B.D.I.C

Pharmaceutical Senior Consultant

Combination products, Medical Devices, Industrialization, Human Factor Engineering Strong experience in matrix organisations and Project / Programme Management / Coaching

MAIN COMPETENCIES

- Product Life Cycle Management
- Business Development
- Matrix and line management
- Industrialisation and product launch
- Project and Portfolio management
- Lean Sigma tools, Risk management, communication and negotiation skills
- Medical devices, cGMP, ISO 13485, combination pharmaceutical products New EU MDR, HFE, Risk management

PROFESSIONAL EXPERIENCES

Since Oct. 2009_FREELANCE SENIOR CONSULTANT

Major missions:

Since February 2019

- **Sanofi, Le Trait, France_Implementation in the Sanofi Medical Devices Unit of a harmonized Quality Management System (QMS)** shared with the global devices organization: optimisation and alignment of practices, benchmark of activities, update of standard operation procedures, deployment of improved documentation management system, implementation of up to date risk management tools, creation of interfaces with local organizations.

Dec. 2018 - Sept. 2018

- **Confinis, 4 months, Switzerland_Evaluation of new European Union 2017/745 Medical Devices Regulation (MDR), impacts on existing devices, pharmaceutical and combination products. Differences between MDR and FDA regulations.**

July 2018 -July 2014

- **Novartis, Basel, Switzerland, 4 years_Development and support to commercialization of different parenteral oncology products from Ph. I through Ph. II&III Clinical studies and up to commercialization**:

- Development for parenteral products of primary packaging and devices to ensure good compatibility with the drug product, optimum delivery and long term stability, formative study evaluation,
- Design of the Clinical testing materials for the defined administration routes in Ph.I studies for new compounds and creation of Clinical readiness plans throughout QbD.
- Elaboration and management of the Design Control Plans and all the Design documents (Design Plan, HFE plan, Product requirements, Design Input Requirements, Design Output, Product and component Specifications, Summative study results, Testing requirements, Manufacturability, Methods...),
- Contribution to the Design reviews and management of the Design Control phases to guarantee good Quality by Design approach (QbD),
- Elaboration and management of the corresponding documentation for Design History Files (DHF) and Device Master Records (DMR) throughout the development and industrialization of products,
- Creation and update of the Risk management and mitigation plans as outputs from Summative studies
- Development of a dedicated subcutaneous pre-filled syringe for high viscosity drug product formulation and its needle safety device within eighteen months with embedded QbD and Human Factors Engineering (HFE) approach.
- Corresponding verification and validation activities (design verification and validation plans, tests and testing reports),
- Identification of potential suppliers and request for quote for an auto-injector dedicated to pre-filled syringes and customized for high viscosity drug product formulation,
- Research on pre-fillable syringes with alternative lubrication to avoid silicone oil, identification and evaluation of best silicone free syringe solutions,
- Post market Surveillance, CAPA, FDA documentation and Regulatory support on design justifications. Based on HFE data and corrective actions.
- Support to commercialized products incorporated into 1 mL Delta auto-injector,
- Contribution to development and preparation of commercialization of Cosentyx 2ml product with new 2.25ml auto-injector,
- Development of an assembly equipment for the manufacturing of this new 2.25 ml auto- injector and request for quote for a future high speed assembly/labelling line,
- Manufacturability of the drug product formulations with the defined devices,
- Technical, logistic and quality interface with the Contract Manufacturing Organisations,
- Interface with device suppliers (logistic, technical and quality aspects).

Feb. 2014 -Sept. 2012

Takeda, Brussels, Belgium, 18 months_Portfolio management and manufacturing optimisation in an Operations Network Rationalisation initiative

- Improvement of manufacturability and registration of alternative production sites,
- Product transfers, security of supply and product compliance for a portfolio of 65 products
- Network rationalisation among 6 different European manufacturing sites,
- Review and consolidation of the Sales & Operations Plan for the different involved sites,

- SWOT analysis for the manufacturing site and orientation of its manufacturing strategy,
- Sustainability, efficiency and adequacy of sites with the company product portfolio,
- Impacts on site master plan and updates of the multi-year investment plans,
- Overall program prioritisation, planning, team coordination and resource optimisation,
- Initiative risk management and remediation, overall communication and reporting for the Network Rationalisation initiative stakeholders.

July 2012 -Jan. 2012

- **Clermont-Ferrand, FR, 7 months_Feasibility studies and development of an innovative ophthalmic laser equipment.** Successful integration of augmented reality tools in the system and improvement of the preparation and of the execution of surgical operations.

Dec. 2011 -July 2011

- **Nyon, CH, 6 months_**Improvement of the product reliability and manufacturing process for an implantable medical device: an artificial joint improved via a FMEA study (large team of different functions). All critical design issues and manufacturing defects have been fixed successfully.

June 2011 -Jan. 2011

- **Wilson, N.C. USA, 5 months_**Training, deployment of Lean Six Sigma approach and validation activities for BD Medical Systems: training of a team of 30 people to Lean Six Sigma tools on a BD pharmaceutical manufacturing site and deployment of Lean Six Sigma approach with corresponding equipment qualification and process validation.

