Curriculum vitae





PERSONAL INFORMATION

Doris Laçej BA MSc.PhD Candidate

Street Frederik Shiroka, Gora ,Tirana (Albania)

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+355697077679

Personal email: doris_lacej@hotmail.com

https://al.linkedin.com/in/doris-la%C3%A7ej-msc-790357115

WORK EXPERIENCE

05/2023

Member of Pharmtech group, NANOALB, Academy of Science of Albania. Full time

01/03/2021-cont...

Head of sterile, LVP unit. - Full time

Profarma Sh.a, Tirana (Albania)

- -The responsible person for Production of Sterile solutions for injections
- -Manage, control and supervise all production stages of final Sterile products, from the raw materials, production processes and the final packaging process.
- -Managing all the documentation, SOP, batch records, log books, of production and other QA documentation requested.
- -Leadership, management and coordination responsibilities for all employees and activities.
- -Manager and trainer of Department's Staff including pharmacist, technicians and operators.
- -Work and collaborate with other departments of the company (R&D, HR, QA, QC)

*Apart from the Head of an Unit Production, I am selected as the responsible person for foreign affairs, covering different aspects.

Business development manager – part time, remotely DLBEEN Group

- -Developing client relationships and strengthening industry partnerships.
- Identifying new clients by researching and creating networking opportunities.
- Negotiating and closing business deals that promote sustained revenue.
- Liaising with Sales, Marketing, and Management to align strategies aimed at increasing revenue.

01/2022.....cont

Business development consultant – part time, freelance

Metabian UK and other companies interested in.

- Finalizing many business agreements between different companies interested to expand their portfolio
- Taking part in advanced negotiations of business agreements.
- Identifying new clients by exploring my network.

01/04/2017-28/02/2021

Supervisor of Sterile Production (Injectables, Infusions) Department- Full time

Profarma Sh.a, Tirana (Albania)

- -Lead Pharmacist for Production of Small and Large volume injections
- -Lead pharmacist and supervisor for aseptic processes and critical aseptic filling
- -Manage, control, and supervise all production stages of Sterile products.
- -Managing all the documentation, SOP, batch records, log books, of production
- -Work and collaborate with other departments of the company (R&D, HR, QA, QC)

Production Pharmacist- Full time

Profarma Sh.a, Tirana (Albania)

- -Production Assistance of Small and Large Injections
- -Documenting some of the Production Stages, SOP, batch records and log books.
- -Implementing GMP regulations upgrades for Ampules and Perfusion Unit.

05/03/2016-11/12/2016_____

Pharmacist-Part time

Elda Farmakrem, Tirana (Albania)

- Processing Prescriptions
- Providing advice about health issues, symptoms, and medications in response to customer inquiries
- meeting medical representatives
- keeping statistical and financial records

04/02/2016-11/12/2016.

Pharmacy Manager- Full time

Italian Pharmacy - Derma Center, Tirana (Albania)

- -providing advice about health issues, symptoms and medications in response to customer inquiries
- -recruiting, training, and managing staff
- -processing prescriptions and dispensing medication
- -ordering and selling medicines and other stock
- -meeting medical representatives
- -managing budgets
- -keeping statistical and financial records
- -marketing services
- -Lead pharmacist of Galenic Productions (Different formulations like creams, solutions, etc. for skin problems.



10/07/2015-03/02/2016

Intern Pharmacist

Agimi 2 Pharmacy, Tirane (Albania)

- -processing prescriptions and dispensing medication
- -ordering and selling medicines and other stock
 - -Providing advice about health issues, symptoms etc.

07/06/2015-09/09/2015

Medical Representative

CFO Pharma, Tirana (Albania)

- -Achieving assigned sales targets and goals.
- -demonstrating or presenting products to healthcare staff including doctors, nurses and pharmacists
- -undertaking relevant research
- -maintaining detailed excel records

EDUCATION AND TRAINING

01/11/2023... PhD in Pharmaceutical Sciences,

- Sapienza University, Rome
- Pharmaceutical Sciences

20/10/2010-09/07/2015

Master of Science in Pharmaceutical Sciences

EOF level

8 University of Medicine - Pharmacy Department, Tirana (Albania)

- Diploma Thesis "A study on preparation, formulation, stability of certain preparations with salicylic acid.
- Grade 10/10.

