Curriculum Vitae

Basic Info.

Name:	Xia Kaiguo	Gender:	Male
Date of Birth:	1983/10/01	Residency:	Suzhou
Yrs. Of Experience:	16 years	Email:	xiakaiguo188@163.com
Mobile Phone:	13716759298		
Hukou:	Suzhou		
Height:	176cm		
Marital Status:	Married		

Self-Assessment

Good professional skills. Team-work spirit. Commitment to excellence

Career Objective

I can start:	Within 1 month
Type of Employment:	Full-time
Desired Industry:	Pharmaceuticals/Biotechnology
Desired Location:	Shanghai; Jiangsu
Desired Position:	Pharmaceutical Manufacturing/Quality Management; Medical Equipment Manufacturing/Quality Control

Work Experience

2023/10—Now **Hefei Xinzhu Biological Technology Co., Ltd** (0-150 people)

Industry: Pharmaceuticals/Biotechnology

Title: Quality Director **Pharmaceutical Manufacturing/Quality Management**

1. Be responsible of Quality Management. Ensure all the quality activities be compliance with regulatory requirement.
2. Build Quality Management System for new site to ensure that local quality system complies with NMPA, EU and FDA GMP.
3. Participate New Site Project. Ensure the GMP compliance of Q&V for facilities, equipment, systems.
4. Be responsible of GMP compliance of technical transfer for new drugs.

2021/07—2023/10 **Suzhou Frontera Therapeutics Co., Ltd** (0-150 people)

Industry: Pharmaceuticals/Biotechnology

Title: QA Director **Pharmaceutical Manufacturing/Quality Management**

1. Build Quality Management System for new site to ensure that local quality system complies with GMP of NMPA and FDA.
2. Participate New Site Project. Ensure the GMP compliance of Q&V for facilities, equipment, systems.
3. Be responsible of regulation management. Organize and coordinate the Manufacturing License application.
4. Be responsible of GMP compliance of technical transfer for new drugs.
5. Be responsible of GMP compliance management of Q&V.
6. Support IND application, ensure that the RFT of RA dossier.
7. Support quality system building of Boston R&D Center.
8. Be responsible of routine quality assurance management of CDMO(Catalent)

2018/10—2021/07 **Jiangsu Alphamab Bio-pharmaceutical Co. LTD** (>100 people)

Industry: Pharmaceuticals/Biotechnology

Title: Sr. QA Compliance Manager **Pharmaceutical Manufacturing/Quality Management**

1. Build Quality Management System for new site to ensure that local quality system complies with GMP of NMPA and FDA.
2. Participate New Site Project. Ensure the GMP compliance of Q&V for facilities, equipment, systems.
3. Be responsible of regulation management. Organize and coordinate the Manufacturing License application.

4. Be responsible of GMP compliance of technical transfer for new drugs.
5. Be responsible of GMP compliance management of Q&V.
6. Global Suppliers Management of Alphamab.
7. Be responsible of Internal and external audit, include EU QP audit and customer audit.
8. Lead KN035 PLI Project. Ensure that the on-site verification for Drug Registration can be implemented smoothly.
9. Coordinate and organize the review and perfection of new drug registration dossier.
10. Lead Supplier and Material Management Team, Quality System Management Team and validation compliance team.

2017/10—2018/10 **JNJ Version AMO Hangzhou Site** (>100 people)

Industry: Pharmaceuticals/Biotechnology

Title: QA Manager Pharmaceutical Manufacturing/Quality Management

1. Be responsible of Quality System Management to ensure that local quality system complies with JNJ global quality system.
2. Be responsible of regulation management. Tracking medical the update of device and drug related regulation. Coordinate the regulation analysis and track action plan trigger from the analysis.
3. Be responsible of Audit Management in AMO Hangzhou Site (FDA/TGA/CFDA/ISO13485/Customer Audit).
4. Be responsible of Quality Culture Management in AMO Hangzhou Site. Organize and implement Quality Culture related activities.
5. Initiate annual GMP training plan and implement GMP training according to the plan.
6. Lead Quality System Integration Project to ensure the implementation of JNJ Global Quality Policy in AMO Hangzhou Site.

