europass

Alessandro Pappalardo

Work : Malta

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Nationality: Italian

WORK EXPERIENCE

[01/2024 – Current]

Qualified Person, Responsible Person, Regulatory Affairs Advisor

Pharmaconsulta Ltd.

City: Ta'Xbiex
Country: Malta

I am a seasoned Pharmaceutical Quality Professional with expertise in ensuring compliance within pharmaceutical and healthcare sectors. As a Qualified Person and Responsible Person, I've upheld rigorous standards in product quality and safety. In my role, I've overseen product validation, ensuring adherence to regulatory requirements, and navigated complex supply chain management, guaranteeing legal compliance. Additionally, in Regulatory Affairs Advisory roles, I've provided strategic guidance, conducted assessments, and facilitated product approvals. Well-versed in global regulatory requirements, including FDA and EMA, I bring a proven track record of successful submissions and a commitment to driving regulatory excellence in the highly regulated pharmaceutical and healthcare industries.

[04/2023 – 01/2024]

Qualified Person – Senior Quality Assurance Pharmacist

Panaxia Operations (Malta) Ltd.

Address: Hal Far Industrial Estate, Hal Far BBG 3000, Malta, HHF001, Hal Far , Malta
Ensure that medicinal products are manufactured, tested, labelled, packed, released, and certified for distribution in compliance with the approved marketing authorizations
Audit material and service suppliers and contractors according to GMP requirement
Implementation of company Quality Management System including issuing and control of master copy of procedures and validations, Batch Manufacture Records and Product Quality review.
Managing of customer and supplier complaints and recalls.
Support and Maintain company Risk Management.
Control/Management of Cannabis Material related with manufacture

Audit material and service suppliers and contractors according to GMP requirement
Implementation of company Quality Management System including issuing and control of master copy of procedures and validations, Batch Manufacture Records and Product Quality review.
Managing of customer and supplier complaints and recalls.
Support and Maintain company Risk Management.
Control/Management of Cannabis Material related with manufacture

[09/2022 – 03/2023]

Qualified Person – Responsible Person

The Force CT GmbH

Country: Germany
Quality system set-up for customers

• Quality System Manager and RP for GDP and API Release for bluefrog GmbH

• Quality System Manager and RP for GDP and API Release for S.B. Pharma GmbH

Consulting services for Quality Unit

Interim Management (Qualified Person, Responsible Person GDP for API)

[11/2019 – 08/2022]

Qualified Person - Pharmacist

Pharmadox Healthcare Ltd.

Address: KW20A, Corradino Industrial Estate Raħal Ġdid, PLA3000, Malta, Malta
In relation to the duties directly related to my tenure as QP for solid, semi-solid and liquid dosage forms:

Manufacturing Site qualifications in accordance with EU GMP requirements.
Formed part of on-site release team for various manufacturing and packaging products.
Ensure that medicinal products are manufactured, tested, labelled, packed, released, and certified for distribution in compliance with the approved marketing authorizations, relevant guidelines and all applicable laws and regulations.
Review of Manufacturer Batch Record and Validation reports as required
Support in laboratory and manufacturing investigations in relation or attributable to any deviations; change control activities or revisions/changes in specifications or methods of manufacture.
Manufacturing Site qualifications in accordance with EU GMP requirements.
Formed part of on-site release team for various manufacturing and packaging products.
Ensure that medicinal products are manufactured, tested, labelled, packed, released, and certified for distribution in compliance with the approved marketing authorizations, relevant guidelines and all applicable laws and regulations.
Review of Manufacturer Batch Record and Validation reports as required
Support in laboratory and manufacturing investigations in relation or attributable to any deviations; change control activities or revisions/changes in specifications or methods of manufacture.

[06/2018 – 11/2019]

Head of QC - Responsible Person for Food Supplement Production

Pharmex Enterprise Ltd.

