In focus:
Medical Device Vigilance

"Obtaining high quality and high throughput at the same time is the major challenge in the Medical Device Vigilance System. This can only be accomplished by automated processing of documents to complement the diligence of highly qualified and experienced personnel. This is our motto at GIMD: Getting Information Management Done."

Dr. Andreas Holst, Managing Director GIMD

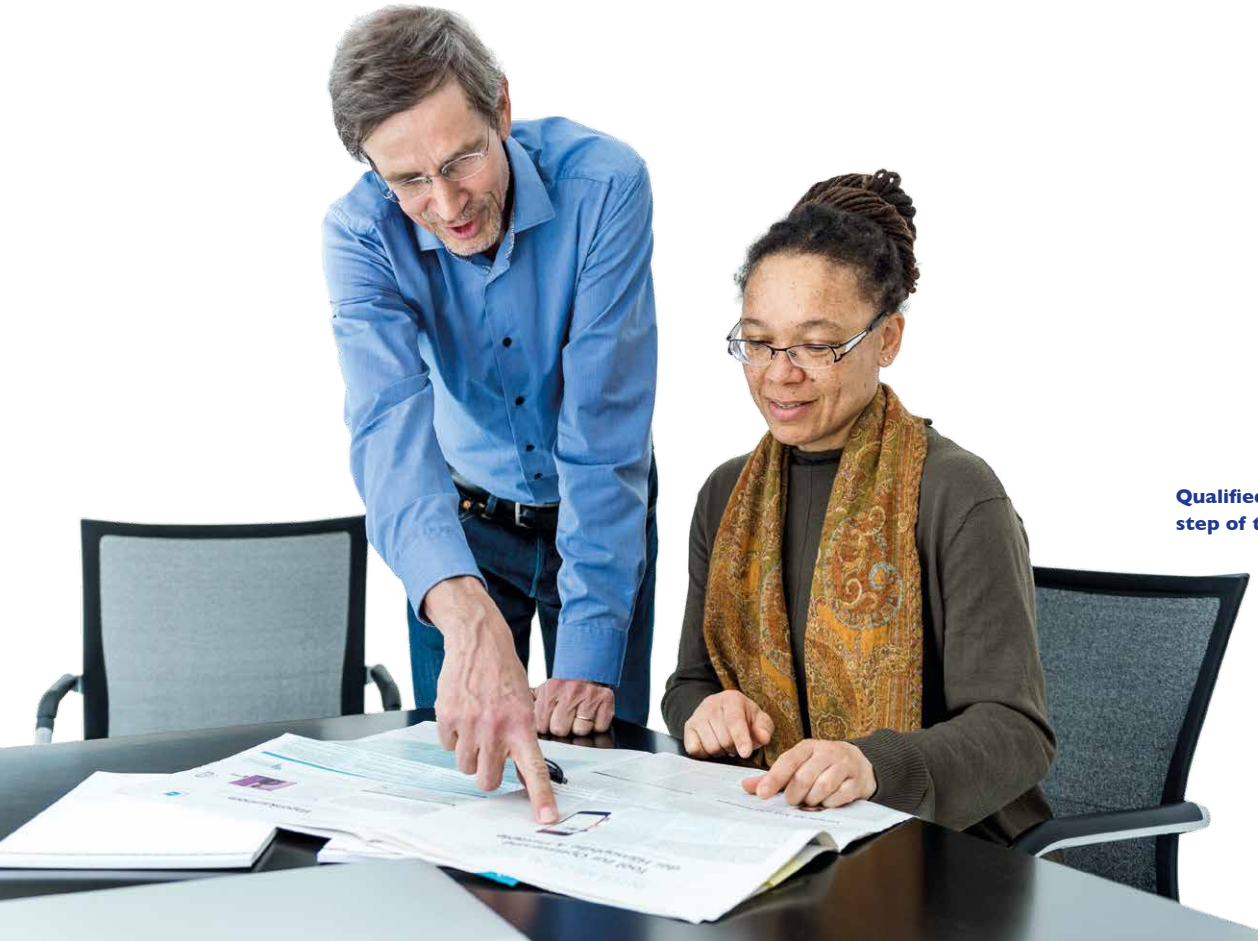
GIMD

Limited Corporation for Information Management and Documentation

Our services

- We help manufacturers to effectively and efficiently meet the requirements of the Regulations on Medical Devices and IVDs
- Support with all means of post-market surveillance and vigilance of your medical device products
- We specialize in document retrieval, identification/elimination of duplicates, cross-referencing and indexing in form and content of all types of medical, scientific, and technical literature
- We process all document types, ranging from published articles and associated communications in medical/scientific journals, published abstracts and online-prepublications, to posters and oral presentations from scientific conferences, and unpublished manuscripts
- We provide regional-literature surveillance for publications not referenced in major international scientific databases and, if required, manage all aspects related to subscriptions to individual journals
- We monitor social media and process retrieved information for medical device/IVD vigilance
- We restructure retrieved documents (e.g. converting PDF format to XML) to comply with customer databases and are prepared to include merging of contents such as online-only supplementary material, providing searchable electronic documents
- For information procurement, we cooperate with renowned German and international service providers, ensuring a minimum time interval between publication, identification, and vigilance-relevant processing
- An expert team with long-standing experience in (pharmaco-)vigilance evaluates each document to detect incidents that have to be reported to the relevant authorities
- We create safety-related text modules for the compilation of vigilance reports, such as “periodic safety update reports” (PSUR)
- Where necessary, we perform routine requests to authors for clarification whether important safety-related information can be provided to comply with regulations (follow-up activities)
- We manage communication with competent authorities, and the responsible manufacturer and incident originator
- Our processes strictly observe the stipulations of REGULATION (EU) 2017/745, the guidance MEDDEVs, MDCG endorsed documents and regional legal requirements
- We are committed to quality assurance through a quality-management (QM) system with regular quality controls (QC) as well as established CAPA plans, available for internal and external audits and inspections at all times

- We can provide internal company SOPs detailing all stipulated activities and timelines and their documentation, ensuring regulatory compliance
