
  Right from the beginning we assist you with registration strategies, plan and execute your conformity assessment route and compile relevant documents.
- OPTIMISATION OF DEVELOPMENT PROCESSES
  We plan development processes in accordance with the Essential Requirements of medical devices.
- CE MARKING
  We support you in all aspects of writing the Technical File, planning technical verification and validation and submitting relevant documents to achieve CE marking.
- COOPERATION WITH A NOTIFIED BODY AND AUTHORITIES
  We coordinate collaboration with a Notified Body and national registration offices like BfArM to prepare CE marking and market approval. For FDA approval we work with experts in the USA.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

Quality Management Systems (DIN EN ISO 13485)

MANAGING QUALITY WELL MEANS OPTIMISATION OF STRUCTURES AND PROCESSES.

Based on legal and regulatory requirements, as well as your business processes, we develop workable and accepted Quality Management processes to prepare and maintain certification.

- QM SYSTEMS
  Together with your organisation we implement and optimise your QM System according to DIN EN ISO 13485 for medical devices.
- PRODUCTION
  We optimise manufacturing processes to conform with regulatory requirements and integrate correction and prevention actions to ensure reliability in quality and efficiency.
- QUALITY ASSURANCE
  We carry out supplier audits, review quality assurance processes during production, sterilisation, packaging, and storage in accordance with regulatory standards.
- PRODUCT SURVEILLANCE
  We integrate post-market product surveillance workability with your QMS. We focus on practicability and workability of implemented QM processes.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

06

Marketing and Market Entry

SUCCESSFUL MARKET ACCESS MEANS KNOWING YOUR STRENGTHS AND THE WEAKNESSES OF YOUR COMPETITOR.

Based on our experience and together with our network of strategic partners, distributors, users and health insurers we assist you in marketing your product.

- PRODUCT MARKETING AND CUSTOMER-SPECIFIC MARKET ANALYSES
  On the basis of market requirements we assess and validate your product idea. We help you to understand the potential turnover and market influencers.
- PRODUCT MARKETING
  With you we create a basis for a successful marketing strategy by putting together convincing arguments of the benefits of your product.
- MARKET ACCESS STRATEGIES
  We develop with you an appropriate marketing and sales concept, optimise the sequence and logistics of your market entry and investigate product pricing and opportunities for reimbursement.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

Company Change and Growth

HEALTHY COMPANY GROWTH MEANS CONTINUOUS ANALYSIS AND OPTIMISATION.

Businesses change and grow. This challenges management competencies and staff. We support change and growth processes of organisations and integrate new strategic goals into operational processes and structures.

- PROCESS AND STRUCTURE ANALYSES
  We analyse existing processes and structures and implement necessary organisational changes to realise new business strategies.
- MANAGEMENT COACHING
  We coach your management by providing practical and specific training in risk management, registration and quality management.
- CONFLICT AND CHANGE MANAGEMENT
  We support your organisation in conflict management by facilitating methods and processes of conflict resolution and collaborative decision-making.
- SEARCH FOR PARTNERS
  Developing a business often needs strong partners. We help you with your search for the right strategic partner or investor.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

Interim Management

BRIDGING A GAP MEANS HAVING A COMPETENT PARTNER ON BOARD.

Together we help you bridge a capacity shortage. As a project manager or member of the management team we support you for a longer period of time.

- R&D MANAGEMENT AND PROJECT MANAGEMENT
  As interim managers we support your strategic plans and operations. We also take on entire projects and independently move your product development forward.
- QM AND CE MARKING
  Based on legal and regulatory requirements and existing business processes we develop optimal processes to achieve certification and CE marking for your product.
- BUSINESS DEVELOPMENT
  We develop your know-how to win customers and enter new markets. We plan your market and sales efforts and analyse market innovations.
- CEO/MANAGING DIRECTOR
  As an interim manager we bring in expertise of managing businesses to take on responsibility for company management.

3R LIFESCIENCE

R&D
REGISTRATION
REALISATION

Please contact us at:

3R LifeScience GmbH
Dahmestrasse 16a
12527 Berlin
Germany

Phone: +49 (30) 93 628 123
Fax: +49 (30) 25 201 712
E-mail: info@3r-lifescience.com

More information:

www.3r-lifescience.com

FIT FOR TOMORROW'S MARKETS

OUR AMBITION

Building on many years of working experience, 3R LifeScience delivers tailored and practical solutions to address challenges and performance issues along the value chain of medical products and healthcare innovations. We consult and guide you through process and strategy changes and help you realise your ambition.

By only deploying what has proved to be successful we turn your efforts into lasting results.

OUR PARTNERS

The medical device and healthcare sector currently faces various challenges. 3R LifeScience works closely with experts to address these demands.

Partners include medical opinion leaders, clinical research organizations (CROs), contract manufacturers (OEMs), US and EU regulatory authorities and Notified Bodies, preclinical test labs, production specialists, clinical trial experts and marketing experts.

Supported by:

EUROPÄISCHE UNION
Europäischer Fonds für
regionale Entwicklung
Investition in Ihre Zukunft

www.3r-lifescience.com