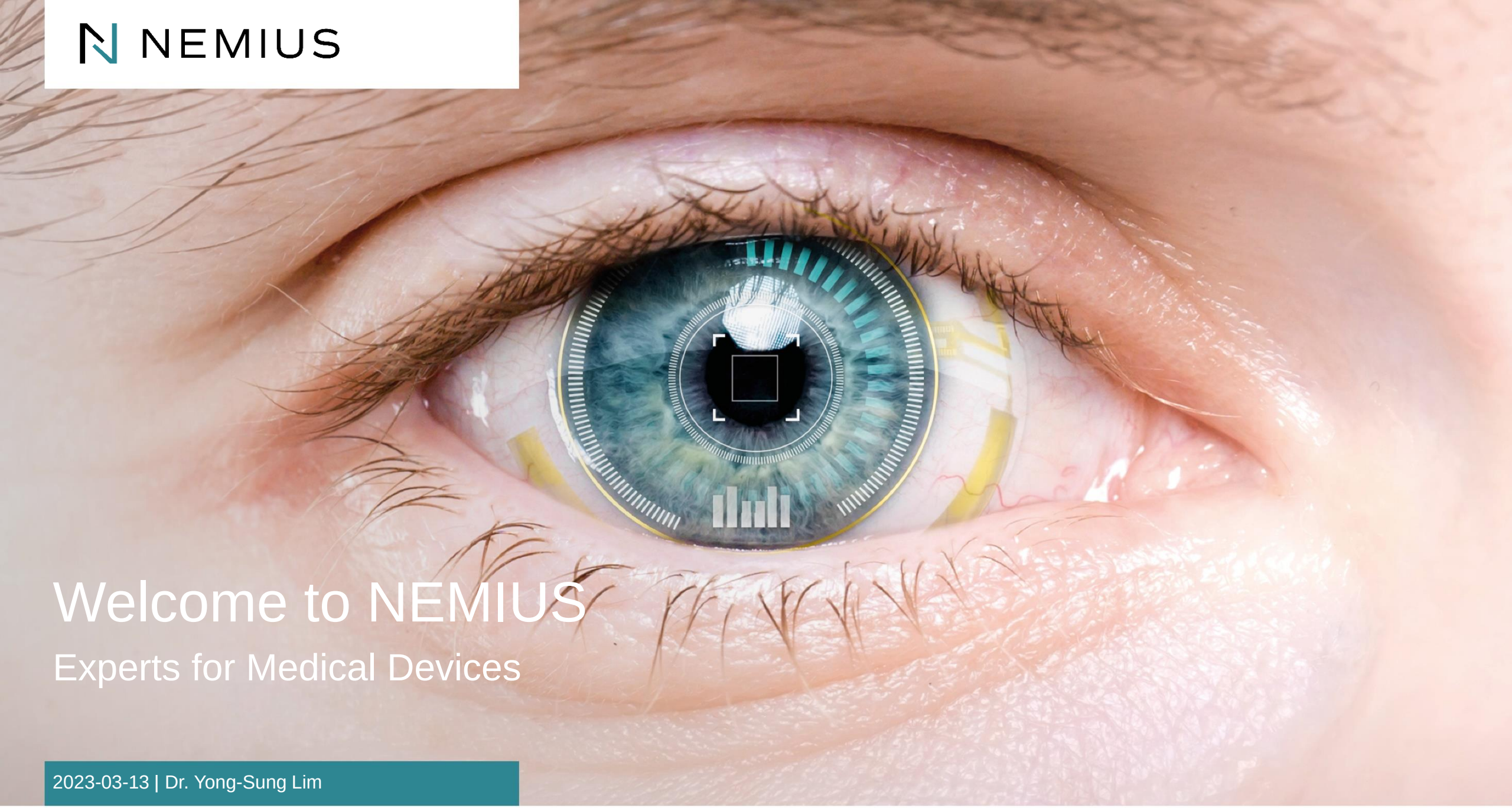
NEMIUS



Welcome to NEMIUS

Experts for Medical Devices

2023-03-13 | Dr. Yong-Sung Lim

VITA

Professional stations

Voluntary work

NEMIUS

Thorsten Schmitt, M.Sc.

