C.V. of Certified English-Chinese -English GMP/FDA Translator Igor Lee

Over 14 Years Experience in GMP Audit Interpreting

(More than 100 audits),

ProZ Certified Pro



Personal Information

English Name: Igor Lee	**Chinese Name: Li Xiaoyi**
Proz Member Name: Igor Lee	**CAT Tools in Use: SDL Trados Studio 2019 (Authentic Version)**
Gender: Male **Member of TAC (Translators Association of China)**	**MTI (Master of Translation & Interpretation)** **Holder of CATTI-1 Certificate (China Accreditation Test for Translators and Interpreters, CATTI-1 is the top level)**
Date of Birth: 1982/01/04	**Residence: Shanghai, China**
Work Experience: >16 years of professional English-Chinese translation TECHNICAL)	**Hometown: Shandong Province, China**
English Name: Igor Lee	**Chinese Name: Li Xiaoyi**
WeChat: china-fanyi	**Mobile: 0086-13262856628**
Email: 13262856628@126.com	**Skype:igor.lee-translation-services**
QQ: 271041867	**PayPal Accepted**

Profile: Since 2011, I have been deeply involved in conducting GMP audits, FDA audits, and pharmaceutical computerized system validation (CSV)/GAMP5 audits for pharmaceutical companies (covering pharmaceuticals, medical devices, and laboratories) across China on an annual basis. To date, I have accumulated over a hundred instances of GMP audit interpretation experience (fourteen years).

My Online CV: https://www.proz.com/profile/1566236

Since first collaborating with an independent Spanish GMP auditor in 2011 (using English as the audit language), our highly successful initial partnership has evolved into a long-term collaboration (now entering our 14th year). Annually, the Spanish auditor conducts multiple audit tours in China, each covering several pharmaceutical manufacturers. Over the past fourteen years, we have jointly audited over a hundred pharmaceutical plants. Beyond this primary collaboration, I actively participate in GMP audit interpretation projects for other clients. Since 2019, I also supported Chinese domestic pharmaceutical companies to accept various GMP audits by foreign regulatories. Selected GMP audit interpretation projects I have engaged in include:

1. Jul 14-16, 2025

Supported a lab in Hangzhou to accept FDA audit (interpreting), with successufl results, i.e. zero-observation, without 483.

2. Jul 2, 2025

Supported GMP audit conducted by a Spanish pharmaceutical company (buyer) at a Dalian API manufacturer (supplier), serving as interpreter for the Spanish auditor.

3. Jun 26, 2025

Supported a CAR-T cell therapy manufacturer (Nanjing) to carry out GMP audit for its contracted USA BSL-3 laboratory.

4. May 26-30, 2025

Served as lead auditor's interpreter for Egyptian Drug Authority (EDA) official audit at Tianjin vaccine manufacturer.

5. Apr 14-17, 2025

Interpretating for Indonesian Drug Authority official audit at a sterile injectables plant (Jilin Province), my area focused on on-site verification of registration documents (including quality studies).

6. Feb 22-27, 2025

Supported QC auditor during Egyptian Drug Authority (EDA) official audit at a sterile injectables plant (Jilin Province).

(Note: I was recommended as an interpreter for this project, based on positive client feedback from previous Egyptian Drug Authority audit in Shandong)

7. Jan 10-13, 2025

Interpreting for QC auditor during Egyptian Drug Authority (EDA) official audit at Shandong sterile injectables facility.

8. Dec 17-18, 2024

Provided interpretation services for TÜV (Poland) to audit a medical device company (Shandong Province).

9. Dec 9-13, 2024

Interpreted for UK GMP expert during PIC/S & EU GMP gap analysis audit at Inner Mongolia sterile injectables plant, commissioned by leading Chinese consultancy.

10. Nov 18-23, 2024

Supported ANVISA pre-approval audit interpretation at Jilin sterile injectables facility.

11. Nov 11-13, 2024

Served as lead auditor's interpreter for WHO PQ audit (HPV diagnostic kits) at multinational pharma's Shenzhen site, receiving commendation from WHO

team (France/Oman).

