VALÉRIE GORDENNE

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23 years of experience in pharmaceutical Research & Development with extensive leadership experience in full development across a range of therapeutic areas (women health: oncology, contraception, menopause) and product application (implantable (biodegradable) devices, oral form, sterile injectable). I have developed a deep operational and strategic knowledge and expertise in drug development through the management of various functions and activities:

- ✓ Chemistry, manufacturing & controls (CMC), clinical supply manufacturing, market supply manufacturing
- ✓ Global drug supply (clinical & market supply distribution)
- ✓ Quality management (FDA, EU, ANVISA …(pre-approval) inspection)
- ✓ Regulatory Affairs (IB, IMPD, IND, Briefing package, interactions with FDA, EMA, Health Canada), e-CTD submission and post approval variations
- ✓ Clinical development (phase I to IV)
- ✓ Intellectual property and trademarks

EXPERIENCE

APRIL 2019 –

MANAGING DIRECTOR, ALIUS MODI, THIMISTER, BELGIUM

- Consulting activities in the field of QA, Regulatory strategy, R&D

CHIEF SCIENTIFIC OFFICER, AUXIN SURGERY, LOUVAIN-LA-NEUVE, BELGIUM

- Management of the Scientific Operations (pre-clinical, clinical, medical, IP, regulatory affairs (RA)) linked to the R&D portfolio. The portfolio is composed of
  - Medical device: a chemically assisted dissection system

STRATEGIC REGULATORY,

ULG SPIN-OFF IN CREATION, LIEGE, BELGIUM

- Creation and support of Development plan (task, pricing and timing) aligned with EU & US regulatory requirements.
  - Combination product: drug & device

CANNOVEX

- Support of Development strategy - Cannabinoids -based medicines (www.cannovex.com)

QP, TRASIS, LIEGE

- Support to the development of a GMP compliant quality system for a Radiopharmaceuticals drug product

INDEPENDENT DIRECTOR, HEDERA-22, Liege

- Spin-off dedicated to the production of new natural molecules from specific bacteria involving bioinformatic tools

- Development of proprietary innovative drug and devices

(www.alius-modi.com)

FOUNDER & CEO, ODIX

- Start-up dedicated to the development and commercialization of Orthopedic Medical Devices

JAN 2015 – MAR 2019

CHIEF SCIENTIFIC OFFICER, MITHRA PHARMACEUTICALS, LIEGE, BELGIUM

- Management of the Scientific Operations (drug substance synthesis, CMC, pre-clinical, clinical, medical, IP, regulatory affairs (RA), Pharmacovigilance) linked to the R&D portfolio. The portfolio is composed of
  - a New Chemical Entity (NCE), estetrol, supported by a full development programs (from pre-clinical to clinical phase IV), declined in different indications, formulations, way of administration
  - complex therapeutics (generic/hybrid application of long acting product based on polymers delivery strategies for different pharmaceutical forms: vaginal ring, intra-uterine devices, subcutaneous implant, oral tablets).
- Due to the size of the company (from 7 people in the R&D team in 2013 up to 33 in 2018), all overseeing activities are de facto completed by more operational activities in support to the team.
- Management of the product portfolio lifecycle in post marketing phase (distribution, RA, Pharmacovigilance, Medical information, advertising).
- Participation to a successful IPO, the company has been listed on the stock exchange since July 2015.

SEP 2007 – JAN 2015

CEO, NOVALON (subsidiary company of Mithra), LIEGE, BELGIUM

- Management of the Scientific Operations (CMC, clinical and RA) linked to the R&D portfolio dedicated to complex therapeutics (generic/hybrid application of long acting product based on polymers delivery strategies for different pharmaceutical forms: vaginal ring, intra-uterine devices, subcutaneous implant, oral tablets).
  - Formulation development
  - Analytical method development & validation
  - Clinical trials management (with the support of a CRO)
  - Regulatory Affairs: Scientific advice, e-CTD compilation
- The expertise gained with these projects led to the creation of a technological platform still active for internal project or in collaborative development with external structure (US/EU).

SEP 2007 – JAN 2013

GENERAL MANAGER, ODYSSEA PHARMA (subsidiary company of Mithra), LIEGE, BELGIUM

- Development of a completely new manufacturing site fully dedicated to an innovative and unconventional manufacturing process for a hormonal intra-uterine device (IUD): user requirements definition (production, QA, QC, engineering), selection of engineering company, work supervision, commissioning, GMP agreement, manufacturing launch.
  In this new manufacturing site, the manufacturing process development and validation of the IUD supported the registration and market launch of the product in EU and in US.

- Team management: Since 2007, the team has been extended from 5 people up to 25 in line with the development of the manufacturing activities of the IUD and the preparation of launch of industrial production.

SEP 2004 – NOV 2007

QUALIFIED PERSON, MITHRA PHARMACEUTICALS, LIEGE, BELGIUM

- Implementation, support and overseeing with a team of 5 people of all activities linked to drugs registration and life cycle management, distribution & commercialization, out-licensing in Europe: RA, Pharmacovigilance, Distribution, European release, Medical Information, Advertising, Quality System (GDP, GMP, GCP and GVP).
- Regulatory and CMC support to the R&D activities in support of project manager (scientific advice, validation of development plan based on regulatory requirements, subcontractors qualification for CMC development, essential documents approval,..)

JUN 2000 – OCT 2004

QUALIFIED PERSON, GALEPHAR M/F, MARCHE-EN-FAMENNE, BELGIUM

- QP responsibilities for release of IMPD for clinical trials
- Batch certification and release
- Quality system improvement
- Review and approval of SOPs and critical document from the quality system
- Training activities
- Process/formulation development & optimization

SEP 1996 – JUN 2000

R&D PROJECT MANAGER, SMB TECHNOLOGY, BRUSSELS, BELGIUM

- CMC development of generic applications: oral pharmaceutical forms (tablets, semi-solid, capsules).
- CRO Selection and coordination for Bioequivalence studies

EDUCATION

JUNE 1995

MASTER IN PHARMACEUTCIAL SCIENCES, UNIVERSITY OF LIEGE, BELGIUM

JUNE 1996

SPECIAL MASTER IN INDUSTRIAL PHARMACY, INTER-UNIVERSITY, BELGIUM

SKILLS

- Leadership
- Teamwork
- Work ethic
- Planning & strategic thinking
- Adaptability & flexibility
- Proactive, Accountable

LANGUAGES

French: mother tongue
English: fluent

PERSONAL DATA

Nationality: Belgian
Date of birth: July 28th 1972
Marital status: Married, two children