COMPANY PROFILE

GBA Medical Device Services

2024

GBA MDS
MEDICAL DEVICE SERVICES

Agenda

1. Company
2. Capabilities & Services
3. Quality

Company

GBA MDS
MEDICAL DEVICE SERVICES

About GBA Medical Device Services

GBA MDS is one of Europe's leading providers for the process qualification and biological evaluation of medical devices

- **1994**: Foundation of Medical Device Services Dr. Rossberger GmbH (MDS) in Gilching near Munich
- **Jun 2022**: Merger with the GBA Group, Hamburg

  GBA Group is an international life science service company with more than 3,000 employees, over 60 sites on three continents and a broad range of analytical, logistical and specialist services in the fields of pharmaceuticals, medical devices, cosmetics, chemicals, food, drinking water and the environmental sustainability.
- **Sep 2022**: Renamed into GBA Medical Device Services GmbH (GBA MDS)
- **Mar 2023**: Appointment of Dr. Timo Lebold and Felix Bunde as Managing Directors
- **Sep 2023:** Merger with ICCR-Roßdorf GmbH to expand range of toxicology services
- **2023**: Growth from nearly 30 to more than 50 employees at GBA MDS in Gilching in order to increase capacities, drive long-term growth projects and professionalize the organization
- **Jan 2024**: Merger with Key2Compliance AB to expand regulatory compliance solutions
- **Summer 2024**: Relocation to another location in Gilching with more than 1,200 sqm state-of-the-art LEAN-optimized laboratory space
- **2024:** Expanding the service portfolio in response to strong customer demand and provide an even more comprehensive range of analyses for medical device customers

Capabilities & Services

GBA MDS
MEDICAL DEVICE SERVICES

Qualification and Monitoring (Process)

Manufacturing and sterilization processes and packaging systems

Testing, qualification, monitoring and evaluation of the

Manufacturing processes, qualification and monitoring (ISO 14971, ISO 13485)

- Product hygiene (bioburden, endotoxins, particulates)
- Water hygiene/purity (bioburden, endotoxins, particulates, cytotoxicity, TOC)
- Production conditions / cleanroom (microbiological (bacteria, yeasts/fungi, spores) contamination on surfaces and air-borne)
- Product cleanliness after pre-cleaning, final cleaning and/or clean production (bioburden, endotoxins, particulates, cytotoxicity, chemical residues and contaminants)

Sterilization processes, microbiological performance qualification (ISO 14937)

- Ethylene oxide (ISO 11135) incl. residual analysis (ISO 10993-7)
- Radiation: Gamma, eBeam and X-ray (ISO 11137)

Packaging systems, qualification (ISO 11607)

- Package integrity, accelerated ageing and mechanical treatment
- Microbial barrier testing, seal integrity, material qualification
- Toxic properties

Qualification (Product)

Biological evaluation (EN ISO 10993)

Product-specific and application-based selection of **evaluation strategy and testing procedures**

Short-term capacities at market-leading turnaround-times available

- **Material characterization of the solubility profile**, organic and inorganic leachable and extractable constituents/impurities of materials and devices and from manufacturing processes: **chemical characterization** by means of GC-MS/-FID, ICP-MS/-OES (ISO 10993-1, -3, -7, -9, -10, -11, -12, -13, -14, -15, -18, -23)
- **Cytotoxicity** (ISO 10993-1, -5, -12)
- **Sensitization** (ISO 10993-1, -10, -12)
- **Irritation** (ISO 10993-1, -12, -23)
- **Acute systemic toxicity** (ISO 10993-1, -11, -12)
- **Hemocompatibility** (ISO 10993-1, -4, -12)
- **Genotoxicity** in vitro and in vivo (ISO 10993-1, 3, -12)
- **Corrosion stability** of metallic materials, identification and quantification of degradation products by means of electrochemical and immersion testing (ISO 10993-1, -9, -15)
- Biostability of implants (ISO 10993-1, -6, -13, -15, -18)
- Summarizing **biological evaluation** including toxicological risk assessment (ISO 10993-1, -17) under consideration of the device's clinical application conditions and clinical history, the characteristics and toxicological profile of the materials used and of released constituents and data from comprehensive literature search
- Additional proof of **biocompatibility over the whole life-cycle** of a medical device after storage (accelerated and real-time ageing) and processing/repeated processing of devices

