

Hong Ai

Language Specialist | ATA Member
ZH(CN)<>EN * ZH(TW)>EN

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Nationality: China

Teams: 1298175595

Gender: Female

Date of Birth: June 28, 1988

CAT tools: Trados 2021, MemoQ, Phrase, Xbench, XTM, SmartCat, and other online CAT tools.

EDUCATION

September 2007 – July 2011 *Shandong Institute of Business and Technology* *Bachelor of Laws*

Major: Social Work (Psychology - Focus)

Courses: Social Psychology, Psychotherapy, Cognitive Behavioral Therapy, Family Therapy, Psychometric Measurement and Evaluation, Psychoanalysis, Clinical Psychology

Suppl. Courses: Civil Law, Contract Law, Criminal Procedure Law, Law of Economy, etc.

September 2007 – July 2011 *Shandong Institute of Business and Technology* *Bachelor of Arts*

Major: English

Courses: Intensive & Extensive Reading, English Writing, Introduction to Linguistics, Advanced English, English-Chinese Translation, Economic and Trade Translation, Applied Translation

Suppl. Courses: Japanese, International Business and Trade, Market Survey, Academic Writing

CREDENTIALS

- English Proficiency: College English Test-6 (CET-6)
- Business Language Certification International-level Translator by China General Chamber of Commerce (ETTBL Certificate)
- C-level Human Resources Professional (HRP)

SPECIALTIES

- Life Sciences (Medical)
- Legal
- Finance
- Other

BOOKS

EN>ZH: Ethnobiology of Corals and Coral Reefs, more than **130,000** words.

Resilient Policies in Asian Cities Adaptation to Climate Change and Natural Disasters, more than **50,000** words.

A finance text book titled Treasury Certificate.

EXPERIENCE&WORKFLOW

2011-2026 (Certified) Freelance Translator (Experience: 15 years)

- A process of "accurate translation + QA" guarantees high-quality project delivery as per ISO 17100.
- Deliverables are submitted **on time** to meet project deadlines.
- **Quick response** to requests enhances work efficiency.
- Reliable **after-sales services** ensure **customer satisfaction**.

Life Sciences (Medical) (Words: 5 million+) *

CLINICAL DOCUMENTS

Protocols & Agreements

- **Global master clinical trial agreements** across multiple investigative sites
- Adaptive **trial protocols** with complex biomarker-driven enrollment criteria
- **Site initiation visit (SIV) manuals** for multinational Phase III studies
- **Investigator brochures (IBs)** and **clinical trial protocols (Phase I-IV)**.
- Monitoring visit reports, site initiation documents, and audit preparation materials
- Central lab specifications, laboratory manuals, and SOPs
- Statistical analysis plans (**SAP**) and case report form (**CRF**) completion guidelines
- Multidisciplinary medical research
 - ◆ Biochemistry & molecular biology: therapeutic applications.
 - ◆ Neuroscience: pharmacodynamics modeling for Alzheimer's disease.
 - ◆ Pharmaceutical Sciences: Bioequivalence studies for generic oncology drugs.
 - ◆ Allied Healthcare: Nurse-led palliative care intervention trials.

Patient-Facing Documentation

- **Simplified Chinese informed consent forms (ICFs)** for 25+ oncology trials
- **eICF platforms** with dynamic Q&A modules for rare disease studies
- Genetic **screening** criteria, patient **recruitment**, **enrollment**, and **patient diaries**, medication adherence guides, and symptom reporting tools
- Pre-screening questionnaires, **EDC**, **visit** windows, and non-compliance flyers

Regulatory Strategy

- **FDA Fast Track/Breakthrough Therapy** designation packages
- **EMA PRIME** program submissions with parallel linguistic validation
- Orphan drug designation dossiers for **rare metabolic disorders**
- Regulatory strategies for advanced therapy medicinal products (**ATMPs**) to support decentralized manufacturing and delivery
- Regulatory submissions for **innovative bioequivalence methods** for locally acting drugs

DRUG SAFETY & PHARMACOVIGILANCE

- **ICSRs** (Individual Case Safety Reports) across the markets
- Periodic safety update reports (**PSURs**) using templates
- Signal detection analysis reports with WHO-UMC causality assessment