12. Oct 30, 2024
Provided GMP interpretation for Brazilian client QA audit at Suzhou biologics plant.

13. Oct 28, 2024
Facilitated interpretation for Bangladesh's largest pharma (Circle Ltd) during audit at Jilin sterile injectables facility.

14. Sep 19-20, 2024
Interpreting for a GMP audit (cell banking/facilities) conducted by Polish auditors (client/third-party auditors) at Shanghai cell therapy leader.

15. Aug 16, 2024
Supported Brazilian client QA audit interpretation at Suzhou biologics plant.

16. Jul 29, 2024
Provided interpretation for third-party Indian auditor (representing Bangladesh client) at Suzhou biologics facility.

17. Jun 24, 2024
Interpreted for Ukrainian client QA audit at Suzhou biologics plant.

18. May 16-17, 2024
Served as lead interpreter during Tanzanian Drug Authority (TMDA) on-site GMP audit at Changzhou sterile injectables facility, resulting in successful certification.

19. May 7-10, 2024
Supported long-term Spanish auditor during GMP audits at Hangzhou & Taizhou pharmaceutical plants.

20. Mar 19, 2024
Facilitated remote GMP audit interpretation for Chinese pharma's evaluation of Indian API supplier.

21. October 25-27, 2023
Interpreting for an FDA audit of a testing laboratory

22. June, 2023
GMP audit interpretation for pharmaceutical factories in Changzhou, Emeishan, Nantong Haian, Shanghai and other places, as well as GMP audit interpretation for Pharmaron (Remark: Pharmaron is the TOP 2 leading CDMO corporate in China) Beijing Branch, Ningbo Branch and Tianjin Branch.

23. September 2, 2022
Interpreting for a remote GMP audit of a pharmaceutical plant in Shenyang,

Liaoning

24. December 2, 2021
Interpreting for remote GMP audit of a pharmaceutical plant in Shangyu, Zhejiang

25. July 6, 2021
Interpreting for remote GMP audit of a pharmaceutical plant in Yancheng

26. April 18, 2021
Interpreting for remote GMP audit of a pharmaceutical plant in Cixi, Ningbo

27. April 16, 2021
Interpreting for remote GMP audit of a pharmaceutical plant in Shangyu, Shaoxing

28. April 15, 2021
Interpreting for remote GMP audit of a pharmaceutical plant in Tianjin

29. March 31, 2021
On-site interpreting for GMP audit of a pharmaceutical plant in Taizhou

30. November 2020
On-site interpreting for GMP audit of a pharmaceutical plant in Nantong

31. October 2020
Interpreting for a CRO company in conducting a computerized system (CSV) GAMP5 audit of a pharmaceutical software company. The auditor was Indian and the audit was conducted remotely. (covering clinical trials and IT)

32. August 2020
On-site interpreting for GMP audit of CSPC Pharmaceutical Group in Shijiazhuang

33. October 30 to November 9, 2017
On-site interpreting for GMP audit of four pharmaceutical plants in Taicang, Jiangsu, Shangrao, Jiangxi, Xinxiang, Henan, and Shijiazhuang, Hebei.

34. July 11 to 12, 2017
On-site interpreting for GMP audit of a pharmaceutical plant in Shenyang

35. March 23rd to 28th, 2017
On-site interpreting for GMP audit of two pharmaceutical plants of Sinopharm Holdings in Nantong and Shanghai.