2015/01—2017/10 **Sanofi Beijing Site** (>100 people)

Industry: Pharmaceuticals/Biotechnology

Title: Solid QA Supervisor Pharmaceutical Manufacturing/Quality Management

GMP Compliance &Training Supervisor (2015.01-2015.05):

1. Be responsible of document management.
2. Be responsible of Batch release. Be sure that the batch release meets the BRCT.
3. Initiate annual GMP training plan and implement GMP training according to the plan.
4. Initiate annual self-inspection plan. Coordinate and implement self-inspection. Track and confirm the completeness of CAPA.
5. Be responsible of Quality System. Coordinate and organize the gap assessment for global quality document.
6. Coordinate and organize the internal and external inspection. Be responsible of reply for inspection finding. Be sure that all the CAPA implemented according to the reply of the inspection.
7. Be responsible of Complaint. Coordinate and organize the investigation of the complaint in Beijing Site.

Solid & Validation QA Supervisor (2015.07-Now):

1. Be responsible of QA management for Solid Manufacturing and Packaging Area.
2. Be responsible of QA management for area of supply chain, Engineering and QC lab.
3. Lead the Qualification &Validation Function Team. Coordinate the valuation and qualification activities in Beijing Site.
4. Support GMP training, Self-inspection, Quality Complaint as QA Supervisor.
5. Be responsible of +QDCI visible management system. Be sure te completeness of quality priority and target for QO.
6. Be responsible of HSE Training for On Site QA Team.

2012/01—2015/01: **Lilly Suzhou Site** (>100 people)

Industry: Pharmaceuticals/Biotechnology

Title: QA Specialist (Area QA) Pharmaceutical Manufacturing/Quality Management

1. Work as On-Site QA of manufacturing and packaging area.
2. Be responsible of cleaning validation (Cleaning method development, cleaning verification, validation and cleaning periodic monitoring)
3. Be responsible of batch release as Release QA. Make sure all the product released on time according to the due date of SAP system.
4. Act as Area QA (Be responsible for change and deviation management, process validation)

5. Be responsible of monitoring for Environment, Water System, Compressed Air System. Complete the Annual Review of the system, trend analysis and evaluate the alert and action limits.

6. Participate in Six Sigma Project (Improve the process capability by optimizing the procedure).

7. Participate in Campaign projects (Sachet granulation and filling) and improve the process capability.

8. Act as process team member to support manufacturing.

9. Act as Q HSE Coordinator (Identifying environment and risk factors of QA department. Be responsible of training for HSE related documents and event)

2008/0--2009/09: Simcere Pharmaceutical Group (500-1000 people) Industry: Pharmaceuticals/Biotechnology

Title: QA Specialist (Shift QA) **Pharmaceutical Manufacturing/Quality Management**

1. Act as Shift QA of Small Capacity Injection Workshop, Sterile Separation Packed Powder Injection and Oral Liquid workshop

2. Participate in qualification and validation activities of Process, Equipment, Facility, and Utility.

3. Be responsible of routine monitoring of Environment, Water System, Compressed Air System and N_2 System.

4. Complete annual review of product.

2006/02--2008/03: Jiangsu Jumpcan Pharmaceutical Group Co., Ltd (500-1000 people) Industry: Pharmaceuticals/Biotechnology

Title: QA Specialist **Pharmaceutical Manufacturing/Quality Management**

1. Take charge of management of process documents, inspection of process discipline, coordination of technology research

2. Be responsible of batch release of raw material, intermediate, product.

3. Participate in site self-inspection

Education

2009/9 -- 2012/6 China Pharmaceutical University Medicinal Chemistry Master

Courses: Medicinal Chemistry, Advanced Organic Chemistry, Advanced Spectral Analysis, Computer Aided Drug Design Research fields: Total synthesis of Mangostin. Synthesis of antianginal drug Ivabradine

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2002/9 -- 2006/6 Nanjing University of Chinese Medicine Pharmaceutical Engineering Bachelor

Courses: Pharmacology, Pharmaceutics, Medicinal Chemistry of Natural Products, Biochemistry, Organic Chemistry, Analytical Chemistry, Pharmaceutical Analysis, Pharmaceutical Technology, Pharmaceutical Engineering, Principle and Equipment of Pharmaceutical Engineering

Training

2016/12 -- 2016/12	Sanofi Training Office in EU Brussels, Belgium	EVOLVE Session: Be aware of your key strengths and skills to be improved.
2015/05 -- 2015/07	Sanofi Frankfurt Site Frankfurt, Germany	Lead a team from Sterile Production. Coordinate and participate the training of Aseptic filling technology for Lantus.

Certifications

2005/12 CET6 443/710

Awards

2019 Tight talents of Gusu (Top Level)