Managing Partner

- 20 years of medical device experience
- 12 years of entrepreneurship

Education

- M.Sc. Chemical engineering (Pharma)
- B.Sc. Chemical engineering (Biotechnology)
- Chemical laboratoy technician
- RAM - International Regulatory Affairs Manager
- Lead Assessor

Voluntary work

- Board of the Alumni and Sponsorship Association for part-time students Höchst
- Ambassador of the DEVELOPmed.aid e.V.
- Member of the Hesse State Expert Commission for Health Care; German Economic Council
- Active member of the Junior Chamber; state of Offenbach am Main
- Active member; German Society for Quality
- Active member; German Institute for Standardization

VITA

Professional stations

Voluntary work

Martin Senger, Dipl.-BW (VWA)

Director Quality & Regulatory Affairs

- 20 years of medical device experience

Education

- Diploma in business management (VWA)
- Businessman engaged in wholesale and foreign trade
- RAM - International Regulatory Affairs Manager
- Lead Assessor

Voluntary work

- Member of the Baden-Württemberg State Expert Commission for Health Care; German Economic Council
- Active member; German Society for Quality
- Active member; German Institute for Standardization

NEMIUS

WHAT DOES NEMIUS DO?

Long story – short

Our companies operate as proven experts in the field of the healthcare industry. This includes the medical technology sector as well as the pharmaceutical, cosmetics and food supplement industries.

NEMIUS ACADEMY
Further education partner for medical device and pharmaceutical specialist and management topics

NEMIUS CONSULTING
Consulting services in medical device regulatory affairs, quality assurance and quality management systems. Provision of normative and regulatory services for companies in the medical technology and healthcare industry. Services as Person responsible for regulatory compliance for legal manufacturers of medical devices and in-vitro diagnostics.

NEMIUS MEDICAL
Services as European authorized representative (EAR) for legal manufacturers of medical devices and in-vitro diagnostics.

Long story – short

The NEMIUS Group is dedicated to the healthcare industry. Thanks to our many years of experience and our great commitment, we are able to intelligently combine all the requirements of the medical technology or pharmaceutical industry day for day for our customers.