Address: Hal Far Industrial Estate, Hal Far BBG 3000, Malta, HHF044, Malta
In relation to the duties directly related to my tenure as Head of QC for solid, semi-solid and liquid dosage forms:

Performed chemical and microbiological analysis, for a wide range of compounds (Raw materials, PW, API, IPC product, bulk and finish product, packaging materials).
Created, revised, and executed, required SOP for Raw Material release tests.
Review of Manufacturer Batch Record as required.
Supported in troubleshooting laboratory equipment including HPLC, HS-GC, IR, UV-vis.
Performed LIMS and Quality System specifications for input/release of raw materials and finish product.
Support in laboratory and manufacturing investigations in relation or attributable to any deviations; change control activities or revisions/changes in specifications or methods of manufacture.
Oversight in system installation, operation, and performance qualification (IQ/OQ, PQ, PM) of all laboratory equipment
Supported in authority inspection (EUcGMP).
Performed chemical and microbiological analysis, for a wide range of compounds (Raw materials, PW, API, IPC product, bulk and finish product, packaging materials).
Created, revised, and executed, required SOP for Raw Material release tests.
Review of Manufacturer Batch Record as required.
Supported in troubleshooting laboratory equipment including HPLC, HS-GC, IR, UV-vis.
Performed LIMS and Quality System specifications for input/release of raw materials and finish product.

Support in laboratory and manufacturing investigations in relation or attributable to any deviations; change control activities or revisions/changes in specifications or methods of manufacture.
Oversight in system installation, operation, and performance qualification (IQ/OQ, PQ, PM) of all laboratory equipment
Supported in authority inspection (EUcGMP).

[11/2017 – 06/2018]

QC Senior Analyst

Chemi Pharma Ltd.

City: Hal Far

Country: Malta

In relation to the duties directly related to my tenure as QC Analyst for aseptically manufactured and terminally sterilised finished products:

Application of US Pharmacopeia-National Formulary, European Pharmacopeia procedures, monographs and guidelines in the course of routine analysis.
Sampling of materials and analysis within Class A area (Isolator).
Creation and review of any SOPs for Raw Material and finished product release tests.
Performed analysis for a wide variety of research projects (Raw materials, WFI, API (Cytotoxic), IPC product, bulk and finish product, packaging materials).
Support in laboratory and manufacturing investigations or attributable to any deviations; change control activities or revisions/changes in specifications or methods of manufacture.
Supported in authority inspection (FDA).

EDUCATION AND TRAINING

[2012 – 2016]

Phd - Moleculer Medicine

University of Catania

City: Catania

Country: Italy

Level in EQF: EQF level 8

Thesis: Role of GABAA receptor on pancreatic alpha cells, and its involvement on FFA's desensitization on Type II Diabetes Mellitus
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[2004 – 2011]

Specialist degree in Pharmacy

University of Catania

City: Catania

Country: Italy

Level in EQF: EQF level 7

Thesis: Involvement of opioid system in the central anti-allodynic effects of Substance P

LANGUAGE SKILLS

Mother tongue(s): Italian

Other language(s):

English

LISTENING C1 **READING** C1 **WRITING** C1

SPOKEN PRODUCTION C1 **SPOKEN INTERACTION** C1

Spanish

LISTENING A2 **READING** A2 **WRITING** A2

SPOKEN PRODUCTION A2 **SPOKEN INTERACTION** A2

Levels: A1 and A2: Basic user; B1 and B2: Independent user; C1 and C2: Proficient user

DIGITAL SKILLS

Open Lab CDS | EmPower3 CDS | • Quality System management tools (LIMS) | Microsoft Office | Prism GraphPad | ImageJ64, Fiji | MATLAB

NETWORKS AND MEMBERSHIPS

ECA Qualified Person Association

Malta Pharmacy Council

MANAGEMENT AND LEADERSHIP SKILLS

cGXP compliance for the manufacturing facility

Preparation, review, training, and approval of standard operating procedures

Review and approval of manufacturer batch record

Handling of investigations and change controls

Preparation of validation protocols and reports

Execution and monitoring of Process validation, cleaning validation and non-Routine validations

Hold time study of products and cleaning validation study

Self inspection, Root cause analysis, Area qualification

HVAC system qualification and validation

Water system and compressed air system validation