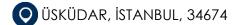
Çiğdem Güler

Certified Translator



+905335570036

cigdemglr@gmail.com



in https://www.linkedin.com/in/%C3%A. %C4%9Fdem-g%C3%

Familiar with the regulatory requirements and standards you are required to keep, I provide the highest quality translation meeting the life-science industry's requirements for uncompromising quality and rapid delivery.



Skills

- Excellent written and verbal communication skills
- Strong attention to details with the ability to multitask
- Ability to work under pressure
- Experienced user of SDL Trados Studio and Memsource
- Excellent problem solving and analytical skills
- Effective time management and ability to meet deadlines
 - Excellent teamwork skills



Work History

Freelance Translator

- Kuzguncuk, İSTANBUL
- Providing translation and QA services for the life-science industry Document types translated:
- -Laws, regulations, directives and guidelines governing the pharmaceutical industry.
- -Clinical Trial Application Forms (and relevant correspondences with RAs and ECs)
- Clinical Trial Documents (i.e., protocols, IBs, case report forms, patient facing materials including ICFs, patient cards)
- Regulatory submission files for human medicinal products (i.e. CTD/eCtd files, variation files, SPC/PIL, BE/BA reports)
- Regulatory submission files for veterinary products (MAA submission and variation files)
- -SOPs, Internal training documents
- -Agreements (i.e. CTAs, Confidentiality Agreement, Service Agreements)

2019-06 - Current

2009-03 - 2019-01

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Co-founder- Translation Project Manager

LINGUIST Dil ve Danışmanlık Hizmetleri Tic. Ltd. Şti, Üsküdar, İSTANBUL

- Developed internal standards to consistently provide translation and regulatory services that meets customer and applicable regulatory requirements.
- Provided technical translation and regulatory consultancy services to the leading pharma companies.
- Successfully passed ISO 9001:2008 quality management system audit and various client audits.
- Established, optimized and enforced business policies to maintain consistency and high-quality standards.

2002-07 - 2009-01

Full-time Translator

Istanbul Reklam ve Danışmanlık Tic. Ltd. Şti, Beyoğlu, İSTANBUL Provided technical translation and validation services as an in-house translator.



Education

1997-01 - 2001-07

Bachelor of Arts: Western Languages And Literatures

İstanbul University - İSTANBUL



Software



CAT tools (SDL Trados Studio, Memsource)

MS Office



Certifications

2017-03

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Regulatory Affairs Training (MAAs, Type I (A-B) and II (Quality, Clinical) variation applications, SmPC, PIL preparation)

2011-10

ISO 9001-2008 QMS Basic Training

2008-07

CTD/eCTD Submission Training