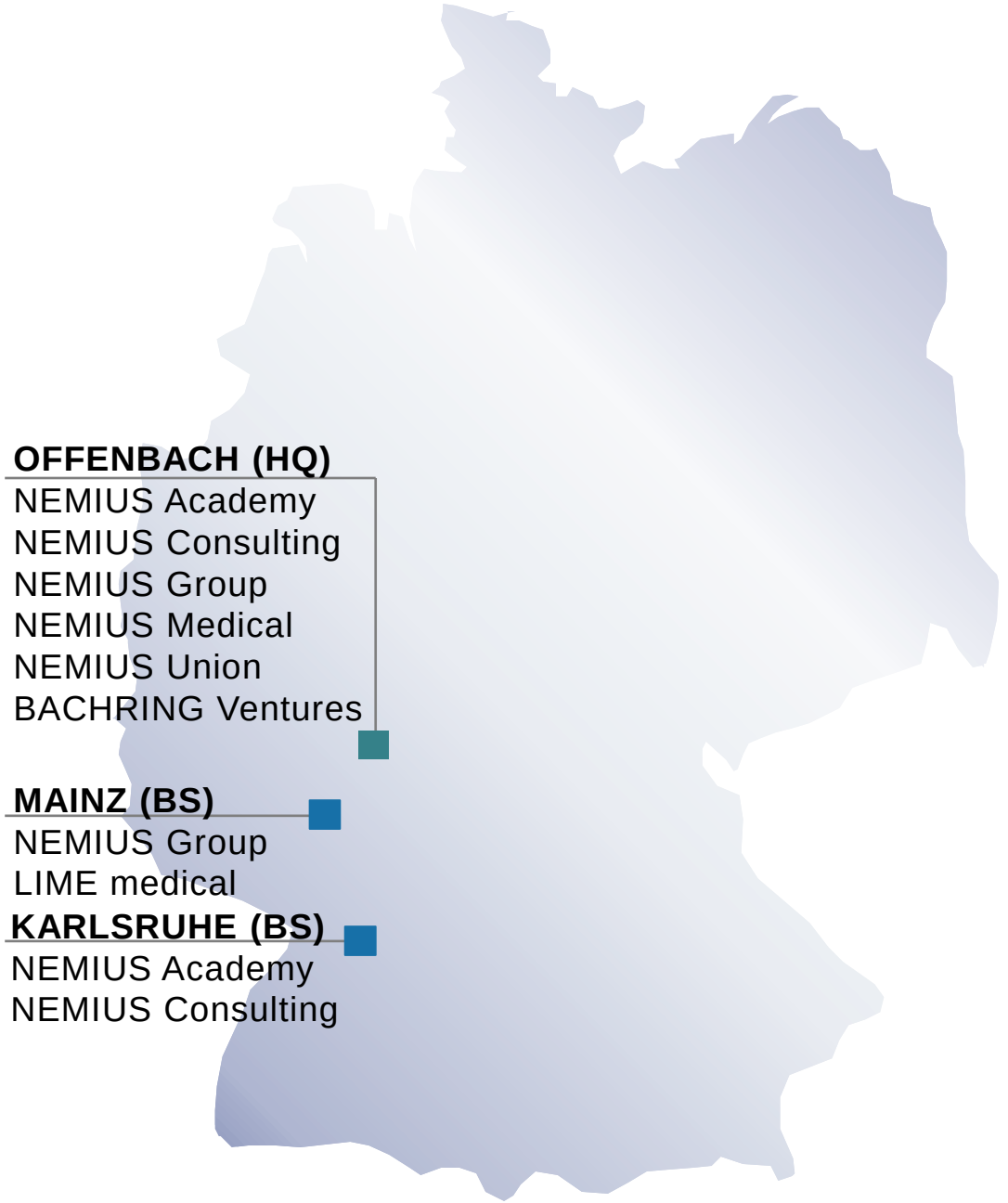
Our milestones:

- 2015: Acquisition of Caribus Deutschland and Caribus GmbH in Cologne.
- 2015: Acquisition of DGbW - Deutsche Gesellschaft für berufliche Weiterbildung mbH in Frankfurt am Main.
- Move to our offices in Obertshausen
- 2015: Foundation of Nemius Polydent GmbH in Mannheim
- 2018: Shareholding in LIME medical GmbH in Mainz
- 2018: Move to our office in Offenbach am Main
- 2021: Opening of the Karlsruhe office
- 2022: Opening of the Mainz office, Award Top Consultant
- 2023: Award TopJob, Employer of the future, Top Service,..

Key facts

We support our customers from the health care industry (medical technology, pharmaceutical, cosmetics and food supplement industry) from the implementation of a quality management system to the implementation of regulatory requirements and mock audits in preparation for official inspections. Of course, we also offer additional services that can make a significant contribution to our customers' competitiveness.

- ✓ Number of employees: 25 FTE + 30 exkl. Freelancer
- ✓ Number of customers: ~ 700
- ✓ Decades of experience in the life science sector
- ✓ Certified according to ISO 9001, EN ISO 13485 and OHM
- ✓ Authorized BAFA Consultant (Federal Office of Economics and Export Control)



