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| Name / Surname | <b>Drinalda Mehja</b>                                                  |
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| Phone          | +39 3208904116                                                         |
| E-mail         | <a href="mailto:drinalda.mehja@gmail.com">drinalda.mehja@gmail.com</a> |
| Citizenship    | Italian                                                                |
| Birthday       | 28/04/1985                                                             |



## Career Background

### **Lundbeck Pharmaceuticals Italy**

09/12/2024 – present

#### **QA Qualification Expert**

Coordination of a resource in quality assurance and responsible for assuring cGMP compliance for production facility equipment, areas, utilities and computerized systems.  
Assure Qualification and maintenance programs availability.  
Qualification and periodic monitoring of equipment, areas and utilities; review and approval of IQ, OQ, PQ.  
Computerized systems activities: Gap assessment for CS GxP relevant, audit trail review assessment, review and approval of validation documentation.  
Lead auditor: external audits, self-inspection and inspections by authorities (AIFA).  
Preparation and submission of essential and non-essential modifications to AIFA.  
GAP assessment of the facility for readiness plan in preparation to authorities' inspections or submissions.  
Change control and deviation management.  
Assure continuous update of Validation Master Plan and Site Master File.  
Cleaning verification and validation.  
Risk Assessment management.  
Contribute to continuous improvement of the Quality Management System.

### **Fresenius Kabi iPSUM**

05/07/2021 – 08/12/2024

#### **I&D QA Lead and Global Auditor**

Coordination of quality system in I&D for GxP implementation in I&D laboratories.  
Management of Quality System and Good Laboratory Practice guidelines in order to assure data integrity, equipment management, materials management, technology transfer, analytical method validation, personnel qualification, investigation on complaints, deviations, OOS/OOT, changes.  
Alignment of quality between I&D laboratories of other sites of Fresenius Kabi  
  
Global auditor qualification for execution of:  
External audits to manufacturing sites and analytical laboratories  
AIFA and FDA inspections  
Planning and execution of audits  
Assessment of the results and classification of supplier

09/03/2020 – 05/07/2021

#### **QA Team Lead Peptides / Quality Assurance Specialist for Innovation & Development Lab**

Coordination of QA team in order to guarantee quality for new facility under authorization from regulatory authorities. Compliance to quality standards as per local procedures, global procedures and guidelines.  
Review of GMP documentation:  
Process validation  
Equipment qualification  
Cleaning validation  
Analytical Method Validation and Analytical Method Transfer  
Deviations, OOS/OOT for root cause identification and relative CAPAs  
Auditor for supplier qualification  
Technology Transfer Documentation  
Changes for quality impact  
Management of Quality System for Innovation & Development laboratories, alignment and collaboration with Innovation & Development laboratories of other sites of Fresenius Kabi in India, Austria and Netherlands

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| 01/11/2019 – 30/09/2020                                          | <p><b>CEP Project Lead / Quality Assurance Specialist for Innovation &amp; Development Lab</b></p> <p>Team Lead for corporate project CEP "Compliance Enhancement Plan" in order to improve the Quality System of the site.</p> <p>Compliance to cGMP for all departments with dedicated training in order to detail the correct application of guidelines.</p> <p>Compliance to GDP, Data Governance and Data Integrity with a dedicated training for each department</p> <p>Compliance to Investigation on production and laboratories events, technical instruments for investigation (5 Why, Fishbone, FMEA, Brainstorming, Pareto Analysis) in order to identify the root cause, define corrective or preventive actions, investigation report emission, Field Alert</p> <p>Management and coordination of work group for implementation of corporate procedures, implementation assessment preparation for global documents and relative evaluation of impact on local procedures</p>                                                                                                                                                                    |
| 21/08/2017 – 05/07/2021                                          | <p><b>Quality Assurance Specialist for Innovation &amp; Development Lab</b></p> <p>Introduction and management of Quality System for Innovation &amp; Development laboratories</p> <p>Alignment and collaboration with Innovation &amp; Development laboratories of other sites of Fresenius Kabi in India, Austria and Netherlands</p> <p>Management of Good Laboratory Practice guidelines in order to assure data integrity, laboratory equipment, materials, personnel management</p> <p>Review of analytical method validation documents</p> <p>Review and approval of I&amp;D reports for evaluation of trend, quality impact, root cause analysis and risk for deviations and claims from customers</p> <p>Identification of corrective and preventive actions (CAPA) e relative efficacy to guarantee quality at the basis and reduce recurrence</p> <p>Evaluation of changes for I&amp;D laboratories</p> <p>Auditor for supplier qualification</p> <p>Preparation and revision of procedures for Innovation &amp; Development laboratories management</p> <p>Self-inspection for I&amp;D laboratories</p> <p>Preparation of GMP and GLP training</p> |
| <p><b>Università degli Studi di Bologna</b></p> <p>2024/2025</p> | <p><b>Adjunct Professor at University of Bologna</b></p> <p>Teaching of "Laboratory Assessment: Good Laboratory Practices" course in Chemical Innovation and Regulation - ChIR Master Degree for the academic year 2024/2025</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>Universitat de Barcelona</b></p> <p>2023/2024</p>          | <p><b>Adjunct Professor at University of Barcelona</b></p> <p>Teaching of "Laboratory Assessment: Good Laboratory Practices" course in Chemical Innovation and Regulation - ChIR Master Degree for the academic year 2023/2024</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>Universidade do Algarve</b></p> <p>2022/2023</p>           | <p><b>Adjunct Professor at University of Algarve</b></p> <p>Teaching of "Laboratory Assessment: Good Laboratory Practices" course in Chemical Innovation and Regulation - ChIR Master Degree for the academic year 2022/2023</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>Università degli Studi di Bologna</b></p> <p>2021/2022</p> | <p><b>Adjunct Professor at University of Bologna</b></p> <p>Teaching of "Laboratory Assessment: Good Laboratory Practices" course in Chemical Innovation and Regulation - ChIR Master Degree for the academic year 2021/2022</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

