



Curriculum Vitae

Personal information **Jörg Engelbergs**

Work experience

1. Employer: Paul-Ehrlich-Institut (PEI), Federal Institute for Vaccines and Biomedicines
 - *Position:* Scientific Regulatory Assessor
 - *Activities actual*
 - (i) Assessment of scientific data regarding (a) Pharmaceutical Quality, (b) Non-Clinic, (c) biomarkers and corresponding assays, (d) Companion Diagnostics (CDx), (e) personalized predictive biomarker guided medicinal products. Concerned are scientific data submitted in the context of Clinical Trial Applications (CTA), CDx Performance Study Applications (acc. IVDR), Decentralized / Centralized (EMA) Marketing Authorization Applications, Centralized (EMA) CDx Consultation Procedures (acc. IVDR) and any Follow-On Procedure for biopharmaceuticals / Biotech (e.g., monoclonal antibodies, biosimilars, immunoglobulins, fusion proteins, ADCs)
 - (ii) Scientific Advice for Medicinal Products (National & EMA level) and CDx (National level)
 - (iii) National and third country (US, Asia) GMP inspections
 - (iv) European Working Party activity: see below
 - *Activities past*
 - (i) Scientific (sub)project leader in experimental cancer research and neuropharmacology research (mutagenesis, carcinogenesis, DNA repair, diagnostic and predictive biomarkers and corresponding assays, IVD development, chemo- and targeted therapy / therapy resistance, development of therapeutic monoclonal antibodies
 - (ii) in parallel to (i): Head clinical core facility: "SNP Genotyping Center" at the West German Headache Center; before: Head core facility: "Monoclonal Antibody Development and Production Unit" of the Institut of Cell Biology (Cancer Research) [IFZ] at the West German Cancer Center [WTZE]

Education and training

1. Subject:
 - Qualification: Degree of Ph.D. (Cell Biology)
 - Country: Germany
2. Subject:
 - Qualification: Postgraduate certificate for the post graduate programme on "cellular and molecular biology of normal and malignant cell systems"
 - Organisation: Deutsche Forschungsgemeinschaft, DFG (German Research Foundation, DFG)
 - Country: Germany
3. Subject:
 - Qualification: Science degree in biology (Diploma) (Microbiology, Biotechnology and Molecular Genetics)
 - Organisation: Heinrich-Heine-University Düsseldorf
 - Country: Germany

Additional information

Publications

SCIENTIFIC ARTICLES

Zander H, Engelbergs J (2024) Requirements for regulatory acceptance of biomarkers. *Allergo Journal International*; 2024 Dec; 33: 309-312

Bivi, N., Graham, D., Joglekar, L., McGuire, K., Stoop, J., Zoghbi, J., ...Buoninfante, A., ... Engelbergs, J, ... Garofolo, F, Hopper, S., ... Zander, H., Wen, Y. (2025) 2024 White paper on recent issues in bioanalysis: Impact of LDT in US and IVDR in EU; AI/ML for High Parameter Flow Cytometry; The rise of Olink Technology; CDx for AAV Gene Therapies; Integrative Bioanalysis by Multiple Platforms; Super Sensitive ADA/NAb LBA (PART 2A –Recommendations on Advanced Strategies for Biomarkers, IVD/CDx Assays (BAV), Cell Based Assays (CBA), and Ligand-Binding Assays (LBA) PART 2B – Regulatory Agencies' Input on Biomarkers, IVD/CDx, and Biomarker Assay Validation; *Bioanalysis*; 2025 Jan; 17(4), 211-248; <https://doi.org/10.1080/17576180.2024.2442218>

Verbaanderd C, Trullás Jimeno A, Engelbergs J, Zander H, Reischl I, Moreno Oliver A, Vamvakas S, Vleminckx C, Bouygues C, Girard T, Day F, Frias Z (2023) Biomarker-Driven Developments in the Context of the New Regulatory Framework for Companion Diagnostics in the European Union (2023) *Clin Pharmacol Ther*; 2023 Aug; 114(2): 316-324

Zander, H., Müller_Egert, S., Zwiewka, M., Groß, S., van Zandbergen, G., Engelbergs, J. (2020) Checkpoint inhibitors for cancer therapy; *Bundesgesundheitsblatt*; 63: 1322-1330

Shahrokh, Z, Schmalzing, D, Rawat, R, Sluzky, V, Ho, K, Engelbergs, J, Bishop, J, Friedl, E, Meiklejohn, B, Ritter, N (2016) Science, Risks, and Regulations: Current Perspectives on Host Cell Protein Analysis and Control; *BioProcess International*; 14 (8): 40-51

Bayerer B, Engelbergs J, Savidou I, Boes T, Küper M, Schorn CF, Wissmann A, Knop D, Diener HC, Limmroth V. (2010) Single Nucleotide Polymorphisms of the Serotonin Transporter Gene in Migraine - An Association Study; *Headache* 2010; 50: 319-322

