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Medi-Phi

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One of the primary purposes of science is to preserve life. We must promptly respond to progress in science and always consider how advances can enhance life. In the fields of medicine, dentistry, and pharmacy, all of which contribute to improving the quality of life, we try our best to help fulfill the mission.

Contribute together to improve human health

Medi-Phi is a company consisting of experienced experts who can effectively managing tasks in these fields

CMC
- GAP analysis and evaluation
- Planning and management of CMC studies
- Management of CRO
- GMP audit and due diligence

Nonclinical
- Planning and management of nonclinical studies
- Management of CRO
- Evaluation of nonclinical studies and new drug candidates
- GLP audit and due diligence

Clinical
- Planning, management, and evaluation of clinical studies
- Management of CRO and regulatory affairs
- GCP audit and due diligence

Medical Devices and General
- R&D strategy and roadmap
- Management of CRO, academia, and regulatory affairs
- Evaluation of in-license drugs, "Due Diligence" assessments
- Consulting on company code and compliance

Consulting service

We develop solutions in all fields and at all stages in the development of medical drugs and devices.

R&D strategy	R&D	NDA	Postmarketing
Basic research and investigation	CMC, nonclinical, and clinical studies	Filings, PMDA inquiries, other necessary services	Clinical studies and investigations

CMC
- Preparation of CTD, DMF, and NDA documents
- Preparation of GMP-related documents
- Translation and QC

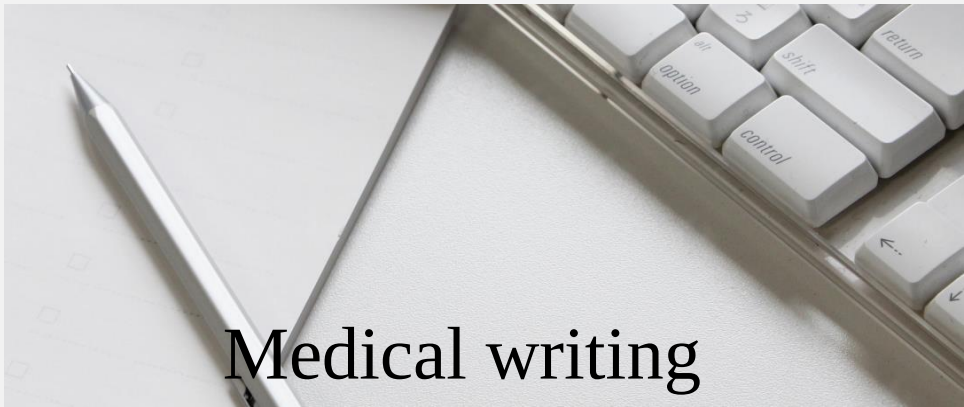
Nonclinical
- Preparation of CTD and NDA documents
- Preparation of study reports and scientific papers
- Translation and QC

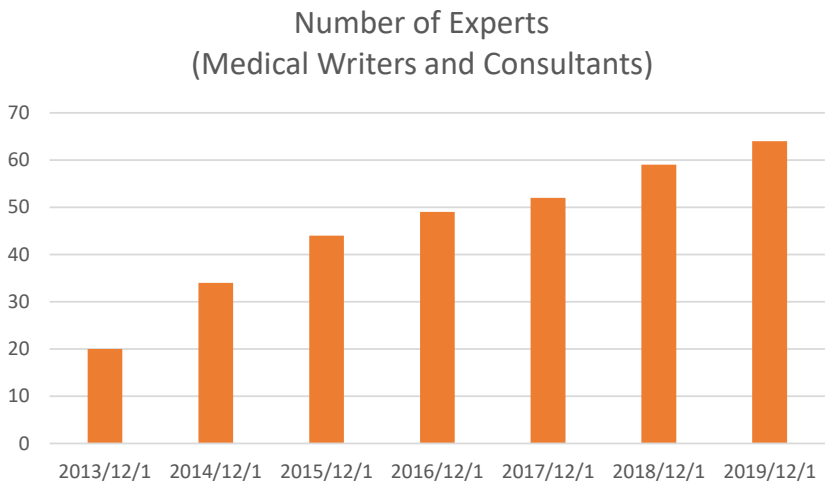
Clinical
- Preparation of documents for clinical studies: protocols, investigators' brochures, CSRs, and others
- Preparation of CTD and NDA documents
- Preparation of scientific papers and meeting materials
- Translation and QC