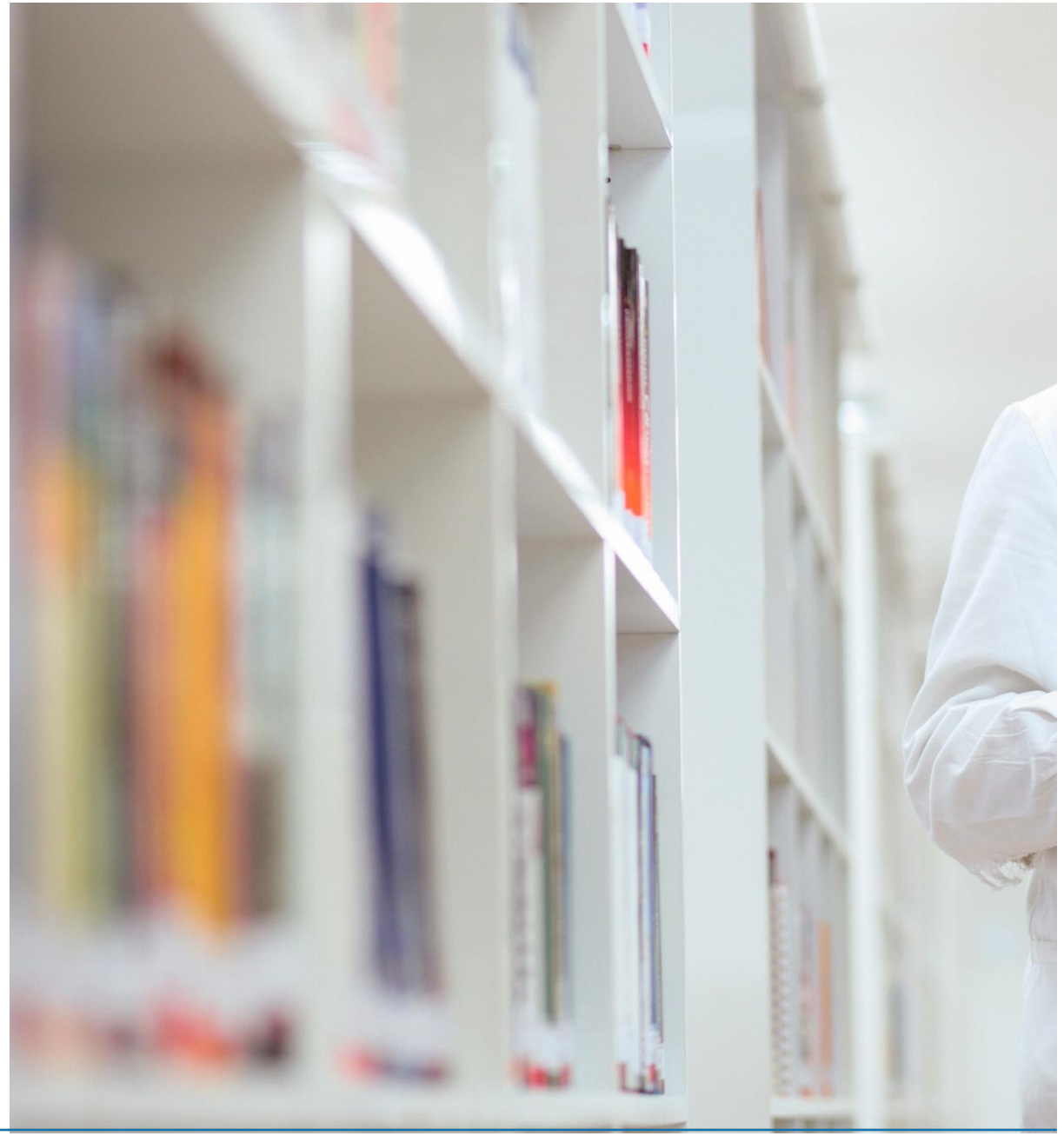
NEMIUS CONSULTING

CULTURE OF QUALITY

NEMIUS Consulting

What we can do for you

We support our customers from the health care industry (medical technology, pharmaceutical, cosmetics and food supplement industry) from the implementation of a quality management system to the implementation of regulatory requirements as well as mock audits in preparation for official inspections. Of course, we also offer additional services that can make a significant contribution to our customers competitiveness.