Oct. 2010 -Oct. 2009

- **Le Pont de Claix, FR, 12 months_**Finalization of the "Prefilled Initiative" business development:
  - Finalization of parenteral generic drug products development in prefilled syringes,
  - Registration of the corresponding portfolio of injectable products,
  - Four of the initial planned drugs registered in the USA,
  - Industrialization of these products on the BD manufacturing site in the USA.

Sept. 2009 -Jan. 2007_BECTON DICKINSON, LE PONT DE CLAIX (France) and FRANKIN LAKES (USA)

Sept. 2009 -July 2008_Head of Sterile Production Unit

- Development, implementation, qualification and start of production of a whole plant incorporating formulation, filling and packaging unit (17 M€ of investment),
- Ramp up from scratch to an annual capacity of 25 million of sterile pre-filled syringes,
- Successful pre-approval inspection by FDA and EMEA and 3 NDA for sterile products approved,
- Management of a team composed of 20 people (5 managers),
- Member of an International Steering Committee directly reporting to Business Unit President.

July 2008 -Jan. 2007_Core Team Leader

- Leader of a team composed of 8 members in charge of the creation of a new business opportunity (annual turnover of 300 M€) in the field of sterile pre-filled syringe products,
- Business Plan elaboration (launch of 30 sterile injectable products over a period of 5 years),
- Definition of the road map for the project and the design of the 2 plants (France and US),
- Implementation of Initiative management tools and processes.
- Validation for new rubber based stoppers of Gamma irradiation sterilisation process
- Revalidation for new syringes of Ethylene Oxide (ETO) sterilisation process

Jan. 2007 -Sept. 1993_ GlaxoSmithKline Group, France and other international locations

Jan. 2007 -Oct. 2004_ Portfolio Management Leader, global group function:

- Consolidation, prioritisation and delivery of Global Aerosol Dose Form technical initiatives:
  - more than 60 global projects aggregated into 15 strategic programmes,
  - requiring 65 M€ of programme investments involving about 130 FTE per year,
- Contribution to Respiratory Products Technical Strategy generating new business over 5 years
- Chairman of Aerosol Programme Management Committee, leader of governance change management system and of group initiatives.

Oct. 2004 -April 200_Head of Packaging and Device Technology Unit, Evreux (France)

- Creation and management of the Unit composed of 25 people (4 managers),
- Contribution to the inhalation dose form devices strategy, transfer from R&D to industrialisation and launch of respiratory products :
  - 1st aerosol dose counter on the market (competitive advantage),
  - Capacity extension for the Diskus product up to 60 million of devices per year,
  - Various changes on aerosol valves for improvements of pharmaceutical product performance and stability (capabilities index increased from 1.2 to more than 4),
  - Management of respiratory inhalation chambers following ISO 13485 directives.
- Implementation of Value Analysis approach on new projects and improvements generating 30% of savings on product costs.

March 2000 -Sept. 1993_New Product Introduction Project Leader, Evreux (France) and Ware (UK)

- Technology and Diskus product transfer from Ware R&D site (UK) to Evreux industrial site:
  - Identification, choice and introduction of a second device supplier,
  - Substantial productivity increase (+70% with installation of a quicker assembly equipment)
  - Implementation of 24 million of devices/year capacity,
  - Total budget of 8.5 M€ and up to 45 Full Time Equivalent people per annum.
- Development of a Reservoir Powder Inhaler Device (inhalation powder) development :
  - Start of pre-industrial moulds for clinical trials supplies,
  - Realisation of assembly and filling equipment,
  - Global budget of 5.9 M€ and 12 Full Time Equivalent people per year.
  - design with low product cost and excellent pharmaceutical performances objectives

Sept. 1993 -Sept. 1991_L'OREAL, Lancôme, Paris (France)_Packaging Development Engineer

- Design to cost and realisation according to marketing briefs of cosmetic Lancôme products
- Launch of the "Bocage" line of products including aerosol, stick, bottle with pump system
- 10 different products successfully launched with approved targeted Net Present Values.

Aug. 1991 -March 1988_Pôle Productique Bois et Ameublement, Pont-à-Mousson (France) New Technologies Engineer

- Implementation of dedicated IT solutions within Computer Integrated Manufacturing (CIM), Use of Operational Research and system optimisation approaches.

EDUCATION

- **March 2007 : Training in Healthcare Product Risk Management System**
- **April-Sept. 2003: Leading and Managing Lean Sigma (Green Belt Lean Sigma level)**
- **1999-2001 : Certification in Integrated Resource Management (CIRM)** from APICS (The Association for Operations Management)
- **1987-1988:DEA (Master)** from Institut National Polytechnique de Lorraine (Automation option)
- **March 2007: Training in Healthcare Product Risk Management System**
- **April-Sept. 2003: Leading and Managing Lean Sigma (Green Belt Lean Sigma level)**
- **1985-1988: Engineer degree** at Ecole Nationale Supérieure d'Electricité et de Mécanique (ENSEM) de Nancy (Major de promotion)

LANGUAGES

- French / Serbo-Croatian : Bilingual
- English : Fluent
- German : Good understanding bases

OTHERS

- Sports : Mountain bike, Swimming, Tennis, Squash, LesMills training
- Leisure activities : Photography, Theatre, Cooking