Contact

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Top Skills

Technology Transfer
Lyophilization
Commissioning

Languages

English (Native or Bilingual)
Spanish (Native or Bilingual)
French

Kalani Coppedge

Biopharmaceutical executive
Austria

Summary

A result driven, self-motivated and resourceful business leader with over twenty-seven years of global pharmaceutical manufacturing experience. Proven ability to develop and bring products to market through the creation of multiple project teams, implementation of new manufacturing technologies, execution of qualification and regulatory strategies meeting marketing forecasted expectations. Vast experience dealing with global and local regulatory agencies, CMO's, OEMs, distribution partners, and Senior Management. Comfortable in setting realistic short- and long-term goals and promoting the vision to fulfill these goals. Experienced in providing direction to support current and future marketing needs tapping onto the strength of local manufacturing operations and partners. Possess excellent communication skills and capable of establishing sustainable and effective relationships with direct reports, staff, customers, suppliers, local and global stakeholders.

Experience

In transition
On Leave
October 2023 - Present (4 months)

Lifera
Chief Operating Officer
January 2023 - October 2023 (10 months)
Riyadh, Saudi Arabia

Execute Lifera's overall vision to become the leading Biopharmaceutical company in Saudi Arabia and the MENA region by implementing business strategies geared to produce life-saving drugs and medical treatments for patients while focusing on quality and operational excellence.

Celltrion Inc.
11 years 2 months

Vice President, Head of the Global Drug Product Expansion Division
January 2019 - January 2023 (4 years 1 month)
Songdo, South Korea

Participate in green field site selection leading to the expansion of Celltrion's new facilities around the Globe for the manufacturing of existing and new mAbs Drug Products. In 2020 completed the installation and qualification of a new high speed PFS facility with newly constructed formulation, filling, packaging, visual inspection, and auto injector suites. Formulation and filling is performed using single-use components and filling is done under an isolator. Syringe visual inspection is performed in manual booths or using an automatic visual inspection machine. Syringe assembly includes automatic placement of plunger rods, backstops, safety guards and/or finger flanges and unloading into pucks carried to a cartoning machine capable of packing multiple formats in diferent presentations and carton sizes. Sealed cartons are then serialized, agregated and automatically case packed. Nude syringes can also be assembled into auto injectors and then packed in different formats. Directed the DP facility design, construction, equipment selection and overall qualification and the training of newly hired staff.
Ensure successful facility transition from the qualification stage into regulatory submissions leading to commercial manufacturing operations.

Managing Director, Head Drug Product Division
December 2015 - December 2018 (3 years 1 month)
Songdo, Incheon, Korea

Direct and control the work and resources of Celltrion’s Drug Product (DP) Division and ensure the recruitment, development and retention of staff responsible for the manufacturing of existing and new mAb biosimilar products.

Represent the Division in all Regulatory inspections and negotiate with inspectors acceptance and implementation of observations. All regulatory inspections have lead to the successful approval of the manufacturing operations allowing for biosimilar DP product distribution to major and minor world markets including the US market. First in the world to attain US FDA approval for mAb biosimilar market distribution in 2016.

Establish and maintain effective formal and informal links with major equipment suppliers, relevant primary and secondary packaging suppliers, existing CMO's and other stakeholders generally, to exchange information and views and to ensure that the Company is providing the appropriate range and quality of material and services.

Provides direction in the implementation of new technologies associated with the expansion of DP manufacturing operations related to vial and syringe filing including new packaging facilities.

Oversee the preparation of the Annual Division budget in relation to its goals, Key performance indexes, and division investment plans and ensure their approval by the Finance Group.

Represent the company in inspections of potential DP CMO partners and provide recommendation for contract implementation.

Fill Finish Divisional Director
December 2011 - December 2015 (4 years 1 month)

Organized and developed manufacturing, engineering, and maintenance programs for a newly built drug product facility commissioned to fill and package biosimilars in liquid and lyophilized formats. Programs were geared to comply and successfully meet future regulatory inspections. Improved the existing Media Fills strategy for new pipeline products.
Directed the Fill Finish and packaging equipment qualification.
Attained EMA market authorization of the first mAb biosimilar in 2013.

Baxter BioScience
11 years

Project Engineering Supervisor
2007 - November 2011 (4 years)

Lead engineer responsible for the conceptual design for the expansion of a new Aseptic Filling complex including new formulation rooms, lyophilization, capping, autoclave and supporting equipment.
Supervise a group of engineers supporting day-to-day operations and mid to large capital projects in the Aseptic Filling and Packaging areas.
Lead engineer in the technology transfer for an existing product from an off-site facility to current facility.
Project manager responsible for the purchasing, installation start-up and commissioning of a complete filling line including isolation technology and aseptic room upgrades..

Sr. Principal Engineer
2005 - 2007 (2 years)

Responsible for managing the engineering group supporting the Final Container organization and the packaging departments interfacing with

manufacturing, QA, validation, RA, and Division stakeholders in the implementation of medium and large capital projects, up to $20M.
• Lead the construction and participated in the technology transfer for a new medical device facility comprised of clean rooms ISO Class 8 (Grade C). Managed the equipment purchasing including installation of a packaging line using robotic technology.
• Lead the technology transfer between the Neuchatel, Switzerland facility to the Thousand Oaks, facility for Advate formulation as part of the Aseptic Filling expansion.
• Successfully managed the process transfer of a first-generation Recombinant product from the Los Angeles facility to the Thousand Oaks facility making Thousand Oaks a multi product facility. FDA regulatory approval granted in 2009.
• Created the first Baxter global Form and Finish “technology-share” council engaging the participation of US and European DP manufacturing and engineering representatives. Discussions related to aseptic filling and lyophilization process issues.

Project Engineer
2000 - 2005 (5 years)

• Supported the Thousand Oaks manufacturing expansion by managing the design, purchasing, installation, and commissioning of a new Aseptic filling line with Isolation technology with equipment manufactured in Belgium, Italy, Germany, Austria, France, Sweden and the USA. Project valued at $25 million involved a SIEMENS program logic controllers platform interfacing with SIEMENS WinCC Supervisory Controls and Data Acquisition system. This project required the engagement of Architectural/Engineering and Construction firms to help in the design and renovation of the Finish area to install the new Aseptic filling line. Installation was performed during scheduled shutdowns.
• Provided engineering expertise to other Baxter facilities in the USA and abroad in Aseptic Filling related processes including Isolation technology focusing on equipment purchasing contracts, RFP’s, development and commissioning approaches, FAT's and SAT's, day to day issue troubleshooting, etc.
Supported the facility contract manufacturing strategy (CMO) by providing engineering and equipment budgets related to implementation of new processes for potential clients.
• Lead the creation of documents in support of the filling Isolator project regulatory submission.

• Supervised the CAD department and brought into compliance all the engineering and process drawings for the Thousand Oaks manufacturing facility, including architectural, mechanical, electrical, process and non-process piping, process flows, and miscellaneous drawings using Autodesk Revit software.
• Facilitated the upgrade of the CAD department hardware and software from single station environments to multiple/dual panel stations interfacing with HP Proliant ML350T G4 servers. The software upgrade included moving from Autodesk to Building Information Model (BIM) Revit series.

Nestle
Production Supervisor
1992 - 1995 (3 years)

Assisted in manufacturing operations with emphasis on process improvements.

Education

Pepperdine Graziadio Business School
MBA, Leadership in Organizations · (2003 - 2005)

University of California, Davis
BS, Mechanical Engineering · (1989 - 1992)