09/07/2016-09/07/2016

Certificate of Excellence

University of Medicine, Tirana (Albania)

- Certificate of Excellence for achieving great results during 5 years of studies.
- Awarded as one of the TOP 3 students of the year.



11/2023-02/2024

Course in Nanotechnology and Nanomedicine.

National and Kapodistrian University of Athens

01/04/2019-07/04/2019

A- Z of sterile products manufacture.

NSF International, Health Sciences, Manchester (United Kingdom)

- All information from A-Z, necessary for a sterile product manufacture
- All stages of terminal sterilization and aseptic processes, steam quality and water.
- Quality control, quality management, quality assurance etc.
- The design, validation, operation and maintenance of: Cleanrooms, Isolators, RABS
- Environmental Monitoring
- Routine Disinfection, Gowning and good aseptic practices
- Certificate from a Well-known National Health Organization. Regulatory Standards for Sterile Products

11/2019-01/2020

Introduction to Marketing- University of Pennsylvania.

Coursera. Online

- Marketing Strategy and Brand Positioning
- The opportunities and Challenges of Costumer Centricity.
- Applied Marketing.
- -Certificate from University of Pennsylvania.

03/2020- 05/2020

Brand and Product Management- IE Business School

Coursera, Online

- -Launching new products and the challenge of managing their life-cycle.
- Understand products and products strategy.
- Developing and launching your product and your brand
- Defining your brand and its key

element.



05/2020

GMP Training 01

PHARMOUT, Online

- All the requirements by the FDA, EMEA etc regarding GMP and cGMP
- -Introducing of Good Manufacturing Practice (GMP)
- -Understanding the major aspects of GMP
- -Importance of GMP compliance for patient safety

05/2020

GMP Training 02

PHARMOUT, Online

- GMP regulations relating to the manufacture of Active Pharmaceutical

Ingredients (APIs)

- -The role of the Quality Unit and Pharmaceutical Quality Systems (PQS)
- -Essentials of Quality Management
- -GMP Audits by Regulatory Authorities
- -The importance of documentation
- -The importance of validation

06/2020

Manufacture of Sterile Medicinal Products -Annex 1 Updates

PHARMOUT, Online

- -All the requirements by the FDA, EMEA
- -GMP and cGMP for sterile medicinal products
- -Cleaning and disinfection.

01/2021

Annex 15 – Qualification and Validation

PHARMOUT, Online

- -This Annex covers the requirements for the validation of GMP facilities.
- -Organization and planning of validation activities.
- -Validation Master Plan
- -Definitions of terminology commonly used in validation.

10/2021

Certificate Course in Drug Regulatory Affairs (DRA), **UPPSALA**

- Basic Understanding and Terminologies related to DRA,
- Need and essential qualities of Regulatory Affairs Professional,
- DRA objectives,
- Investigational New Drug Application (INDA),
- New Drug Application (NDA),
- Abbreviated New Drug Application (ANDA),
- Drug Master File (DMF),
- Common Technical Document (CTD),
- Electronic Common Technical Document (eCTD),

01/2023

Pharma Drug Regulatory Affairs course

UDEMY

- DMF preparation and submission
- CTD & eCTD
- Module 1
- Module 2
- Module 3
- Module 4
- Module 5
- Overview of Registration Process

04/2023

Drug commercialization - University of San Diego.

Coursera Online

- -Marketing Srategy
- Sales strategy
- Business development

CONFERENCE/PROJECTS/PARTICIPATIONS

01/2023-06/2023

GMP - Pharma congress 2024 . Wiesbaden Germany

SPEAKER, oral presentation: "Challenge in the use of nanoformulation for

drug delivery.

14/03/2023-15/03/2023

Conference, World Pharma 2024

SPEAKER, oral presentation "A practical approach towards disinfection challenges in sterile manufacturing area."

