Celine Sung (宋玉雯)

Celinesung@genius-gh.com

WORK EXPERIENCE

2018~ **Genius Holdings Co., Ltd. Taiwan Branch(傑尼斯台灣)** *QA Manager&Management Representative*

2014~2018 **General Life Biotechnology Co., Ltd.(勤立生技)** *QA Manager&Management Representative*

- Responsible for ISO 13485:2016 transition
- Responsible for maintaining Quality System harmonization for compliance with FDA QSR, ISO 13485, GMP, 98/79/EC, CMDCAS, and SFDA.
- Responsible for the review of multiple quality reports including Incoming Quality Control, In-Process Quality Control, and Outgoing Quality Control to ensure product and process integrity.
- Responsible for review of the quality aspects of the calibration and equipment maintenance program, the complaint handling program, the nonconforming material program, the supplier quality program and the quality inspection program.
- Responsible for the review of training programs to ensure all personnel are adequately trained in accordance with ISO 13485, QSR and GMP.
- Responsible for the Corrective and Preventive Action system to resolve all quality issues.
- Responsible for the Document Control/Change Control Program through leadership of the Document Control Center.
- Responsible for product certification on Taiwan, China, European, ASEAN, Middle East
- As the Management Representative, responsible for the maintenance of quality system and ensuring the effectiveness of quality system.

2005- 2012 **Health & Life Co., LTD, Taiwan(合世生醫)***QA Manager&Management Representative*

- Responsible for maintaining Quality System harmonization for compliance with FDA QSR, ISO 13485, GMP, 93/42/EEC, 98/79/EC, CMDCAS, JIS and SFDA.
- Responsible for the review of multiple quality reports including Incoming Quality Control, In-Process Quality Control, and Outgoing Quality Control to ensure product and process integrity.
- Responsible for review of the quality aspects of the calibration and equipment maintenance program, the complaint handling program, the nonconforming material program, the supplier quality program and the quality inspection program.
- Responsible for the review of training programs to ensure all personnel are adequately trained in accordance with ISO 13485, QSR and GMP.
- Responsible for the Corrective and Preventive Action system to resolve all quality issues.
- Responsible for the Document Control/Change Control Program through leadership of the Document Control Center.
- As the Management Representative, responsible for the maintenance of quality system and ensuring the effectiveness of quality system.
- Established IVD Quality System and certified by TFDA (GMP and market approval), CE NB

(ISO13485 & IVDD).

- Experiencedin FDA facility inspection in 2010, 2011, 2013 and 2014, and determined a firm's compliance with QSR.
- Collaborated with Boyce consultants to reconstruct Quality System for compliance with FDA QSR in 2009~2010.
- Achieved in Quality System qualification by 2nd party audit, including Homedics, P&G (Braun) and Jason & Jason.

2003– 2005 **EPS Bio Technology Corp(福永生物科技)** *QA Manager &Management Representative*

- Responsible for maintaining Quality System harmonization for compliance with FDA QSR, ISO 13485, GMP, 98/79/EC.
- Responsible for the review of multiple quality reports including Incoming Quality Control, In-Process Quality Control, and Outgoing Quality Control to ensure product and process integrity.
- Responsible for review of the quality aspects of the calibration and equipment maintenance program, the complaint handling program, the nonconforming material program, the supplier quality program and the quality inspection program.
- Responsible for the review of training programs to ensure all personnel are adequately trained in accordance with ISO 13485,QSR and GMP.
- Responsible for the Corrective and Preventive Action system to resolve all quality issues.
- Responsible for the Document Control/Change Control Program through leadership of the Document Control Center.
- Responsible for regulatory affairs and premarketsubmission.
- As the Management Representative, responsible for the maintenance of quality system and ensuring the effectiveness of quality system.
- Established IVD Quality System and certified by TFDA (GMP and market approval), CE NB (ISO13485 & IVDD).
- Established and maintained the IVD Quality System
- Got traditional 510(k) clearance letter for BGM.

EDUCATION

National Taiwan Institute of Technology *Bachelor of Chemical Engineering*

Patent

- US20220354736A1, Medical vast and using method thereof

CERTIFICATE

- Barcode Management Specilist – On UDI
- ISO 27799_2016
- Lead Auditor of ISO 13485:2016
- CQT.
- CRE.

PROFESSIONAL TRAINING

2022.04	AI (by Qualcomm)
2020.09	ISO 14971_2019 (by BSI)
2020.08	MDR (by ITRI)
2019.04	MD UDI (by GS1)
2019.04	MD SW_Cybersecurity (by IDB)
2019.04	Software Validation (by SGS)
2018.08	ISO 27799_2016 (by BSI)
2017.08	MDSAP (by BSI)
2017.08	Post-Market Surveillance and Vigilance (by BSI)
2017.03	Lead Auditor of ISO 13485:2016 (by BSI)