36. August 6 to 25, 2016
On-site interpreting for GMP audit of 12 pharmaceutical plants in China.

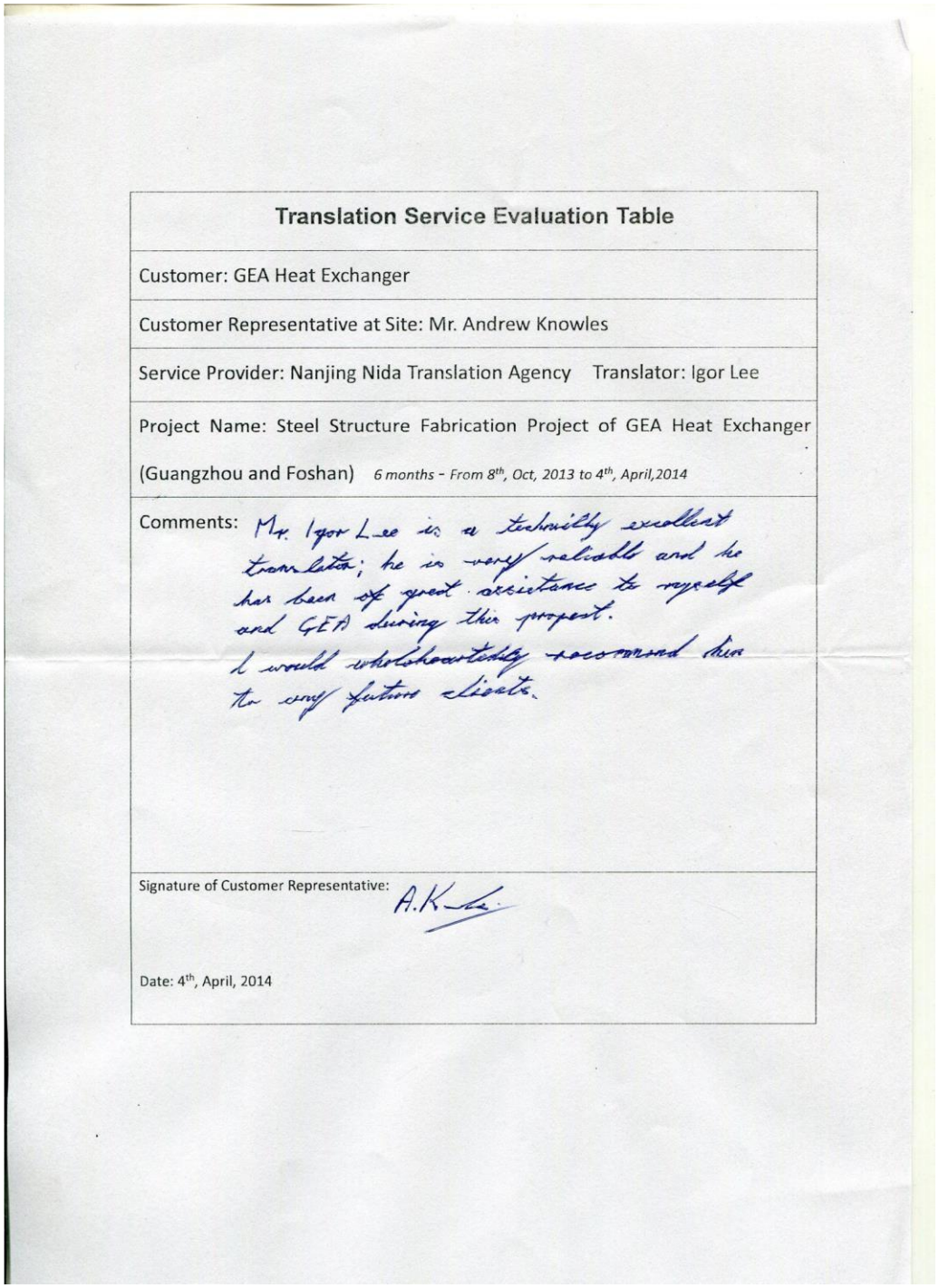
37. June 2014

On-site interpreting for GMP audit of pharmaceutical plants in Taicang, Jiangsu, Chizhou, Anhui, Tiantai County, Zhejiang, and Shijiazhuang.

The following pages are some of my project photos and customer reviews.