GBA MDS
MEDICAL DEVICE SERVICES

Validation (Product / Process)

Reprocessing procedures (EN ISO 17664 / ANSI AAMI ST81)

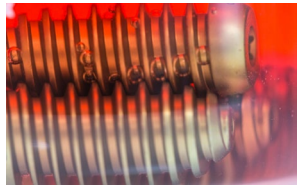
Testing, qualification, monitoring and evaluation of the

Processing/repeated processing of reusable devices (ISO 17664, RDS 007, AAMI TIR 12)

- Worst-case selection
- Microbiological efficiency control of manual/automated cleaning and disinfection (including procedures for non-critical medical devices)
- Efficiency control of manual/automated cleaning by protein test/TOC test (including procedures for non-critical medical devices)
- Microbiological efficiency control of sterilization process (steam,…)
- Toxicologically relevant material changes
- Repeated processing

Case Studies

Read our newsletter to benefit from interesting case studies



19.10.2023

Cytotoxicity of medical devices

Cytotoxicity is a biological endpoint that must be evaluated according to ISO 10993-1:2018 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process) for the biological evaluation of any medical device.

The cytotoxicity test according to ISO 10993-5:2009 (Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity) is a rapid, standardized, sensitive and cost-effective method for testing whether a medical device or its manufacturing materials contain potentially biologically harmful, material- and manufacturing-related leachables. Thus, the performance of the cytotoxicity test serves the medical device manufacturer not only to prove the biocompatibility of its product, e.g. in the context of a CE marking, but also to identify biological hazards and to assess the risk of the product already during product development, to validate product cleanliness or to prove that biocompatibility is still given after a change in product composition or manufacturing.

Read more …

23.10.2023

Chemical characterization of medical devices

With ISO 10993-1:2018 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process) and ISO 10993-18:2020 (Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process), the importance of material characterization by chemical analysis in the course of biological evaluation of medical devices has greatly increased.

Also, with regard to the 3Rs principle with the aim of completely avoiding animal testing (*Replacement*), limiting the number of animals (*Reduction*) and their suffering (*Refinement*) in tests to the indispensable level, the material characterization of medical devices by means of chemical analyses has become essential.

GBA Medical Device Services from GBA Group Pharma & Medical Devices has been working successfully with numerous medical device manufacturers for many years to improve patient safety through precisely tailored chemical analyses and has been implementing the significantly expanded requirements directly since the publication of ISO 10993-18:2020-01 (DIN EN ISO 10993-18:2021-03) and the updated ISO 10993-18:2020-01 + Amd 1:2022-05 (DIN EN ISO 10993-18:2023-11).

Read more…

Quality

Quality

- GBA MDS is accredited (with ILAC Mutual Recognition Arrangement) for biological, microbiological and hygiene testing according to **DIN EN ISO/IEC 17025** (for medical devices) by the Deutsche Akkreditierungsstelle (German Accreditation Body) (DAkkS, D-PL-13392-01)

- GBA MDS is **GLP** (Good Laboratory Practice) certified by the Bayerische Überwachungsbehörde (Bavarian supervisory authority)

GBA MDS
MEDICAL DEVICE SERVICES

If you seek efficient and safe qualification of your products, please contact us. Thank you!

Felix Bunde
Managing Director
f.bunde@gba-group.de

Dr. Kristina Then
Professional Customer Service
k.then@mdservices.de

GBA Medical Device Services GmbH
Lilienthalstrasse 4
82205 Gilching
Germany

Tel. +49 8105 77835-0
Fax +49 8105 77835-59