

## PERSONAL INFORMATION

Egbert Flory

## WORK EXPERIENCE

- 2002- Present **Head of Group Cell Therapy**  
Paul-Ehrlich Institut (PEI), Langen (Germany)  
German (Altn) Member of the Committee for Advanced Therapies at the European Medicines Agency (EMA), London, UK
- Responsible for Somatic Cell Therapy & Tissue-Engineering Products: Assessment of marketing authorization applications, clinical trial applications and scientific advices for cell-based medicinal products; National Expert Advisor & Participation on Good Manufacturing Practice (GMP) related matters; Expert Advisor for Advanced Therapies of the German Federal Ministry of Health
- Development and Execution of Basic Research in the areas: Virus/host interactions: Intracellular signalling mechanisms by immunodeficiency viruses; Molecular mechanism of differentiation in human adult stem cells
- 1999- 2001 **Research Group Leader**  
Paul-Ehrlich Institut (PEI), Langen (Germany)  
Development and Execution of Basic Research in the areas: Signal transduction pathways regulating immunodeficiency virus gene expression; Characterization of viral & cellular determinants in lentiviral pathogenesis; Development of retroviral gene transfer vectors to interfere with signaling pathways
- 1998- 1999 **Head of Diagnostic Laboratory**  
University Hospital Rostock, Institute of Dermatology and Venerology (Germany)  
Dermatology Diagnostic Laboratory and Research on human malignant melanoma signaling
- 1995- 1998 **Post-doctoral Scientist**  
Julius-Maximilian University of Wuerzburg, Institute of Medical Radiation and Cell Research (Germany)  
Basic Research on Mitogen activated protein kinase (MAPK) signaling pathways regulating NF-kappa B and HIV-1 gene expression in immune cells
- 1994- 1995 **Research Fellow**  
Laboratory of Viral Carcinogenesis, National Institute of Health (NIH), National Cancer Institute (NCI), Frederick, Maryland, U.S.A (United States)  
Basic Research on Raf-kinase dependent intracellular signal transduction pathways

## EDUCATION AND TRAINING

- 1990- 1993 **PhD thesis on Coronavirus-induced demyelinating encephalomyelitis: immune reactions against defined viral structure proteins influence the disease process**  
Julius-Maximilian University of Wuerzburg, Institute of Virology and Immunobiology (Germany)  
PhD in Biology
- 1982- 1990 **Diploma Degree in Biology**  
Julius-Maximilian University of Wuerzburg (Germany)  
Diploma thesis on influence of antiviral antibodies on persistent coronavirus infections in rat glia-cell cultures

## ADDITIONAL INFORMATION

**Expertise** Regulatory expertise: Quality and safety of gene and somatic cell therapy medicinal products including tissue engineered products; 10 original regulatory publications listed in PubMed of the National Library of Medicines, NCBI, USA and 7 reviews/book chapters

Scientific research: Major focus on intracellular signalling mechanism related to diseases and human stem cells; 46 original scientific publications listed in PubMed of the National Library of Medicines, NCBI, USA and 21 reviews/book chapters

**Publications** (20 Latest Peer-reviewed journals)

Horn AV, Klawitter S, Held U, Berger A, Jaguva Vasudevan AA, Bock A, Hofmann H, Hanschmann KM, Trosemeier JH, Flory E, Jabulowsky RA, Han JS, Lower J, Lower R, Munk C, Schumann GG. (2013). Human LINE-1 restriction by APOBEC3C is deaminase independent and mediated by an ORF1p interaction that affects LINE reverse transcriptase activity. *Nucleic Acids Res.* Oct 7. [Epub ahead of print]

Melchiorri D, Pani L, Gasparini P, Cossu G, Ancans J, Borg JJ, Draï C, Fiedor P, Flory E, Hudson I, Leufkens HG, Muller-Berghaus J, Narayanan G, Neugebauer B, Pokrotnieks J, Robert JL, Salmonson T, Schneider CK. (2013). Regulatory evaluation of Glybera in Europe - two committees, one mission. *Nature Rev Drug Discov.* 12(9):719.

Barkholt L, Flory E, Jekerle V, Lucas-Samuel S, Ahnert P, Bisset L, Buscher D, Fibbe W, Foussat A, Kwa M, Lantz O, Maciulaitis R, Palomaki T, Schneider CK, Sensebe L, Tachdjian G, Tarte K, Tosca L, Salmikangas P. (2013). Risk of tumorigenicity in mesenchymal stromal cell-based therapies-bridging scientific observations and regulatory viewpoints. *Cytherapy.* 15(7):753-9.

Reinhardt J, Flory E, Buttel I, Schroder C, Fricke S, Vucinic V, Cross M, and D. Niederwieser (2013). MSCs: Clinical Application & EU Regulatory Aspects. *Stem Cell Biology and Regenerative Medicine*, Springer Science & Business Media New York.

Baldauf HM, Pan X, Erikson E, Schmidt S, Daddacha W, Burggraf M, Schenkova K, Ambiel I, Wabnitz G, Gramberg T, Panitz S, Flory E, Landau NR, Sertel S, Rutsch F, Lasitschka F, Kim B, König R, Fackler OT, Keppler OT. (2012). SAMHD1 restricts HIV-1 infection in resting CD4(+) T cells. *Nature Med.* 18: 753-9.

Kopietz F., Kramer M., Muckenfuss H., Sanzenbacher R., Cichutek K., Flory E., Munk C. (2012). Interaction of Vif with APOBEC3G is not Dependent on Serine/Threonine Phosphorylation Status. *J. Gen Virol.* 93:2425-30.

Berger A, Sommer AF, Zwarg J, Hamdorf M, Welzel K, Esly N, Panitz S, Reuter A, Ramos I, Jatiani A, Mulder LC, Fernandez-Sesma A, Rutsch F, Simon V, König R, Flory E. (2011). SAMHD1-deficient CD14+ cells from individuals with Aicardi-Goutieres syndrome are highly susceptible to HIV-1 infection. *PLoS Pathog.* 7:e1002425-101371.

Berger A, Schule S, and E. Flory. (2011). The certification of advanced therapy medicinal products : A quality label for product development in small and medium-sized enterprises. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz:* 54: 816-821.

Hamdorf, M., Berger, A., Schule, S., Reinhardt, R. and E. Flory. (2011). PKC-induced PU.1 phosphorylation promotes hematopoietic stem cell differentiation to dendritic cells. *Stem Cells* 29: 297-306.

Tschulena, U., Sanzenbacher, R., Muhlebach, M., Berger, A., Munch, J., Schindler, Kirchoff, F., M., Plesker, R., Coulibaly, C., Raupp, S., Prufer, S., Muckenfuss, H., Schweizer, M., Cichutek, K. and E. Flory. (2011). Mutation of a diacidic motif in SIV-PBj Nef impairs T-cell activation and enteropathic disease. *Retrovirology* 8: 14.

Committee for Advanced Therapies (CAT); CAT Scientific Secretariat, Schneider CK, Salmikangas P, Jilma B, Flamion B, Todorova LR, Paphitou A, Haunerova I, Maimets T, Trouvin JH, Flory E, Tsiftoglou A, Sarkadi B, et al. (2010). Use of unregulated stem-cell based medicinal products. *Lancet* 376: 514.

Salmikangas P, Flory E, Reinhardt J, Hinz T, Maciulaitis R. (2010). Regulatory requirements for clinical trial and marketing authorisation application for cell-based medicinal products. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz:* 53: 24-9.

Berger A, Munk C, Schweizer M, Cichutek K, Schule S and E. Flory. (2010). Interaction of Vpx and apolipoprotein B mRNA-editing catalytic polypeptide 3 family member A (APOBEC3A) correlates with efficient lentivirus infection of monocytes. *J Biol Chem.* 285: 12248-54.

Committee for Advanced Therapies (CAT); CAT Scientific Secretariat, Schneider CK, Salmikangas P, Jilma B, Flamion B, Todorova LR, Paphitou A, Haunerova I, Maimets T, Trouvin JH, Flory E, et al.

(2010). Challenges with advanced therapy medicinal products and how to meet them. *Nature Rev Drug Discov.* 9: 195-201.

Perkovic M, Norley S, Sanzenbacher R, Battenberg M, Panitz S, Coulibaly C, Flory E, Siegismund C, Munk C, Cichutek K. (2010). SIVagm containing the SHIV89.6P Envelope gene replicates poorly and is non-pathogenic. *Virology* 399: 87-97.

Pauli EK, Schmolke M, Hofmann H, Ehrhardt C, Flory E, Munk C, Ludwig S. (2009). High level expression of the anti-retroviral protein APOBEC3G is induced by influenza A virus but does not confer antiviral activity. *Retrovirology* 6: 38.

Taylor, A., Verhagen, J., Akkoc, T., Wenig, R., Flory, E., Blaser, K., Akdis, M. and C. Akdis. (2008). IL-10 suppresses CD2-mediated T cell activation via SHP-1. *Mol. Immunol.* 46: 622-629.

Montag, T., Nicol, S., Schurig, U., Heiden, M., Huber, H., Sanzenbacher, R., Flory, E., Schwanig, M., and C. Schneider. (2008). Microbial safety of cell based medicinal products - what can we learn from cellular blood components. *Clin. Chem. Lab. Med.* 46: 963-965.

Sanzenbacher, R., Dwenger, A., Schuessler-Lenz, M., Cichutek, K. and E. Flory. (2007). European regulation tackles tissue-engineering. *Nature Biotechnol.* 25: 1089-1091.

**Projects** Scientific activities in the research areas: Virus/host interactions: Intracellular signalling mechanisms by immunodeficiency viruses; Molecular mechanism of differentiation in human adult stem cells

**Memberships** Since 2009: German Member of the Committee for Advanced Therapies (CAT) at the European Medicines Agency (EMA), London, UK  
2010 - 2012: Co-Chair of the Committee for Advanced Therapy (CAT) Working Party on Cell-based Products (CPWP) at the European Medicines Agency (EMA), London, UK  
2010 - 2012: Core-Member of CAT Working Party on Cell-based Products at the European Medicines Agency (EMA), London, UK  
2006 - 2010: Co-Chair of the Committee for Human Medicinal Products (CHMP) Working Party on Cell-based Products (CPWP) at the European Medicines Agency (EMA), London, UK  
2005 - 2010: Core-Member of CHMP Working Party on Cell-based Products at the European Medicines Agency (EMA), London, UK

**Other Relevant Information**