IV. Comments from customers:

1. Comments from Mr. Andrew Knowles, Site Manager of GEA (Fortune 500 Germany Enterprise)



Translation Service Evaluation Table
Customer: GEA Heat Exchanger
Customer Representative at Site: Mr. Andrew Knowles
Service Provider: Nanjing Nida Translation Agency Translator: Igor Lee
Project Name: Steel Structure Fabrication Project of GEA Heat Exchanger (Guangzhou and Foshan) *6 months - From 8th, Oct, 2013 to 4th, April,2014*
Comments: Mr. Igor Lee is a technically excellent translator; he is very reliable and he has been of great assistance to myself and GEA during this project. I would wholeheartedly recommend him to any future clients.
Signature of Customer Representative: A.K. Lee Date: 4th, April, 2014

2. Comments from Mr. Cameron Sutherland (Director of Scottish Development International)

Many Thanks

Cameron Sutherland 2014/12/2
收件人: toppertranslation@hotmail.com

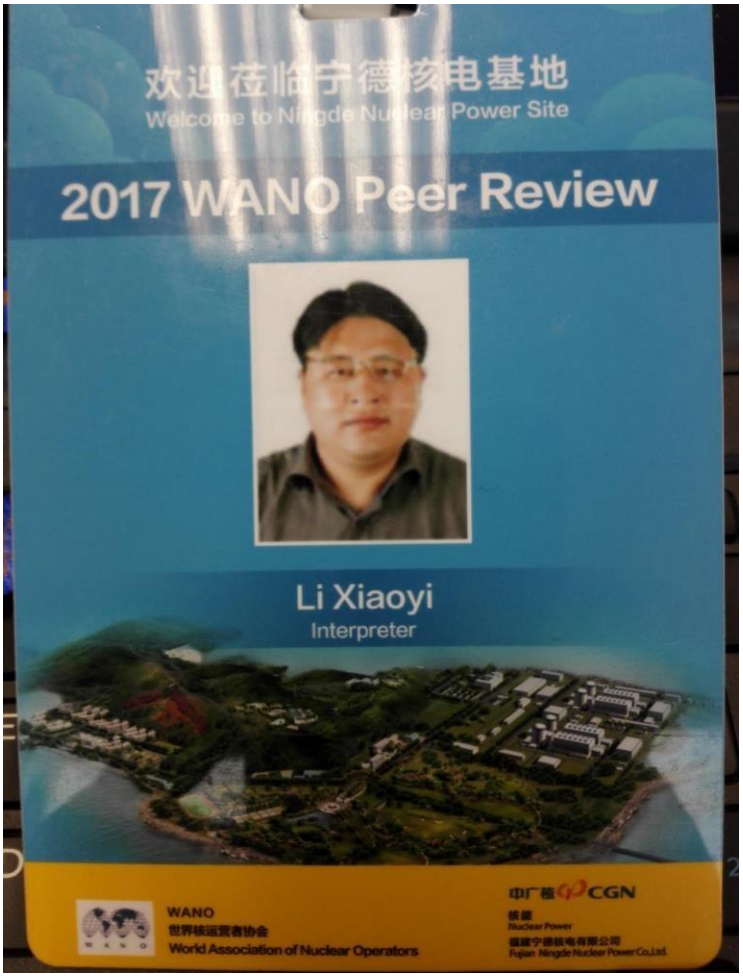
Dear Igor,

I wanted to drop you an e:mail to thank you once again for all your hard work over the 3 days at the China Seafood Show in Qingdao. You were excellent and I would not hesitate to use you in the future.