What we can do for you

Nemius Consulting stands for reliable management consulting at eye level for interactive and integrated management systems in the healthcare industry. The profound expertise of our consulting team masters a wide range of standards and tools, which are selected and implemented with experience from the internal and external network for our customers and your company in a customized way.

The goal is to tailor perfectly functioning management solutions for a process-optimized and profitable company. We also accompany product launches and CE markings, take on the role of QMR or safety officer for medical devices in outsourcing and lead projects at management level quickly and efficiently to success.

- ✓ We stand for excellent strategy consulting and innovative process management.
- ✓ We pursue a sustainable consulting approach, which also includes close cooperation with renowned technology specialists

What we can do for you

- ✓ Implementation, maintenance and development of quality management systems (ISO 13485, ISO 9001, ISO 14971, ...)
- ✓ Implementation, maintenance and further development of regulatory affairs systems (MDD, AIMD, IVD, MDR, IVDR, STED, ...)
- ✓ Integration of multiple norms and standards into one management system (central/decentral) e.g.
  - ✓ MDSAP (Medical Device Single Audit Program)
  - ✓ ISO 14971
  - ✓ ISO 62304
  - ✓ ISO 62366
- ✓ Support in selecting the right certification body or Notified Body
- ✓ Support in the selection of the right testing laboratory, e.g. for tests according to:
  - ✓ ISO 10993
  - ✓ ISO 60601

What we can do for you

- ✓ Conducting audits; 1st party (internal) and 2nd party (suppliers/customers)
- ✓ Performance of DELTA, GAP and MOCK audits
- ✓ Support during audits and inspections
- ✓ Performance of due diligence checks (technical)
- ✓ Research to differentiate the medical product from pharmaceuticals or wellness articles

- ✓ External Position of:
  - ✓ Quality Management Representative (QMB)
  - ✓ Person Responsible for Regulatory Compliance (PRRC)

- ✓ Support in the creation of relevant documentation such as
  - ✓ Quality assurance agreements (QSV/QAA)
  - ✓ Technical documentation
  - ✓ Design Dossiers
  - ✓ Verification and validation plans and reports

NEMIUS MEDICAL

EXPERTICE BY CONVICTON

Service as EC-REP / EAR

NEMIUS Medical

Every Manufacturer of medical devices and in vitro diagnostics located in non-European countries need an authorized representative (EC-REP) according to Article 11 of the European Medical Device Regulation 2017/745 [MDR] or 2017/746 [IVDR].

NEMIUS can take over the service function of the European authorized representative for legal manufacturers in the medical technology industry.

With years of experience in regulatory affairs our experts support you in every way including dealing with notified bodies.

EC REP NEMIUS

NEMIUS Medical GmbH & Co. KG
Berliner Straße 116
63065 Offenbach, Germany
+49 (0)800 13485 00

NEMIUS ACADEMY

What we can do for you

The Nemius Academy is your specialist for advanced training in the normative and regulatory environment of medical and pharmaceutical technology. Our experienced instructors are not only proven experts in their field but also specially trained knowledge brokers.

Furthermore, we offer the possibility to book all seminars in-house. In this case we will adapt the seminar contents to your individual needs. Thus we are your competent partner from the training of single persons up to the whole company.

What makes us outstanding:

- ✓ Experienced speakers from the practice
- ✓ We are allowed to say what others are not allowed!
- ✓ Small groups of up to 10 participants (if necessary, also individual coaching)
- ✓ We take time for you during the training and afterwards
- ✓ Each seminar ends with a written examination and the issue of a certificate of participation or a certificate
- ✓ In general, we recognize the models of other further education institutions

What we do

Nemius Academy offers you the opportunity for a variety of internationally recognized qualifications:

