

# CURRICULUM VITAE

## Annette Romeike

DR.MED.VET., DIPLOMATE A.C.V.P., FTA PATHOLOGIE, FELLOW IATP

**Nationality** German, French

**Languages** German (mother tongue), English (fluent), French (fluent)

### ► QUALIFICATION & ACCREDITATIONS

- **2021:** Fellow of the International Academy of Toxicologic Pathology (FIATP)
- **1999:** Diplomate, American College of Veterinary Pathologists (DACVP)
- **1999:** Fachtierärztin für Pathologie (German Certified Veterinary Pathologist, FTA Pathologie)
- **1995:** Dr.med.vet, University of Veterinary Medicine, Hannover, Germany
- **1993:** Veterinarian, University of Veterinary Medicine, Hannover, Germany (DVM)

### ► PROFESSIONAL CAREER/EXPERIENCE

- **Since 2016: Director Pathology Münster, Germany, Covance Preclinical Services GmbH & Scientific Director, Global Pathology**
- **2012-2016: Director of Pathology Europe & Safety Assessment Site Lead (from 2013), Covance Laboratories, Porcheville, France**
- **2009-2012: Consultant in PreClinical Drug Development** (Toxicology & Toxicopathology), Director of International Preclinical Services Annette Romeike (IPSAR), France.
- **2004-2009: Therapeutic Area Leader (Senior Director), Infectious Diseases Therapeutic Area (Antivirals), Pfizer Global Research and Development (PGRD), Drug Safety Research & Development (DSRD), Amboise Laboratories, France.**
- **2000-2004: Scientific Project Leader, Pfizer Global R&D, DSRD, Amboise Laboratories, France.**
- **1998-2004: Senior Pathologist, Pfizer Global R&D, DSRD, Amboise Laboratories, France.**
- **1996-1998: Junior Pathologist, Department of Toxicology Pathology, Bayer Pharma Research Center, Wuppertal Germany.**
- **1993-1996: Graduate Student, "Aufbaustudium Pathologie", Institute of Pathology, University of Veterinary Medicine, Hannover Germany**

## PROFESSIONAL SOCIETIES

- Chair of the *Committee for Scientific Standards* (2013-) of the **European Society of Toxicologic Pathology (ESTP)**, Past President (2012-2014), President (2010-2012), Secretary (2004-2010), Councillor for the Younger Generation (2002-2004); Founding ESTP EC Member (2013); Member since 1996 (formerly GTP German Society of Toxicologic Pathology)
- Member of **American College of Veterinary Pathologists (ACVP)**; *since Board Certification in 1999*
- Member of American **Society of Toxicologic Pathology (STP)** *since 1999*
- Committee Member “European Liaison” in the **STP Scientific and Regulatory Policy Committee (SRPC)** *since 2011*
- Member of the **French Society of Toxicologic Pathology (SFPT)** *since 2009*
- Member of the **American Society of Toxicology (SOT)** *since 2009*
- Member of the **French Society of Toxicology (SFT)** *since 2012*
- Fellow of the **International Academy of Toxicologic Pathology (IATP)** *since 2021*

## CURRENT PROFESSIONAL ACTIVITIES & CONTRIBUTIONS

- ESTP Executive Council member & ESTP/STP liaison
- Chair of the ESTP Guideline/Scientific Standards Committee
- STP – SRPC Working group participant (since 2014) “Pathology Peer Review”
- STP – SRPC Working group (2019) “Non-Blinded vs. Blinded Histopathology Evaluation”
- STP-SRPC Working group (2019) “Points to Consider in Nonclinical Safety Assessment of *In Vivo* Gene Therapy Products, Emphasizing Adeno-Associated Virus (AAV) Vectors
- STP – SRPC Working group (2020) “Best Practices for determining and reporting the cause of death or moribundity in nonrodent species in toxicology studies”

## AWARDS

- **2003**
  - **Pfizer Central Research Award for Innovation and Teamwork** in leading the Safety Risk Management for UK-xxx-xxx (NEP inhibitor)
- **1995**
  - **Carl-Norden Award (Smith-Kline Beecham)** for the doctorate thesis on “Immunohistochemical studies in Equine Recurrent Uveitis”

## PUBLICATIONS

**Romeike A** (1995): Immunohistochemische Untersuchungen zur equinen rezidivierenden Uveitis, Hannover, Univ.Vet.Med., Diss.