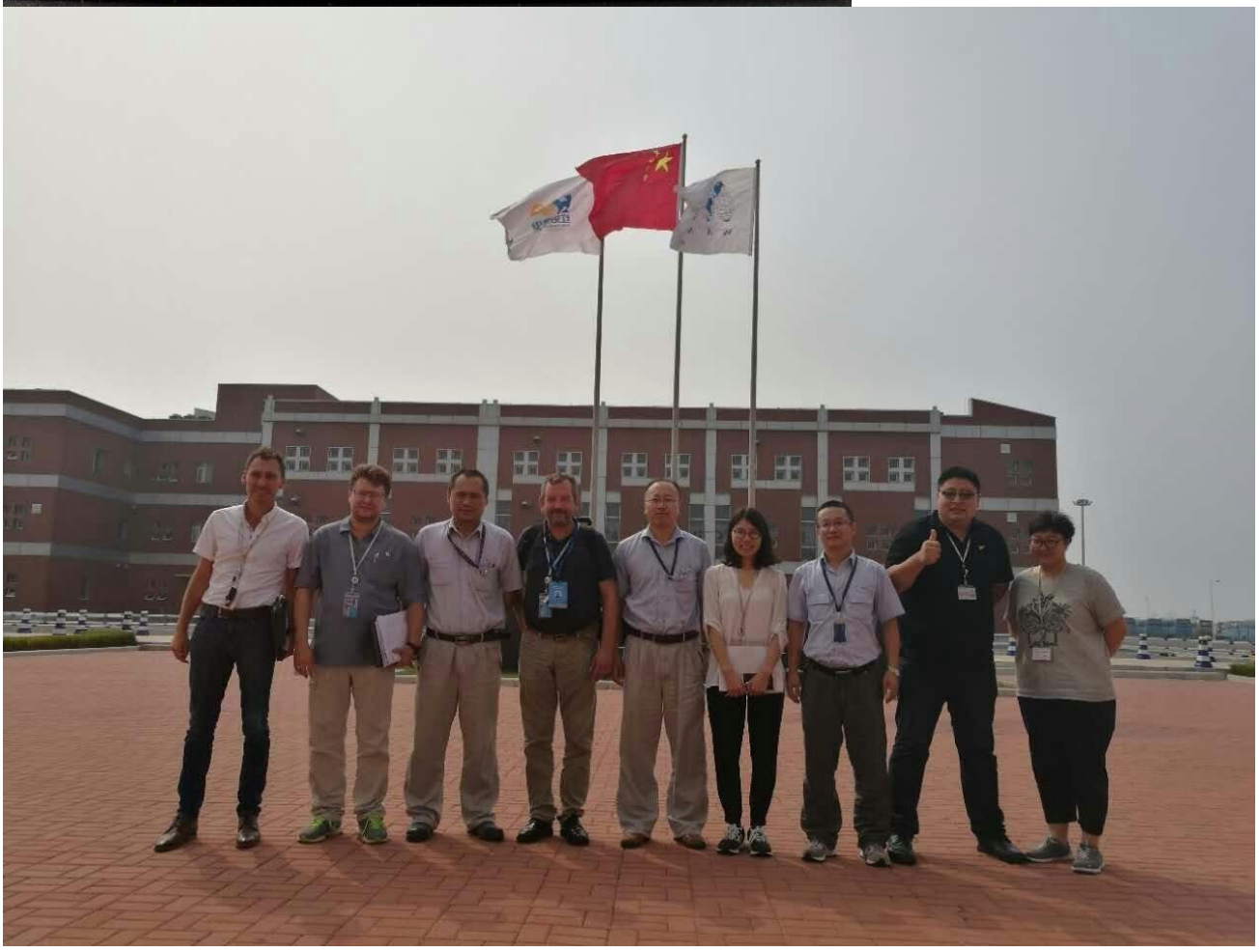
You have a special ability to make people warm towards you, and I know that the Chefs and companies involved in the show enjoyed watching you perform and translate on the Scottish Seafood Kitchen.

Please do not hesitate to use me as a reference in future.

V. Some of my working photos:







The three photos above are examples related to my working as interpreter/translator in nuclear power plants.



Working as Project Technical Translator and Interpreter in BASF NanjingProject



Working as interpreter with Holland Customer in Exhibition



In India, working as interpreter and translator in Mitsui & Co. chemical project construction site



Meeting in India Mitsui & Co chemical project



Accompanying Spanish independent GMP consultant for auditing several pharmaceutical plants in various cities in China



6 months project (steel structure) in Guangzhou and Foshan, working as technical interpreter and translator for GEA, which is Fortune 500 Germany Company



Working as interpreter with Mr. Don Jassen, the Dutch supplier (Caotech) of Chocolate equipment, for installation and commissioning of the chocolate production line in China.



Working as interpreter for the Peer Review by WANO (World Association of Nuclear Operators) to CNNP (China National Nuclear Power Corporation), which takes around 20 days. During that period, we visited and reviewed Fuqing Nuclear Power Plant and headquarter of CNNP.

THANK YOU!