Capability Statement

Easyglobaltraining.com

Easy Global Training, develops educational training material and conducts training for individuals/companies in the pharmaceutical, medical device, and medical/clinical fields (online training, e-learning, classroom, and continuing education). We also provide consulting in regulatory/technical/grant writing, and GXP training for the pharmaceutical/medical device industry.

Easy Global Training has a proven track record supporting companies in medical affairs, medical information, scientific communications, regulatory writing, grant writing, and medical/continuing education.

Core Services

Medical/regulatory writing/editing services:

- Regulatory writing/submission (pharmaceutical/medical device)
- All therapeutic areas (hematology/oncology, reproductive medicine, bone health, orthopedics, dermatology, cardiovascular, neurovascular, urology, infectious disease, rare disease, cancer Immunotherapeutics, vaccines, pharmacogenetics)
- Drafting clinical reports, SOP, consent, protocol, case reports, summary of clinical efficacy/safety, clinical study report (CSR), aggregate reports (integrated summary of safety [ISS], development safety update report [DSUR], periodic safety update report [PSUR], periodic benefit-risk evaluation report [PBRER], periodic adverse drug experience report [PADER]), individual safety reports (SCS), risk management plan (RMP)
- Gap Analysis/Remediation Report in compliance with MEDDEV 2.7/1 Rev. 4 / MDR 2017/745 Liaising to payers, employer medical directors, medical policy personnel, and healthcare professionals

Medical Affairs Services:

- Supporting pharmacovigilance (PV)/drug safety medical component
- Market research, market/regulatory intelligence (Cortellis), literature surveillance, competitive/KOL intelligence, survey development/management (Qualtrics)
- Publication planning (abstracts, manuscripts, white papers)
- Medical marketing document development/compliance review (abstract, manuscript, proposal, product knowledge material, poster, websites, blog, e-learning modules, social media marketing)

Educational Services:

- Developing educational materials/CMEs for health care professionals and patients (webinars, Classroom, e-learning training, e-books) using Criterion-Referenced Instruction (CRI) instructional design
- GXP (GLP, GCP, GMP, GDP, GPP, …) Training

Primary NAICS Codes

541690 - Other Scientific and Technical Consulting Services
541990 - All Other Professional, Scientific, Technical Services
541711 - Research And Development In Biotechnology
541715 - Research & Development in the Life Sciences
541714 - Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)
541611 - Administrative Management and General Management Consulting Services
611430 - Professional and Management Development Training
823110 - Administration of Education Programs

Company Snapshot

CAGE: 9VGZ7 **UEI:** ZM3HJHTCDTS5 **D-U-N-S:** 041219295
Gov. Business POC: Dr. Afsaneh Motamed Khorasani, PhD
Phone: +1 (310) 430.4993
E-Mail: amotamed@easyglobaltraining.com
Address: 8021 Inverness Ridge Rd., Potomac, MD 20854
Work Area: Nationwide
Years in business: Since 2015
Certificates:

- Minority-Owned Small Business (self-identified)
- Woman Owned Small Business (WOSB) Certificate by WBENC
- Women's Business Enterprise (WBE) Certificate by WBENC

Differentiators

- Multifaceted Scientific/Clinical Expertise
- Highly qualified team of contractors with advanced degrees [post doctorate, PhD, MSc])
- Commitment to innovation
- Client-focused approach
- Extraordinary project management (PMP experts/candidates)
- Strong 10-year track record of successful collaborations
- Serving commercial, non-profit, and government sectors
- Top Senior Consultant with PhD and post-doctorate training:
  - Medical and scientific Affairs expert
  - Senior Scientist with a strong background in biomedical science, molecular biology, and clinical trial/research
  - Tenured/diverse range of experience in medical affairs, basic and industrial clinical research and development (R&D), clinical trials, Medical/regulatory writing, intellectual property
  - Over 20 years of experience in the industry
  - Many National/international certificates in GLP, GMP, ICH-GCP, and global regulatory compliance for clinical trials
  - Member of several professional associations (American Medical Writers Association [AMWA], Project Management Institute [PMI], and Women Impacting Public Policy [WIPP])
  - 4 years of experience with the development/delivery of training materials provided by US Pharmacopeia (USP) (2012 to 2016) for National/International organizations and government
  - Well-published (presented over 50 papers, abstracts, and articles in highly regarded scientific journals, high-profile conferences, and scientific meetings)
- Proven track record of success:
  - Delivering high-quality regulatory/clinical/educational solutions
  - Serving various industries, including:
    - Commercial (Public, private, non-profit, large businesses)
    - Government
- High customer satisfaction ratings for reliable/efficient services
- Delivering solutions that drive business success
- Leveraging deep scientific knowledge, industry expertise, and the latest guidelines to provide solutions for the client's specific needs
- Delivering results that exceed expectations

Dr. Afsaneh Motamed Khorasani
(Primary Point of Contact)

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amotamed@easyglobaltraining.com
8021 Inverness Ridge Rd., Potomac, MD 20854

Clients Served

Selected Project List

Client	Descriptive Project Name	Date
CSL Behring (Commercial Sector) Easy Global Training (First-tier sub)	**Regulatory Writing, Oncology, Rare Disease** Global regulatory writing (Phase I, II, III) of Garadacimab (Factor XIIa inhibitor monoclonal antibody [CSL312]) for respiratory indications	Jan 2024- Present
Immunovant Inc (Commercial Sector) Easy Global Training (First-tier sub)	**Regulatory Writing, Oncology/Rare disease** Global regulatory filing (Phase I-III) of IMVT-1401 "batoclimab", a novel, fully human monoclonal antibody targeting the neonatal Fc receptor (FcRn), for myasthenia gravis, thyroid eye disease, warm autoimmune anemia	Sep 2022 – Aug 2023
NIH (Government Agency) **Atara Biotherapeutics (Prime)** Easy Global Training (Second-tier sub)	**Regulatory Writing, Oncology** FDA response letters for Global regulatory filing (Phase III) of Tabelecleucel (tab-cel®) (Chimeric Antigen Receptor [CAR) T-cell Therapy]) for the treatment of Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV+ PTLD)	Mar 2022 – Jan 2023
NIH (Government Agency) **Astex Pharmaceuticals (**Otsuka America, Inc.) Easy Global Training (Second-tier sub)	**Regulatory Writing, CNS / Rare disease** Global regulatory filing (Phase I/II) of ASTX-03, ASTX-06, ASTX-07 (INQOVI [decitabine and cedazuridine]) alone or in combination with venetoclax for in adults with myelodysplastic syndromes, chronic myelomonocytic leukemia, and acute myeloid leukemia (CSR, Protocol, Protocol amendment, ICF for IND submission)	May 2021 – Apr 2022
PTC Therapeutics Inc. (Commercial Sector) Easy Global Training (First-tier sub)	**Regulatory Writing, Rare disease** Global regulatory filing (Phase I/II) of PTC857 drug for oral administration in subjects with Alzheimer's disease and Amyotrophic Lateral Sclerosis (ALS) (Protocol, Protocol amendment, CSR, IB, General Investigational Plan)	Jan 2021 – Feb 2022
NIH (Government Agency) **AstraZeneca** Easy Global Training (Second-tier sub)	**Regulatory Writing, Cancer Immunotherapeutics** Regulatory Writing, Cancer Immunotherapeutics sBLA filing of IMFINZI® (durvalumab) oncology drug for the treatment of patients with unresectable stage III NSCLC with no progression with concurrent platinum-based chemoradiation therapy	Jan 2019 – Mar 2022

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