Management Systems

- ✓ ISO 13485 – Basic Knowledge
- ✓ ISO 13485 – Implementation
- ✓ ISO 13485 – Internal Auditor (1st Party)
- ✓ ISO 13485 – Supplier Auditor (2nd Party)
- ✓ ISO 13485 – Lead-Auditor
- ✓ ISO 13485 – Quality Management Representative
- ✓ ISO 13485 – Quality Manager

- ✓ GxP – GMP, GDP, GCP, GLP

- ✓ ISO 14971 – Basic Knowledge
- ✓ ISO 14971 – Implementation
- ✓ ISO 14971 – Risk Management Officer
- ✓ ISO 14971 – Risk Manager

- ✓ MDSAP – Basic Knowledge
- ✓ MDSAP – Implementation

What we do

Nemius Academy offers you the opportunity for a variety of internationally recognized qualifications:

- ✓ **Regulatory Affairs**
  - ✓ 745/2017/EU (MDR)
  - ✓ 746/2017/EU (IVDR)
  - ✓ Qualified Person (Art. 15)
  - ✓ CE-Mark
- ✓ **Other management systems**
  - ✓ ISO 9001
  - ✓ ISO 14971
  - ✓ ISO 15189
  - ✓ ISO 17025
  - ✓ GxP (GMP, GLP, GDP, GCP)
  - ✓ ISRS; International Safety Rating System
- ✓ **Tools**
  - ✓ CAPA
  - ✓ 8D-Report
  - ✓ FMEA


SUCCESS

Our claim for excellence

NEMIUS is the first consulting company for medical and pharmaceutical technology to receive TOP CONSULTANT Award from customers and the TOP SERVICE Award form the German Institute for Innovation

- ✓ The mentor of the TOP CONSULTANT Award is the former **German President Dr. Christian Wulff**.

Our claim for excellence

NEMIUS is the first consulting company for medical and pharmaceutical technology to receive TOP JOB Award from employees and the EMPLOYER OF THE FUTURE Award form the German Institute for Innovation

- ✓ The mentor of the TOP JOB Award is the former **German Vice-Chancellor Sigmar Gabriel**.

Our claim for excellence

Certified integrated quality management system:
ISO 9001:2015

- ✓ Provision of consulting services in the area of quality assurance and quality management systems as well as services in the field of training and interm management for companies in the medical technology industry.


Bureau Veritas Certification

Zertifikat

für

NEMIUS Group GmbH
Berliner Straße 116
63065 Offenbach, Deutschland

Bureau Veritas Certification bestätigt, dass das Management-System der oben genannten Organisation bestätigt wurde und die in den folgenden Normen und Regelwerken festgelegten Anforderungen erfüllt.

Normen / Regelwerk

DIN EN ISO 9001:2015

Geltungsbereich

Erbringung von Beratungsdienstleistungen im Bereich der Qualitätssicherungs- und Qualitätsmanagementsysteme wie auch von Dienstleistungen im Bereich der Weiterbildung und des Interimsmanagement für Unternehmen in der medizintechnischen Industrie.

Gültigkeit: 27. Februar 2022
Voraussetzung, dass während der Gültigkeitsdauer dieses Zertifikates alle Anforderungen der Normen kontinuierlich erfüllt sind, ist das Zertifikat gültig bis: 26. Februar 2025
Datum der Erstzertifizierung durch Bureau Veritas: 27. Februar 2019
Zertifikat-Nr.: DE012665-1 Datum: 23. Februar 2022

Certification Manager (A. Stoel)

DAkkS


Bureau Veritas Certification

Certificate

awarded to

NEMIUS Group GmbH
Berliner Straße 116
63065 Offenbach, Germany

Bureau Veritas Certification certifies that the Management System of the above organisation has been assessed and found to be in accordance with the requirements of the standards detailed below.