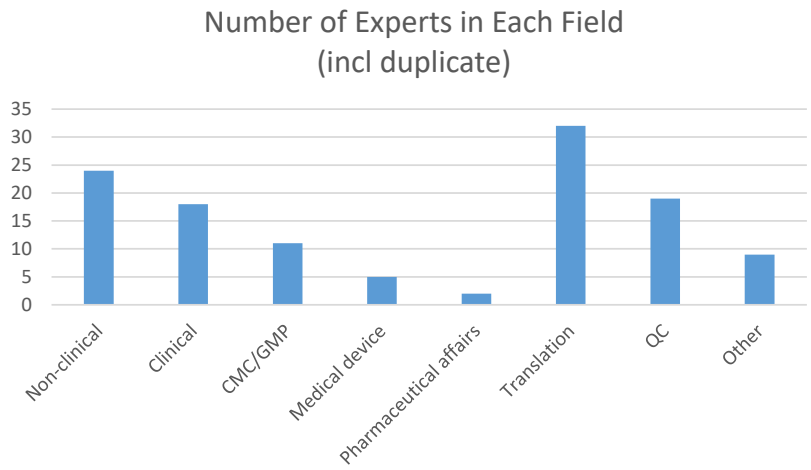
Medical Devices and General
- Preparation of necessary documents in the development and registration of medical devices
- Translation and QC

Medical writing service

We provide high-quality medical writing services for all fields and stages in the development of medical drugs and devices.







With experts having enough experiences in the new medical drug and devices, we provides services with high quality.

■ Experts (Medical writers and consultants)

- Since the establishment of Medi-Phi, number of experts are steadily increasing year by year.
- All experts have sufficient and practical experiences in research, development, and registration of medical drugs and devices at pharmaceutical companies, and can provide professional services in medical writing and consulting.
- Medi-Phi has enough number of experts in each field to deal with any request of clients. Eight to 15 experts are ready in each of 3 major fields, non-clinical, clinical, and CMC/GMP.
- QC of prepared documents certificates the reliability quality of and translation of any kind of documents.
- Translators are experts in respective field and give a professional translation meeting client's demand.

If you have any inquiry or request,
please mail to info@medi-phi.jp

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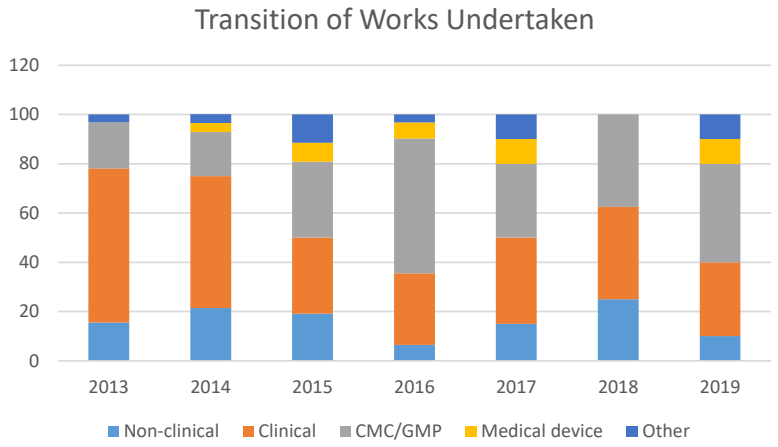
We provide high-quality medical writing and consulting services for all fields and stages in the development of medical drugs and devices.

Common Technical Document (CTD)



In 2013, 60% of works undertaken were clinical-related ones. Nowadays, CMC works are increasing, and have became our most important field of specialty.
For 7 years after the establishment of Medi-Phi, we completed 40 CTD and CTD-related works. We also experienced preparation of ASEAN CTD.