HEALTH ECONOMICS & OUTCOMES RESEARCH/ MANUFACTURING COMPLIANCE

- Translated **Medicare** Part D reports and related criteria documents
- Translated **Medicaid** criteria documents
- Translated **FDA** response letters for **GMP** remediation
- Localized **medical device** and **drug audit reports**
- Translated comparability **protocols** for biosimilar **manufacturing process** changes

ACADEMIC PAPERS & WEBSITE LOCALIZATION

Core Expertise

- 300+ medical research papers across oncology, diabetes, immunology, and neurology, etc.
- Localized and reviewed abstracts and supplementary materials for enhanced readability

Multilingual Digital Solutions

- Pharmaceutical Companies: Product pages, MOA animations, safety information hubs
- SEO-optimized medical content (blogs, FAQs, disease awareness campaigns)
- Websites for large-scale enterprises such as PCI Pharma Services and Labvantage

STRATEGIC VALUE-ADDED SERVICES

Interdisciplinary Localization

- **Economics/Statistics:**
Health technology assessment (HTA) models for cost-effectiveness analyses
- **Engineering/Technology:**
AI-driven drug discovery white papers and medical device validation protocols
- **Environmental Science:**
WHO chemical safety profiles for antineoplastic drug disposal guidelines
- **Psychology:**
Quality-of-life questionnaires in psycho-oncology survivorship studies, as well as other questionnaires

STRATEGIC CLIENT PORTFOLIO

Tier 1 Pharma Partners

- Pfizer ● Novartis ● Roche ● Merck & Co. ● AbbVie ● BMS
- AstraZeneca ● Sanofi ● Takeda ● Gilead ● Bayer ● J&J

Government & Payers

- CMS (Centers for Medicare & Medicaid Services) ● VA Healthcare System
- NHS England ● INESSS (Quebec) ● PBAC Australia

Premier Service Providers

- IQVIA ● Parexel ● PPD ● Syneos Health ● ICON ● LabCorp

Finance (Words: 500,000+) *

- Projects**
- Memorandum and Articles of Association of a BVI Company** - Foundational documents governing the operations of a British Virgin Islands company.
 - Annual Report** - Provides an overview of performance, governance, and future outlook of enterprises.
 - Equity Management Measures** - Guidelines for managing equity within a company.
 - ESG (Environmental, Social, and Governance)** - Framework for assessing a company's ethical impact and sustainability practices.
 - Financial Statements** - Reports summarizing the financial performance and position of a company.
 - Audit Report** - An independent examination of financial statements to ensure accuracy and compliance.
 - Loan Facility** - Terms under which a lender provides funds to a borrower.
 - IPO (Initial Public Offering)** - Document outlining the details of a company's first sale of stock to the public.
 - Financial Counseling** - Services providing advice on managing finances and investments.
- Customers**
- McKinsey & Company
 - Boston Consulting Group (BCG)
 - Fidelity Investments
 - PwC (PricewaterhouseCoopers)
 - Deloitte
 - EY (Ernst & Young)
 - Morgan Stanley
 - KKR (Kohlberg Kravis Roberts & Co.)
 - Bridgewater Associates
 - HSBC

Legal (Words: 1 million+) *

- Projects**
- Shareholder Agreement** - Governs the rights and responsibilities of shareholders in a corporation.
 - Letter of Undertaking** - A document where one party commits to fulfilling certain obligations.
 - Security Agreement** - Establishes the terms under which collateral is pledged for a loan.
 - Equity Agreement** - Specifies the rights and responsibilities related to equity ownership in a company.
 - Class B Facility Agreement** - Relates to specific financing arrangements under Class B terms.
 - Corruption Prevention Act** - Legislation aimed at preventing corrupt practices in business.
 - IPO Regulations** - Rules governing the process of companies going public.
 - Litigation on Intellectual Property Rights** - Legal proceedings concerning the protection of intellectual property.
 - Confidentiality Agreement (Non-Disclosure Agreement)** - Protects sensitive information shared between parties from being disclosed to third parties.
 - License Agreement** - Allows one party to use intellectual property owned by another party under specified conditions.
 - M&A Agreement** - Details the terms and conditions under which two companies agree to merge into one entity.
- Customers**
- KPMG
 - Giorgio Armani
 - King & Wood Mallesons
 - Hainan High People's Court
 - Shanghai Higher People's Court
 - JP Morgan Chase
 - Clifford Chance
 - Baker McKenzie
 - China Securities Regulatory Commission (CSRC)