Standard

DIN EN ISO 9001:2015

Scope of application

Provision of consulting services in the area of quality assurance and quality management systems as well as services in the field of training and interim management for companies in the medical technology industry

Certification cycle start date: 27. February 2022
Subject to the continual satisfactory operation of the organisation's Management System, this certificate expires on: 26. February 2025
Bureau Veritas Original certification date: 27. February 2019

Certificate n°: DE012665-1 Date: 23. February 2022

Certification Manager (A. Stoel)

DAkkS

BUREAU VERITAS 1828

BUREAU VERITAS

DAkkS Deutsche Akkreditierungsstelle

Our claim for excellence

Certified integrated quality management system:
ISO 13485:2016

- ✓ Provision of consulting services in the area of regulatroy affairs, quality assurance and quality management systems as well as the provision of normative and regulatively required service functions for companies in the medical technology industry.


Bureau Veritas Certification

NEMIUS Group GmbH
Berliner Straße 116, 63065 Offenbach, Deutschland

Bureau Veritas Certification Denmark A/S bescheinigt hiermit, dass das Managementsystem des oben genannten Unternehmens beurteilt wurde und die in den folgenden Normen festgelegten Forderungen erfüllt.

Standard

DS/EN ISO 13485:2016

Geltungsbereich

Beratungsdienstleistungen in den Bereichen Zulassung von Medizinprodukten, Qualitätssicherung und Qualitätsmanagementsysteme. Erbringung von normativen und regulatorischen Dienstleistungen für Unternehmen der Medizintechnik- und Gesundheitsindustrie. Dienstleistungen als Qualitätsmanagementbeauftragter, europäischer Bevollmächtigter, Sicherheitsbeauftragter und verantwortliche Person zur Einhaltung der Regulierungsvorschriften für legale Hersteller von Medizinprodukten und In-vitro-Diagnostika.

Erstzertifizierung: 27-Februar-2019
Gültigkeit des vorherigen Zertifikats: NA
Datum des Re-Zertifizierungs-Audits: NA
Start Re-Zertifizierungszyklus: 27-Februar-2022

Vorausgesetzt, dass während der Gültigkeitsdauer dieses Zertifikates alle Anforderungen der Normen/Regelwerke kontinuierlich erfüllt sind, ist das Zertifikat gültig bis: 26-Februar-2025

Zertifikatsnummer: DNKFRC102219 Version: 1 Revisionsdatum: 23- Februar-2022

DANAK


Bureau Veritas Certification

NEMIUS Group GmbH
Berliner Straße 116, 63065 Offenbach, Germany

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

DS/EN ISO 13485:2016

Scope of application

Consulting services in medical device regulatory affairs, quality assurance and quality management systems. Provision of normative and regulatory services for companies in the medical technology and healthcare industry. Services as Quality Management representative, European authorised representative, Safety officer and Person responsible for regulatory compliance for legal manufacturers of medical devices and in-vitro diagnostics.

Original cycle start date: 27-February-2019
Expiry date of previous cycle: NA
Certification/Recertification Audit date: NA
Certification/ Recertification cycle start date: 27-February-2022

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 26-February-2025

Certificate No.: DNKFRC102219 Version: 1 Revision date: 23-February-2022

DANAK

BUREAU VERITAS

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DANAK

Our claim for excellence

- ✓ Accredited consultant of the Federal Office of Economics and Export Control
- ✓ Certified corporate health management of the German Heart Foundation
- ✓ ICEM Certification - International member of the German Association of Consultants and Experts based on EN ISO/IEC 17024

Let´s stay in touch

Please, do not hesitate to contact us if you have any further questions, suggestions or information:

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Business Development Manager

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ISO 9001 BUREAU VERITAS Certification

ISO 13485 BUREAU VERITAS Certification

Bundesamt für Wirtschaft und Ausfuhrkontrolle

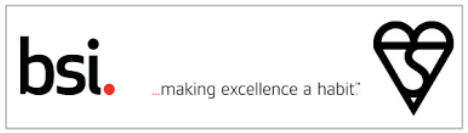
BAFA akkreditierter Berater

charta der vielfalt
Für Diversity in der Arbeitswelt

Joint success

NEMIUS

is based on the selection of the best partners:




THANK YOU!
www.nemius.com