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Objective: Industrial | Quality Manager

Qualification summary

- Executive MBA (Master of Business Administration) Worldwide at University of Pittsburgh, Joseph M. Katz Graduate School of Business – Brazil/USA/China, 2019; Master of Sciences (MSc) in Management in Health Care Institutions – Focus: Pharmaceutical Management at Donau-Universität Krems – Austria, 2009; e Bachelor in Pharmacy-Biochemistry at the Faculty for Pharmaceutical Sciences from the University of São Paulo (FCF-USP), 2006.

- Managerial experience in operations and leading department leades focusing on KPIs aiming at fulfillment of Key Performance Indicators in order to achieve, short, medium and long term goals established together with the company's board, focusing on the maintenance of the organizational atmosphere and at the same time on the obtention of high performance teams with expressive results.

- Expertise in the conception, design and management of the construction project and operation of the first manufacturing facility in industrial scale for biological products (monoclonal antibodies) in Brazil using a single-use platform. Direct relationships established with national and international partners during the technology transfer of these products.

- Experience in quality management focusing on the obtention of the certification on Good Manufacturing Practices by national and European Health Authorities in the pharmaceutical, biologics and Active Pharmaceutical Ingredients (APIs) manufacturing sites.

- International exposure through the execution of audits in Brazil, Europe, China and India as part of the efforts to develop and qualify suppliers of active pharmaceutical ingredients and synthesis intermediates for pharmaceutical.

- Fluent in Portuguese and English, advanced German and intermediate Spanish.

Professional records

From January 2006 to November 2018 — **Libbs Farmacêutica Ltda.**, São Paulo, SP

Following positions were occupied in this organization:

⇨ **Industrial Manager**
From September 2016 to November 2018

- Responsible for the management of two manufacturing sites: Manufacturing of Active Pharmaceutical Ingredients (chemical synthesis and classical fermentation) and Biologics (recombinant proteins in a mammalian cells platform).
- Direct report to the Operations Director focusing on regulatory compliance, fulfillment of client's expectations and business needs.
- Responsible for the revamping of the APIs manufacturing site, considering the company's expansion and maintenance of the supply chain sustainability.
- Responsible for ensuring the success of the operations of the biologics manufacturing with direct involvement in the tech transfer activities. Support in the identification of new business opportunities for both sites.
- Full responsibility for the preparation and approval of the budget (OPEX and CAPEX) for the entire site.

Main results:

- Organizational reestructuring in production, eliminating redundancies and reduction of different job positions leading to a more horizontal structure with higher empowerment.
- Leadership of a multidisciplinar group aimed at review of the strategy for production of biologics with a projected reduction in the cost of production of 30%.
- Reduction of 30% in the budget for the operation of the manufacturing facility through different initiatives (saving on water, materials, etc...).
- Succesful manufacturing of several batches of biotechnology product for an innovative regulatory filing in Brazil, within expected cost and yield.

⇨ **Quality Assurance Manager**
From March 2016 to August 2016

- Responsible for all Good Manufacturing Activites, including Compliance, supplier qualification and validation (analytical, process, cleaning and qualification) of all the company's manufacturing sites (API manufacturing, biologics manufacturing and pharmaceutical products manufacturing).
- Management of 7 coordinations including one offshore, located in China (native), focusing on the fulfillment of regulatory guidelines, client's expectations and business' needs.
- Direct report to the Quality Director.

Main results:

- Approval from Anvisa (Brazilian national regulatory agency) for the first manufacturing facility in Brazil for biotechnological products in large scale using single-use technology.
- Redesign of the structure and quality culture focused on corporative alignment and elimination of silos.

⇨ **Quality Assurance Coordinator**
From December 2010 to March 2016

- Responsible for the management of the GMP and validation teams, maintenance of the company's certified status, presentation and accompaniment of audits from clients and health authorities (national and international), release of products to the market, international regulatory affairs, department budgeting and design of strategic and operational goals for the department.

Main results:

- Approval and maintenance of the certified status of the facility by national (Anvisa) and international (EMA) regulatory authorities.
- Certificate of Suitability to the European Pharmacopeia (CEP) granted for three products destined to the international market.

⇨ **GMP Analyst**
From January 2006 to November 2010

- Responsible for supplier qualification (raw materials and services), planning and execution of internal and external (national and international) audits, direct relation with clients, preparation of quality indicators reports, development of GMP related activities, internal audits, document preparation and management (SOPs, reports, protocols, manufacturing instructions), deviation management and general support to the remaining analysts.

Personal data

- Brazilian, born on Apr., 19th 1981, married, no children.