Denys NALBAT

DATA INTEGRITY SPECIALIST

PROFILE

Master in Biotechnology and Bioengineering with experience in Regulatory Affairs and Operations, of Medicinal Products, in Switzerland, Europe, and RoW. Passionate about common development and fostering team cooperation. Demonstrate fast-learning, responsibility, proactivity, and attention to details.

I am seeking a partnership in a Pharmaceutical Organization to innovate, improve, and positively impact patients and the world.

CONTACT

Valid working permit
19.07.1995
denysnalbat@gmail.com
+41 79 555 39 82
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LinkedIn
Portfolio
GitHub

LANGUAGES

English	C1
German	B1
Polish	B1
Ukrainian	Mother Tongue
Russian	C2

REFERENCES

References are available upon request

IT SKILLS

Advanced LORENZ Life Science, Jira
Intermediate HTML, CSS, JavaScript, Python, SQL, C, Java, SAP, TrackWise, Power BI, Power Automate, SketchUp, Lumion, Agile (Scrum) PM, Git & GitHub

WORK EXPERIENCE

11.2020 – 12.2023

Global Regulatory Operations Specialist (Manager) / Acino - Pharmaceutical Manufacturing, 3000+ employees

- Medical Products **Dossier Compilation** and Validation for Switzerland, Europe and RoW. **Change Control** Records management
- **IMS, DMS, Databases and Master Data governance:** LORENZ drugTrack and docuBridge, TrackWise, SAP. Data Governance.
- **OQ**, **PQ** and **UAT** for system updates
- **Data analysis**, **validation** and **reporting. KPIs** development and tracking
- Data **migration. Audit Trail** review and **Protocols** creation
- **SOPs and WIs update/development.**
- Performing **trainings** on Procedures Regulations and Systems functionality
- **Managing** 7 employees. IT ticket request handling.
- Cooperative projects and coordination with **Vendors** and internal **functions** (IT, Regulatory, Management, QA, etc.)

02.2018 – 02.2019

Regulatory Affairs Specialist / Delta Medical - Pharmaceutical Manufacturing, 700+ employees

- **Pharmaceutical** Products **dossier compilation**
- **Coordination** of **dossier preparation** and **collaboration** with teams: labeling, legal, project manager, product owner, marketing
- **Health Authorities communication** and **submissions**
- **Regulatory Intelligence**

01.2017 – 04.2017

Engineer-technologist for Medicines development / Borshchagiv chemical and pharmaceutical plant - Pharmaceutical Manufacturing, 900+ employees

- Development, implementation and testing of the **production technology** of new medicines
- Development of **composition** and **technology** of products
- **Development** of **regulatory documentation** in accordance with **GMP** requirements.
- Preparation of parts of the **registration dossier** in **(e)CTD** format.

HOBBIES

VOLLEYBALL
I really enjoy team sports. Playing volleyball with locals improves cooperation and keeps me active.

RUNNING/HIKING
It is important to stay motivated, and morning runs and weekend hikes keep me energized and ready for new challenges.

DESIGN
I am passionate about building 3-D designs of Houses, Interior and exterior for letting my imagination run free and change a focus.

WORKING PREFERENCES

AVIABILITY
Immediately.

WORKING TIME
Up to 100%.

RELOCATION
Flexible.

WORK ENVIRONMENT
Hybrid, full remote or full office.

CONTRACT PERIOD
Up to permanent.

EDUCATION

09.2024– 12.2024
Powercoders Bootcamp – ICT Work Integration Program, Bern
- Foundations in HTML, CSS, JavaScript; Data science: Python, SQL, Power BI and -Automate
- Weekly business & social skills training (team work, communication, etc.)

09.2016 – 06.2017
Master of Science (M.S.) / National University of Food Technologies, Kyiv, Ukraine
- Biotechnology and bioengineering
- Chemical, physical, microbiological and biochemical bases of pharmaceutical production
- Produce pharmaceutical products
- Develop and test technology projects

09.2012 – 06.2016
Bachelor of Science (B.S.) / National University of Food Technologies, Kyiv, Ukraine
- Biotechnologies
- Design and modes operations of equipment
- Lab analysis

CONTINUOUS EDUCATION

02.2024 – PRESENT
CS50: Introduction to Computer Science – Harvard, Online
- Computer Science; Data Structures; Algorithms; Programing; SQL; Python; Web Development; CSS; HTML; JavaScript

04.2024 – 07.2024
Access Fast Track program Cycle 9 – Capacity, Zurich, Switzerland
- Networking approaches
- Ways to engage + Job market and search strategies

11.2023 – 11.2023
Audit Trail Review – European Compliance Academy, Heidelberg, Germany
- US FDA Title 21 CFR Part 11 and Annex 11 / Chapter 4 requirements for audit trail

01.2021 – 01.2022
drugTrack and docuBridge advanced user and admin – LORENZ, Online
- Document and Product Lifecycle management and content reuse
- Document Versioning and Submission Quality Control
- EU ISO IDMP; Management of a medicinal product database
- Advanced Reporting and Dashboard