- Additionally, we provide cutting-edge benchmarking of Healthcare Professionals (international, including Asia and the US) as Key Opinion Leaders in specific disciplines and/or areas of research
- Our modular system allows us to tailor all our services according to your company needs, from information procurement to the retrieval, evaluation, assessment, re-structuring, and archiving of vigilance-relevant information



Qualified personnel review each step of the screening process

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Your benefits

- An unfailingly reliable partner with over 20 years of scientific-literature management perfectly integrated with comprehensive IT capabilities
- Guarantee of meeting regulatory reporting obligations of marketing authorization holders (MAHs) within EEA and non-EEA, provided by an experienced team with in-depth knowledge of the medical device/IVD vigilance requirements related to scientific literature and reporting
- Proof of compliance with legal requirements
- Customized, made-to-order screening of regional literature not indexed in international scientific databases to comply with regional regulatory requirements
- Continuous document workflow combined with log-file documentation and daily monitoring of all process steps
- Guaranteed delivery within specified time limits to achieve regulatory compliance combined with the highest standard of quality
- Effective pre-selection of large quantities of potentially relevant documents based on comprehensive expertise and long experience, incl. documented selection criteria
- Expert manual screening of every single relevant article to complement detection of relevant literature using text-mining tools
- Retrieved documents are restructured/converted into easy-to-handle formats in order to meet the demands of vigilance-related requirements, using highly specialized database software
- Modular approach achieves customized solutions, which can be commissioned individually and tailored to client specifications
- Outsourcing of time/personnel-intensive processes as a means of cost reduction and to support peak workloads or backlogs to complement your in-house processes

Outsource time-intensive processes to support peak workloads with a guarantee to meet regulatory reporting obligations.

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About us

- GIMD, Limited Corporation for Information Management and Documentation (Gesellschaft für Informations-Management und Dokumentation mbH)
- A distinguished service provider with an established client base consisting of numerous prestigious companies in the pharmaceutical industry
- Your partner for a complete range of services covering every aspect of scientific information management and documentation

Contact us! We look forward to hearing from you. Additional information and various project examples can be found on our website at **www.gimd.de**

- GIMD – Gesellschaft für Informations-Management und Dokumentation mbH

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