Davide Marchesini

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AVAILABLE TO RELOCATE
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Place and date of birth: Messina,26 September 1993

WORK EXPERIENCE

01/2020 – On-going

Quality Assurance Logistic Division & QA/QC Clinical trial Division
STM PHARMA PRO Srl - Grezzago (MI)

Implementation, maintenance and improvement of the Quality Management System in accordance with GxP(GDP, GMP, GLP, GCP) requirements and UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 standards. Management of the auditing activity (Self-audit and supplier audit). Management and analysis of quality KPIs (Key Performance Indicators). Management of the procedures (SOPs) and the work instructions (WIs). Management of complaints, deviations, corrective actions and related CAPA Plan. Planning of the trainings related to the Quality Management System. Drafting and review of the QTA with Transport Partners and Partner/Sponsors. Opening and management of change controls related to the Quality Management System. Management of the warehouse and manufacturing area temperatures and calibration activities of temperature monitoring probes. Management of the qualifications about instruments, climatic chambers, primary and secondary packaging rooms and management of temperature mapping activity. Support to PR in the management of narcotics (import, statements, etc.). Support to PR/QP in obtaining/maintaining authorization. Batch record review. Management of quarantined products (GMP) and support to the QP in order to release on the market medicinal products and IMPs. QC activity support for IMPs: calibration and validation of laboratory instruments (HPLC, Dissolution, Karl Fischer, Balance, etc.), control of incoming goods, sampling activity, chemical-physical analysis, development of analytical stability protocols for IMPs, management of retain and reference samples, environmental microbiological control, in process control.

04/2019 – 01/2020

NCQ QA SPECIALIST GMP & Compliance
Novartis Farma SpA, Largo U.Boccioni 1

QAA review, SOP review, monitoring of third parties trough KPIs, QRA review, take part self and external inspection (AIFA, ISO 9001), Batch release commercial product, management of complaints and monthly reconciliation with Patient Safety and

Medical Dept., management of fundamental activities in QA (e.g. SOP, CAPA, Deviations, Quality Events, Complaints), Activity of process validation, Data Integrity, internal and external trainer (GMP, GDP, Complaint, DI).

04/2018 – 03/2019

INTERSHIP, PH CPO QA GMP & Compliance
Novartis Farma SpA, Largo U.Boccioni 1

Batch release IMPs, monitoring of third parties trough KPIs, management of complaints, QAA (Quality Agreement) review, SOP review.

12/2016 – 12/2017

HEAD BOY OF FARMACY FACULTY
University of Messina

Spokesman for the requests of students in the departmental council and in the Teaching-Student Committee

01/2016 – 03/2017

INTERSHIP, PHARMACIST
Pharmacy Abate Dott.Antonino Viale San Martino, 39 Messina

Preparation, pricing and labeling of magisterial and officinal galenic preparations.

EDUCATION

05/2022

QUALIFIED PERSON ACCORDING TO D. Lgsv 219/2006
Aifa

14/05/2021

INTERNAL AUDITOR ISO 9001:2015
Area ISO

08/01/2019

PHARMACIST QUALIFICATION
University of Messina

04/2018 – 10/2018

MASTER OF II LEVEL IN PHARMACEUTICAL TECHNOLOGIES AND REGULATORY ACTIVITIES (TFAR
University of Pavia

Marketing Authorization Application (MAA) (centralized, decentralized, mutual recognition procedures and national). Common technical document (CTD and e-CTD) and module 3 Quality, GCP, GMP, GLP

10/2012 – 12/2017

DEGREE IN PHARMACEUTICAL CHEMISTRY
University of Messina

Research activity aimed at the synthesis of "PIRIDIN 2,4 DIONI N-1 RAMIFIED AS NON-NUCLEOSIDIC REVERSE TRASCRIPTASE INHIBITORS ".
The project was presented as an experimental thesis for graduation.

Vote 103/110

SKILLS

- COMPUTER — Microsoft Office package: Microsoft Word, Excel, Access, PPT
  Database operation:SAP, Trackwise, D2, AS400, Parcel

- LANGUAGE — English

Speaking	B1
Reading	B1
Speaking	B1

- TECHNICAL — Synthesis of organic compounds and use of laboratory equipment (TLC, Chromatography NP-LC, H-1 NMR, C-13 NMR), acquired during my activity of researcher in the University of Messina.
  Development of QA project: Training third parties, elimination of paper documentation GxP relevant and use of Computer system validated, tracking of medicinal, simplification of QA processes.
  QC activity support for IMPs: calibration and validation of laboratory instruments (HPLC, Dissolution, Karl Fischer, Balance, etc.), chemical-physical analysis, development of analytical stability protocols for IMPs, environmental microbiological control.

SOFT SKILLS

- PERSONAL AND RELATIONAL — Ability to work in a group, listening and communicative gained during my role as Head boy and QA Specialist at the pharmaceutical company

- ORGATIZATIONAL AND MANAGEMENT — Ability to work independently achieved during my research work and my work in the pharmaceutical company.
  Ability to manage the time gained during my university career having to reconcile the study with the work of head boy.
  Excellent predisposition to face any problems and situations characterized by a significant level of stress.