**Quality Assurance Specialist**

Tutor of a junior resource in QA from 09/02/2017 till 20/08/2017  
Tutor of a stagist resource in QA from 24/10/2016 to 21/04/2017  
Follow quality inspections by customers  
Auditor during self-inspections and support during quality inspections from Authorities (AIFA, FDA)  
Quality / GMP and Regulatory review of Change control,  
Review of Deviations evaluating trend, Quality, GMP and regulatory impact, risk analysis, root cause analysis and impact on quality agreements with customers  
Investigation on non-conformities,  
Handle of Out of specifications, and Out of trend  
Evaluation of Corrective and Preventive Actions  
Handle of Recalls from customer  
Management of Returns to suppliers  
Supplier qualification: review of GMP questionnaire, preparation of Raw Material Purchase Specification and quality agreement with supplier, risk assessment to evaluate audit to supplier  
Perform Annual Product Reviews  
Review of Quality Agreements with customers  
Review of shipping documents for delivery to customers  
Preparation of Cleaning Validation Protocol and Report  
Held annual GMP training  
Monitoring and management of materials passed the retest period  
Review of audit trail for informatic systems as SAP and LuDO to guarantee data integrity  
Contribute to improve local quality SOPs according to QM/GL and GMP trends  
Review of Master Batches; Batch record review and quality approval to permit QP release of the API  
Update of VMP  
Documental electronic system coordinator for the management of SOPs in the system

10/09/2012 – 13/11/2015

**GMP and Regulatory Support**

Follow quality inspections by customers  
Auditor during self-inspections and support during quality inspections from Authorities (AIFA, FDA)  
Handle of change control, deviations  
Perform Annual Product Reviews  
Supplier qualification  
Held annual GMP training  
Review of batch record and of shipping documents for delivery to customers  
Review of logbooks used in production and in quality control lab  
  
Regulatory Activities:  
Preparation of Drug Master Files (DMF) for the registration of APIs to AIFA/ FDA/ Japan  
Preparation of LoAs  
Preparation of annual stability protocol / report  
  
Monitoring:  
Supervision to PW system / report on trend;  
Warehouse storage conditions;  
Pest Control  
  
Use of management electronic systems as SAP, LuDo, Pluto.  
LuDo coordinator for the management of SOPs in the system

23/01/2012 – 20/07/2012

**Quality Assurance and Regulatory Support Trainee**

Batch record review  
Training registrations  
Preparation and review of logbooks used in production and in quality control lab  
Perform Annual Product Reviews  
Supplier qualification

## Education

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| Working years                                                           | Course "Data Integrity & Computer Systems Validation"<br>Course "Contamination Control Strategy in Production Facility"<br>Course "Environmental monitoring: Risk assessments, Training, Data integrity, Trend analysis"<br>Course Nitrosamines evaluation<br>Course "Risk Analysis: Tools and applications in pharmaceutical area"<br>Course "Analytical Method Validation"<br>Course "Efficient Management of Audit in API and medicinal specialties"<br>Course "Application of Risk Analysis for process control and management: investigation on deviations and change control" |
| <b>Università degli Studi di Bologna</b><br>19/11/2014                  | <b>State certification for the qualification of Pharmacist – Pharmacist license</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Università degli Studi di Padova</b><br>28/09/2005 – 12/10/2011      | <b>Specialist Degree in CTF "Pharmaceutical Chemistry and Technology" (102/110)</b><br><br>Thesis: "The human A1 adenosine receptor: a computational study."<br>Computational analysis of the behavior of compounds within the receptor pocket<br>Formulation, preparation of pharmaceutical and cosmetic products; extractive preparation and synthesis of drugs;<br>Pharmaceutical Chemistry; Pharmacology; Inorganic / Organic Chemistry etc.                                                                                                                                    |
| <b>Cason Pharmacy</b><br>03/08/2009 - 03/02/2010                        | <b>Stage in Pharmacy</b><br>Preparation of galenics; Dispensing of drugs to the public; Entry-output register of narcotics; Disposing expired drugs                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Liceo Scientifico "Enrico Mattei"</b><br>2000 - 2005<br><br>Language | <b>Scientific High School Diploma (100/100)</b><br><br>Bilingualism Italian, Albanian. English, French                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Personal skills</b>                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Social Competencies                                                     | Team working; Troubleshooting, Versatile, Open to dialogue; Collaborative; Positive; Goal focused; Organizational capabilities; Precision and Accuracy                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Computer knowledges                                                     | SAP, Trackwise, PE e-notebook, LIMS for quality control lab, ADIUTO, Suite Office as Excel, Word, Power Point. Specific programs for computational analysis SCHRÖDINGER (MAESTRO, GLIDE), MOE, GOLD, PLANTS.                                                                                                                                                                                                                                                                                                                                                                        |
| Sports & Hobbies                                                        | Travelling, swimming, reading, cycling, fitness, cooking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Driving licence                                                         | B, own car                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |