

# GELENA DLUGASH

## Quality Manager

Date of birth: 07.02.1992  
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## PROFESSIONAL EXPERIENCE

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08.2024 – 01.2025 **Quality Manager** | Medena AG, Affoltern am Albis

- Led the QM System, enhancing compliance with cGMP, ISO 9001, ISO 13485, and ISO 22716
- Operational tasks, e.g., product release authorization, deviations / non-conformities, complaints, CAPAs
- Second auditee during client and regulatory audits and inspections
- Document Handling System Manager
- Safety Officer

03.2022 – 02.2024 **Quality Engineer** | Biotronik AG, Bülach

- Ensured compliance with cGMP, cGDP, CFR, MDR, and ISO13845
- Managed deviations, non-conformities, and lead CAPAs
- Defined KPIs, analyzed data, and reported trends
- Developed and reviewed approval-relevant documents, release testing methods, and work instructions
- Conducted training sessions

11.2016 - 02.2022 **Research Assistent** | Friedrich-Alexander-University, Erlangen-Nürnberg

- Radiation Protection Officer and Laboratory Manager of Radioisotope Laboratory for Hormone Measurement
- Developed, optimized, and validated analytical methods for Radioimmunoassay (RIA) and ELISA
- Supervised staff and master students
- Managed international projects

## EDUCATION

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- 09.2018 - 2025      **Ph.D. Student in Chemistry**, Friedrich-Alexander-University, Erlangen-Nürnberg  
Thesis title: Multi-center and multi-method comparison of biomarkers in saliva
- 10.2011- 06.2016    **State Examination in Food Chemistry**, Friedrich-Alexander-University, Erlangen-Nürnberg  
Thesis title: Development and validation of an LC-MS/MS method for assessment of hordenine in beer

## SOFTWARE

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Microsoft Dynamics AX, SAP, PLM (Aras), LIMS, SYSTAT, Windows (MS Office)

## LANGUAGES

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German (native), Russian (native), English (C1), Ukrainian (B1), French (A2)

## PUBLICATIONS

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- 1) Dlugash, G., Rauh, M., Carré, J., Marcellus, A., Plachecki, S., Hampson, E., & Schultheiss, O. (in press). Multicenter comparison of LC-MS/MS, radioimmunoassay, and ELISA for assessment of salivary cortisol and testosterone. *Psychoneuroendocrinology*.
- 2) Dlugash, G., Rauh, M., Carré, J., Marcellus, A., Plachecki, S., Hampson, E., & Schultheiss, O. (in press). Multicenter comparison of LC-MS/MS, radioimmunoassay, and ELISA for assessment of salivary progesterone and estradiol. *Psychoneuroendocrinology*.
- 3) Dlugash, G., & Schultheiss, O. C. (2021). Suitability of saliva stimulants for valid assessment of steroid hormones via radioimmunoassay. *Psychoneuroendocrinology*, 127, 105175. <https://doi.org/10.1016/j.psyneuen.2021.105175>.
- 4) Schultheiss, O. C., Dlugash, G., & Mehta, P. H. (2019). Hormone measurement in social neuroendocrinology: A comparison of immunoassay and mass spectrometry methods. In *Routledge international handbook of social neuroendocrinology* (pp. 26-40). Routledge
- 5) Sommer, T., Dlugash, G., Hübner, H., Gmeiner, P., & Pischetsrieder, M. (2019). Monitoring of the dopamine D2 receptor agonists hordenine and N-methyltyramine during the brewing process and in commercial beer samples. *Food Chemistry*, 276, 745-753. <https://doi.org/https://doi.org/10.1016/j.foodchem.2018.10.067>.
- 6) Lorenz, D., Dlugash, G., & Schultheiss, O. C. (2017). Not just a game – Examining the “Social Death Penalty” and its effects on affiliation motivation and hormonal parameters. *Psychoneuroendocrinology*, 83, 69. <https://doi.org/10.1016/j.psyneuen.2017.07.425>