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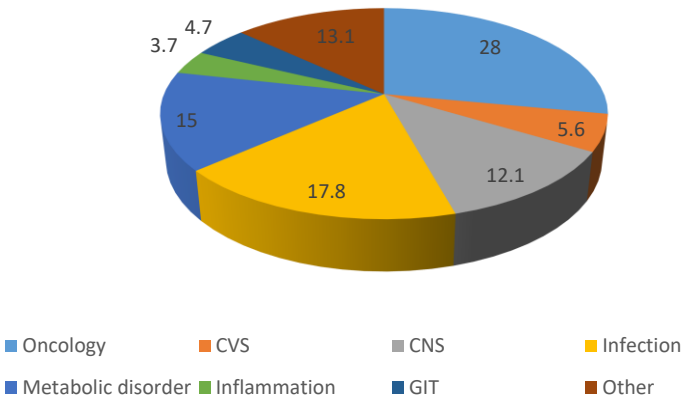
During 7 years since the establishment of Medi-Phi, we completed or are conducting 139 business items. Therapeutic area of these items were widely distributed, such as oncology, cardiovascular system (CVS), central nervous system (CNS), infection, metabolic disease, inflammation, gastro-intestinal tract (GIT), etc.

Nowadays, oncology works are increasing to reach approximately 50%. Most of anti-cancer drugs are biological ones, such as antibodies, peptides, proteins, blood derived products, etc. Experts of Medi-Phi have practical experiences in biological drugs in pharmaceutical companies, enabling to provide services with high quality and reliability.

Therapeutic area of works undertaken (%)



Since our medical writers and consultants have a lot of experiences at pharmaceutical companies and were involved in many therapeutic areas, we can flexibly and timely deal with any request.

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Contribute Together to Human Health

The origin of the company name and our promise

The letter phi (Φ) of pharmakon (Φαρμακον), which means pharmacy in Greek, was considered to be the mark of our company, and the company name Medi-phi reflects our close association with medicine. Honoring our company name, we promise the following:

- We will use our company's business expertise to support the development of new drugs and medical devices that contribute to social health.
- We will provide services with high reliability and high quality.
- We will adapt to change flexibly and in a timely manner.
- We will maintain good relationships with the medical community, clients, and regulatory agencies and aim to achieve win/win outcomes.

Core Members

Akihiro Matsuura, PhD: President

Education: PhD in Pharmaceutical Science, The University of Tokyo

Job History: Established Medi-Phi in 2013; R&D Director at Sosei Co. Ltd., Proteus Science Co., Ltd., and Oxygenix Co., Ltd.; Director of Japan Operations at Icon Japan K.K.; and Director of the CMC Research Center of Serono Japan Co., Ltd. Group Manager of the Research Center at Shimizu Pharmaceutical Co. Ltd. and Grelan Pharmaceutical Co., Ltd. Research Leader of the Nippon Roche Research Center.

Background and Experience: Nonclinical research (pharmacology, toxicology, and ADME) and CMC research. NDA filings for 15 launched products and more than 50 basic and clinical science published papers.

Yutaka Takahashi: Senior Advisor for Clinical Science

Education: BS, Hokkaido University

Job History: Freelance medical writer for 10 years. Manager of the Medical Writing Department at Pfizer Japan Inc. Clinical Research Director at Pharmacia & Upjohn. Manager of the Clinical Development Department at Sumitomo Pharmaceutical Co. Ltd.

Background and Experience: Obtained many new drugs via clinical research. Medical writing in the clinical field; prepared more than 15 CTDs.

Shuichi Soma: Senior Advisor for Pharmaceutical Affairs, Nonclinical and Medical Devices

Education: BS in Pharmaceutical Science, Tohoku University

Job History: Director of Pharmaceutical Affairs and Development at Next 21 K.K. Manager of Regulatory Affairs at Seikagaku Corp. Manager of Development Regulatory Affairs at Novo Nordisk Ltd. Researcher in Toxicological Science at Nippon Soda Co., Ltd.

Background and Experience: Nonclinical research (toxicology and pharmacology). Regulatory affairs and medical writing involving the development of new drugs and medical devices.

Yuko Hasegawa, MS: Senior Advisor for CMC

Education: BS in Agricultural Science, Nagoya University

Job History: Manager for NDA of new drugs and medical devices including DMF at Baxter Japan and Serono Japan. QC tests and NDA for new drugs and API at Pharmacia.

Background and Experience: CMC and GMP of new drugs, API, marketed drugs, and investigational drugs. Obtained many approvals of drugs icluding partial changes.

Medi-Phi Co., Ltd.

President: Akihiro Matsuura, Ph.D.
Establishment: 8 Jan., 2013
Number of contracted experts: 64 (as of 29 Dec., 2019)

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