CURRICULUM VITAE – PROFESSIONAL PROFILE

Name-Last Name:	**ALESSANDRA MARIANI**
Address:	Via Tor Tre Ponti N° 44 – 04100 LATINA
Place and Birth date:	Trieste, 23-June-1959

EDUCATION:

- Qualified Person (Technical Director Functions Recognition) issued in October 2003 by AIFA Italian Ministry of Health - Decree N° DGFDM/ 5376/P/I.5.F.C
- Included in Biology Professional Register in "La Sapienza" in November 1984
- Biology Degree at "La Sapienza" University in March 1983

CURRENT RESPONSIBILITIES:

Hired at Janssen Pharmaceuticals in 1988, currently based in Latina (Italy). Covered many different roles in 33 years of work, expert for Quality & Compliance topics in Johnson & Johnson. Take jobs with Site Responsibilities or belonging to international organizations.

Current Job covered is "Product Quality Owner Senior Manager" in Pharma Product Quality Management Organization (PQM)

KNOWLEDGE:

English language fluent in speaking and writing.

Present Actual Position - Senior Manager, Product Quality Management, Quality Owner – since Feb 2019

End-to-end accountability for the quality strategy and quality aspects of commercial products for an assigned portfolio of products.

Principal Duties:

- Single point of Global Quality contact for an assigned group of marketed products with medium to high complexity.
- Responsible for ensuring end-to-end Quality for assigned products across DS site(s), DP site(s), packager(s) and QC testing and release. The Quality Owner (QO) knows the product history and understands the processes across the various manufacturing sites.
- Establishes and maintains site Quality contacts and drives communication with all Q&C stakeholders.
- Drive New Regulations about RUSSIA – CHINA Requirements in PQM organization as Subject Matter Expert
- Assures Quality milestones and Quality deliverables are achieved and approves content of spec changes to ensure spec changes are aligned end-to-end. Assures multisite/global/high level product CAPAs and change controls are approved and closed appropriately.
- Supports the business continuity process including VST strategy and BCP projects.
- Accountable for all stability related activities of commercialized products including change management study management. Liaises with Product data specialists or Product quality specialists to gather input on stability topics (e.g. draft stability protocols and reports). Handles regulatory questions related to stability, prepares regulatory PA inspections with regard to stability topics.
- Ensures standard Global Quality processes (PPQS risk assessments, product risk management, technology transfers) are used across sites and facilitates communication throughout Global Quality

Decision making and Problem Solving:

- Drives/coordinates decisions and makes decisions on behalf of Global Quality including sites. Gives input to the development of new strategies and implements and deploys strategies. Aids in the creation of product portfolio guidelines on the control strategy for commercial products which will influence the life cycle management strategy and the total quality cost during commercial production.
- Provides Quality structure, direction and decision making to the teams (Quality and VST) in situations of medium risk, uncertainty, and ambiguity.

Previous roles covered

a) **Internal Audit – Regulatory Audits – External Audit Leader =** Responsible for the preparation and conduction of external inspections (Ministry of Health - FDA - Corporate - Regulatory Authorities - Inspections by Customers and Corporate Johnson & Johnson), by developing and consolidating with the Site a strategy to guarantee the final inspection result

b) **Site Compliance Senior Manager =** Ensure that Site procedural system is aligned with Regulatory

Requirements required by the current Good Manufacturing Rules contained in the following GMPs', through periodic audits. Interpret new Regulations and emerging trends, applying the strategy of "Risk Management" to quality processes based on the requirements of the ICH Q8-Q9-Q10

c) **Risk Management Site Leader =** Responsible for managing the risk at the site level, using global tools for assigning criticality, occurrence, and the impact that potential weaknesses might have on business processes. Responsible for preparing documented assessments of global standards and procedures versus local documents, to align and standardize process execution and give guidelines for training.

d) **GLOBAL PROCESS OWNER** for quality processes of APR/PQR and Batch Management, Batch Disposition, Quality Control topics.

I declare that the information contained in this Curriculum Vitae is true and correct.
As per Italian Law 675/96 I'm authorizing the use of my personal data included in this document for the selection of personnel

Best Regards

Alessandra Mariani

ALESSANDRA MARIANI

Firmato digitalmente da ALESSANDRA MARIANI
Data: 2021.11.02 18:08:00 +01'00'