11/2023-11/2026

COST action CA21147

European Network on Optimising Treatment with Therapeutic Antibodies in chronic inflammatory diseases (ENOTTA)

Management Committee from Albania

01/2023-06/2023

RESEARCH Project, University of Medicine Tirana

Co-author on the Study:

"The pharmacist's role in raising public awareness on cause of dry eye."

RESEARCH Project, University of Medicine Tirana

Co-author on the Study:

"The Grey area of Cosmetology and the pharmaceutical practice"

01/2023-06/2023

RESEARCH Project, University of Medicine Tirana

Co-author on the Study:

"Enhancing therapeutic efficacy through optimizing drug delivery from

nanoparticles"

01/2023-06/2023

RESEARCH Project, University of Medicine Tirana

Co-author on the Study:

The safety of Using Nanotechnology in cosmeceuticals and their availability in

the Albanian market

06/2022-05/2023

RESEARCH Project, University of Medicine Tirana

Co-author on the Study:

A review of antioxidant effects and anti-tumoral effects of polyphenols founded in Vacinium Myrtillius, Hypericum Perforatum, Sideritis Scardica species in Albania territories

04/11//2022-06/11//2022

A Pathway into the Pharmaceutical Industry Academy of Pharmacy "EUREKA" & UFSH.

Certificate of appreciation

Trainer of the following topics:

- EU GMP, FDA requirements for sterile production
- Manufacture of sterile medicinal products
- Methods of sterilization etc.

01/2020-03/2020 International Conference on Pharmaceutical Manufacturing and Industry

Main author of the study:

Article: "A Practical Approach Towards Disinfection Challenges in Sterile Manufacturing Area".

Antibiotic Resistance-National Campaign

Active contribution on the survey and the study: "Awareness on the use of antibiotics during COVID19"

Ca author of the Study:

Article: Analysis of the level of knowledge, attitude and public awareness towards the use of antibiotics and antimicrobial resistance during COVID 19

PERSONAL SKILLS

DIPLOMA in Foreign Languages

- 1- CELI 3 Italian Language
- **2-** DELF B2 French Language
- **3-** TOEFL IBT English Language
- **4-** APTIS English Language

Foreign language(s)	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	0.110000000
English	C1	C1	C1	C1	C1
	Diploma from Faculty of Foreign Languages, University of Tirana				
French	B2	B2	B2	B2	B2
	Diplôme d'études en langue française , DELF B2				
Italian	C1	C1	C1	C1	B2

Communication skills

- -Good communication skills gained through my experience as pharmacist of an well-known pharmacy in town Elda Farmakrem and through my experience and collaboration with different departments of a big company like Profarma Sh.a
- Excellent multi linguistics skills, different projects in French, Italian and English through my jobs. I am the responsible person for foreign affairs in my company.
- Excellent communication skills in different languages gained through my work as business development for an international company.

Organizational / managerial skills

- -leadership (currently responsible and leader for a team of 30 people)
- -good organizational skills gained as head and supervisor of specific productions department
- -good team-leading skills gained as the manager of Italian Pharmacy Derma Center and Head of a Production unit.

Job-related skills

- -Excellent pharmaceutical knowledge in all the fields
- -Business skills gained through my experience as business development
- -Hardworking & determined.-Problem solving gained through my experiences as head of an important and delicate production department like Sterile Unit.
- -Ability to grow with the job, handle responsibility and build positive relationships with work colleagues at all levels
- -I am someone who knows how to set goals and achieve them and have a proven track record of being able to conceive, develop & execute strategies.
- -Capable and professional individual who can perform **to the highest standards.**

Digital skills

SFLF-ASSESSMENT

Informatio n processing	Communicatio n	Content creation	Safety	Problem - solving
Proficient user	Proficient user	Independent user	Proficient user	Proficient user

- Master Microsoft Excel from Beginner to Advanced Learn the most common Excel functions used in the Office. Harness the full power of Microsoft Excel by automating your day-to-day tasks through Macros and VBA
- Maintain large sets of Excel data in a list or table.

Driving licence, B