Allan Lin

Senior Project Management Consultant

Core Competencies

- Biologics/Sterile Products
  - ~ CAR T-Cell Immunotherapy
  - ~ Monoclonal/Bispecific Antibodies
  - ~ Antibody Drug Conjugate
  - ~ Fusion Proteins
- GXP Quality Systems
- CDMO/CRO Management
- Vendor Qualifications

Products

- Reblozyl®
- Mepact®
- Neupogen®
- Aranesp®
- Liso-Cel

Professional Summary

Mr. Lin has over 34 years of diversified technical and operational leadership with extensive global pharmaceutical/biotech operations experience, that includes companies manufacturing fusion protein, CAR T-cells, bispecific/monoclonal antibodies, and antibody-drug-conjugate.

He has hands-on involvement in product quality, quality assurance, cGMP compliance, biological process development/engineering, manufacturing, and capital GMP project management.

His global experience includes projects in the United States and Europe as well as Japan, China, and India.

Education

M.B.A	MBA	University of Southern California
M.S.	Chemical Engineering	University of Southern California
B.S.	Chemistry	National Tsing Hua University

Professional Experience

Design Space InPharmatics, LLC **2021 - Present**

Senior Project Management Consultant

- Diverse technical and operational leadership and extensive international experience with global pharmaceutical and biotech operations,
- Extensive hands-on knowledge in CMC for parenteral drug development and commercialization of CAR T-cell immunotherapy, monoclonal antibodies, antibody-drug-conjugate, and fusion protein,
- Overseeing CMC projects at major global biopharmaceutical CDMOs,
- Biological process development and engineering, manufacturing, capital GMP project management, product quality, quality assurance, and cGMP compliance.

BMS CO. (legacy Celgene Corp.) **2014 - 2020**

Senior Director, Global Quality Product Lead

Represent Quality to review and approve Module 3 CMC sections, and to respond to regulatory questions (IR) for global submissions. Resulted in on-time HA approval of BLA and MAA, and no product specific 483 observations. Led PAI Readiness Assessment, and the development and management of action plans as the results of mock-PAI-audits and other internal assessments for all manufacture and testing sites, and informed Corp. Quality management to file declaration of FDA-356h PAI readiness.

- Represent the global quality functions on Technical Product Team (TPT), and cross functional teams for brand life cycle management,
- Accountable for quality monitoring, annual product quality review, and site selection post initial launches,
- Responsible for data integrity and quality verification in regulatory submissions,
- Represented the global quality functions on the launch team in support of product commercialization,
- Coordinated the approval and change control of the commercial specifications for product release and stability between development and commercial team,
- Established product complaint handling work practice for cold chain biologic parenteral drug,
- Led teams responsible for cross-site (US, Europe, and Asia) product quality investigations,
- Defined re-processing steps that require validation,
- Developed product risk-based tools to managing leachables and changes in single use systems,
- Represented Celgene to conduct compliance audits of multiple CMOs for lentiviral vectors and drug product,
- Served on various cross-site subteams: CMC Strategy, Product Launch, MSAT, Quality, Raw Materials, and Analytical Methods,
- Supported CMC team for cross-functional risk assessment of regulatory filings readiness,
- Partnered with clinical and RA to establish Protocol Product Deviation Plan for clinical trial submissions,
- Fast tracked to establish commercial quality management systems at European and USA CMOs that included work practice for material review board, forms for the batch release package and product distribution, product release workflow, tech transfer protocol and reports, etc.,
- Participated in complex deviation investigations and Product Complaints team,
- Reviewed and approved isolator qualification, and media fills for validation of aseptic preparations,
- Instrumental in establishing rapid sterility test method, method qualification/validation, and comparability studies between harmonized USP <71> and USP<1223>/Ph. Eur. 5.1.6.

Senior Director, Head CMC QA Biologics for GQO

Managed and coached a group of 6 direct reports (3 with PhD and 3 with Master), and responsible for overseeing over a dozen biological products, including bispecific monoclonal antibodies, fusion protein, E coli-based protein fermentation, antibody-drug-conjugate, and CAR T (Juno Therapeutics JCAR015 and JCAR017 since 2016).

- Instrumental in building infrastructure for biologic therapeutics inclusive that included internal capacity, quality management system, hiring and training,
- Assessed risks for all aspects of the manufacture activities and supply chain as a SME,

- Supported FMEA to identify and resolve gaps in process capability and control, and determine the level of risks prior to and post PPQ,
- Approved GMP protocols for development, the validation of processes and analytical testing methods,
- Approved process descriptions/ master batch records for cell bank, cell culture, purification, and sterile processing,
- Approved product release specifications, product batch release, and stability program.

Daiichi Sankyo **2008 - 2014**

Global CMC Lead, Biological CMC Management & Operations

Led global CMC teams for oncology biotherapeutic product development in Germany, Japan and USA, and directed activities in manufacturing, analytical development, formulation, dosage form development, drug product supplies, and CMC regulatory.

- Led a team to win a company excellence award in June '13 on "Rapid biologic manufacturing tech transfer and successful comparability CMC package endorsed by both FDA and PEI" for a mAb transferred from Amgen to a Phase 3 and commercial manufacturing site. The complex product comparability studied on the changes in cell line, process, formulation, dosage form, and manufacture site,
- Led a for-cause audit as a CMC SME and project lead to investigate, and resolved a major cell culture system contamination during a 3-month plant shutdown,
- Responsible for developing and integrating CMC strategies, team goals, project timelines, and budget into overall product development plan,
- Designed pharmaceutical development strategy for phase 3 till BLA, encompassing commercial stability, reference standards, process characterization, process validation, and BLA batches,
- Applied DOE in characterization studies for process and formulation development,
- Approved manufacturing procedures, release and stability specifications, and validation documentation; and CMC sections for regulatory filings,
- Developed a simulation tool in Excel for Internal Production Capacity Planning and Cost Analysis,
- Instrumental in implementing single-use systems in a biological bulk production facility design. The success of the first build-out led to replicating a second suite,
- Evaluated extensively outsource options and conducted due diligence visits to over 16 major biological CDMOs in the US and Europe for partners selection,
- Represented CMC to evaluate 6 in-licensing and collaborations opportunities in conjunction with Business Development and External Scientific Affairs.

Sagent Pharmaceuticals **2007 - 2008**

Vice President, Manufacture Operations (Generic Sterile Injectable for Oncology)

Directed key aspects of Manufacture Operations for a greenfield $50MM parenteral facility for formulation, aseptic liquid filling, and lyophilization.

- Selected equipment vendors as a part of DQ and URS for two lines of washer, filling machine, full filling-line isolator, and lyophilizer with automatic loader/unloader,
- Led client team for FAT at equipment suppliers, Bosch and Edward,
- Sourced components and raw materials from global suppliers,

- Established equipment qualification program, and key production and quality systems for washing, filling, lyophilization, and isolator operations.

Additional Experience

Millennium Pharmaceuticals/IDM Pharma - Director, Global Product Quality
Amgen - Sr. GMP Project Manager/Manager, New Product Launch, Process Engineering, Regulatory Compliance, and Corporate Quality.
Pfizer/Upjohn - Sr. Process Engineer/Project Manager