Schürks, M., Limmroth, V., Geissler I., Tessmann G., Savidou, I., Engelbergs, J., Kurth, T., Diener, H.C., Roskopf, D. (2007) Association between migraine and the G1246A polymorphism in the hypocretin receptor 2 gene; *Headache*; 47: 1195-199

Bayerer, B., Savidou, I., Engelbergs, J., Wissmann, A., Limmroth, V., Diener, H.C. (2007) Migraine: Is it a Question of the Genes? *Akt. Neurol.*, 34, 444-447

Engelbergs, J., Thomale, J. and Rajewsky, M.F. (2000) Role of DNA repair in carcinogen induced ras mutation; *Mutation Research*; 450: 139-153

Rajewsky, M.F., Engelbergs, J., Thomale, J. and Schweer, T. (2000) DNA repair: Counteragent in mutagenesis and carcinogenesis - accomplice in cancer therapy resistance; *Mutation Research*; 462: 101-115

Engelbergs, J., Thomale, J. and Rajewsky, M.F. (1998) Both, overall and gene-specific repair of O6-alkylguanines modulate mutagenesis and malignant transformation of rat mammary cells; *Proceedings of the American Association for Cancer Research*; 39: 239

Rajewsky, M.F., Engelbergs, J., Thomale, J. and Schweer, T. (1998) Relevance of DNA repair to carcinogenesis and cancer therapy; *Recent Results Cancer Res.*; 154: 127-146

Engelbergs, J., Thomale, J., Galhoff, A. and Rajewsky, M.F. (1998) Fast repair of O6-ethylguanine, but not O6-methylguanine, in transcribed genes prevents mutation of H-ras in rat mammary tumorigenesis induced by ethylnitrosourea in place of methylnitrosourea; *Proc. Natl. Acad. Sci. USA. (PNAS)*, 95: 1635-1640

Engelbergs, J., Thomale, J. and Rajewsky, M.F. (1996) Relevance of gene-specific repair of DNA O-alkylation products for mutagenesis and carcinogenic risk. *Cancer Detection & Prevention*, 20, 400

Vogel, E.W., Nivard, M.J.M., Ballering, L.A.B., Bartsch, H., Barbin, A., Nair, J., Commendador, M.A., Sierra, L.M., Aguirrezabalaga, I., Tosal, L., Ehrenberg, L., Fuchs, R.P.P., Janalbinz, R., Maenhaut_Michel, G., Montesano, R., Hall, J., Kang, H., Miele, M., Thomale, J., Bender, K., Engelbergs, J. and Rajewsky, M.F. (1996) DNA damage and repair in mutagenesis and carcinogenesis: Implications of structureactivity relationships for cross-species extrapolation. *Mutation Res.*, 353, 177_218

Thomale, J., Engelbergs, J. and Rajewsky, M.F. (1995) Gene-specific repair of O-alkylation products in mammalian cells: Relevance for mutation induction and carcinogenesis. *J. Cell. Biochem. Suppl.*, 21a, 292

Engelbergs, J., Thomale, J. and Rajewsky, M.F. (1995) Overall and gene-specific repair of DNA O-alkylation products: Relevance for mutagenesis and carcinogenic risk. *J. Cancer Res. Clin. Oncol.*, 121, 13

SCIENTIFIC BOOK ARTICLES

Thomale, J., Engelbergs, J., Seiler, F. and Rajewsky, M.F. (1996) Monoclonal antibody-based quantification and repair analysis of specific alkylation products in DNA. In: Pfeifer, G.P. (ed.), *Technologies for Detection of DNA Damage and Mutations*. Plenum Press, New York, US A, pp. 87_101

BOOKS

Diesel, A. and Engelbergs, J. (2002) *CELL BIOLOGY*; Hagemann Bildungsmedien Verlag, Düsseldorf, Germany

Projects

Memberships

Regulatory-Scientific Memberships:

- EU Combine Project (member)
- EMA CHMP/CAT Companion Diagnostic Expert Group (chair)
 - www.ema.europa.eu/en/committees/working-parties-other-groups/chmp-working-parties-other-groups/companion-diagnostic-cdx-expert-group
- EMA Combination Products Operational Group - IVD stream (member)
 - www.ema.europa.eu/en/human-regulatory-overview/medical-devices/combination-products-operational-group
- EMA Methodology Working Party (member)
 - www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/methodology-working-party
- EMA: Specialised Interest Area (SIA) Pharmacogenomics (leadership team)
- EMA Methodology European Specialized Expert Community (ESEC) (member)
- EMA Oncology European Specialized Expert Community (ESEC) (member)

Academic Memberships:

- German Society for Research on DNA Repair (DGDR)
 - dodr6.webnode.page

Other Relevant Information