**Romeike A**, Brüggmann M and W Drommer (1998): Immunohistochemical studies in equine recurrent uveitis (ERU). *Vet Pathol* **35** (6): 515-526

Drommer W, **Romeike A** and E Deegen (1996): Immunopathologic findings in equine recurrent uveitis (ERU). 14. Arbeitstagung der Fachgruppe Pferdekrankheiten, Deutsche Veterinärmedizinische Gesellschaft, Wiesbaden

Hanton G, **Romeike A**, Longeart L, Comby P, Provost J-P and P Baneux (1999): "Sulfamethoxazole 4-week oral toxicity studies in FVB and XPA transgenic mice", *Toxicology Letters*, Suppl 1, **51**, 109

**Romeike A** (2005): *Endothelin Antagonists*, In: Classic Examples in Toxicologic Pathology, European Society of Toxicologic Pathology, eds. W. Drommer, E. Karbe, P.-G. Germann, G. Morawietz, CD ROM, ISBN 3-9522681-2-7

**Romeike A**, Germann PG, and M Kohler (eds.): "Endocrine Disruption, Juvenile Pathology & Neuropathology, Edinburgh (2008), ESTP Series of Current Topics in Toxicologic Pathology, CD-ROM, ISBN 978-3-00-029395-5

Germann PG, **Romeike A** and M Kohler (eds.): "Drug Induced Toxicologic Pathology, The Hague (2009)", ESTP Series of Current Topics in Toxicologic Pathology, CD-ROM, ISBN 978-3-00-029394-8

Mohutsky MA, **Romeike A**, Meador V, Lee WM, Fowler J, and S Francke-Carroll (2010): Hepatic Drug Metabolizing Enzyme Induction and Implications for Preclinical and Clinical Risk Assessment. *Tox Path* **38**: 799-809

**Romeike A**, Germann PG and M Kohler (eds.): "Respiratory System Toxicopathology & Biopharmaceuticals, Budapest (2010)", ESTP Series of Current Topics in Toxicologic Pathology, CD-ROM, ISBN 978-3-00-032837-4

**Romeike A**, Germann PG and M Kohler (eds.): "Cutting Edge Pathology, Uppsala, Sweden (2011)", ESTP Series of Current Topics in Toxicologic and Veterinary Pathology, CD-ROM, ISBN 978-3-9814653-1-0

Thiel A, W Braun, MG Cary, JA Engelhardt, DG Goodman, WC Hall, **A Romeike**, JM Ward (2013): Calcium lignosulphonate: Re-evaluation of relevant endpoints to re-confirm validity and NOAEL of a 90-day feeding study in rats. *Regulatory Toxicology and Pharmacology* **66**: 286–299

Schorsch F (2013): Serious inadequacies regarding the pathology data presented in the paper by Séralini et al. (2012) – Letter to the editor (collaboration with ESTP Executive Committee representatives and members (R Alison, S Gröters, R Mueller, A Lanzoni, T Nolte, J McKay, M Rinke, **A Romeike**): *Food Chem Toxicol* **53**: 465-466

Fikes JD, D Patrick, S Franke, K Frazier, J Reindel, **A Romeike**, R Spaet, L Tomlinson, and K Schafer (2015): Review of the Office of Economic Co-operation and Development (OECD) Guidance on the GLP Requirements for Peer Review of Histopathology. *Tox Path*, **43**: 907-914

Mecklenburg L & **A Romeike** (2016): Recommended Diagnostic Approach to Documenting and Reporting Skin findings of Nonhuman primates from Regulatory Toxicity studies. *Tox Path* 44: 591-600

Lenz B, Braendli-Baiocco A, Engelhardt J, Fant P, Fischer H, Francke S, Fukuda R, Gröters S, Harada T, Harleman H, Kaufmann W, Kustermann S, Nolte T, Palazzi X, Pohlmeier-Esch G, Popp A, **Romeike A**, Schulte A, Silva Lima B, Tomlinson L, Willard J, Charles E. Wood, Yoshida M (2018). Characterizing Adversity of Lysosomal Accumulation in Nonclinical Toxicity Studies: Results from the 5th ESTP International Expert Workshop, *Tox Path*, vol. 46, 2: pp. 224-246

Bindu M. Bennet, K S. Regan, **A Romeike**, K Schafer, M Thibodeau, H Thomas, K Colman, J Fikes, S Francke, F Geoly, N Keirstead, F Schorsch, J Vahle (2018). Pathologist's interpretation of GLP processes for pathology peer review – rebuttal to Settiagounder's publications by the STP. *J Reg Sci*, Vol 6 (1) v-xi

AR Irizarry-Rovira, BM. Bennet, B Bolon, A Braendli-Baiocco, S Chandra, R Fleurance, R Garman, D Hutto, J Lane, A Romeike, A Sargeant, and B Zimmerman (2018). Scientific and Regulatory Policy Committee Points to Consider: Histopathologic Evaluation in Safety Assessment Studies for PEGylated Pharmaceutical Products. *Tox Path*, Vol. 46(6) 616-635.

B Bolon, J C Rae, K Colman, S Francke, K Jensen, K Keane, EF McInnes, K Nakano-Ito, R Perry, E Polack, K Regan, **A Romeike**, J K. Young, E Galbreath (2020). Toxicologic Pathology Forum Opinion Piece: Current Use of Non-blinded vs. Blinded Histopathologic Evaluation in Animal Toxicity Studies. *Tox Path* 48(4):549-559.

S Korte, J Luft, A von Keutz, F Runge, L Mecklenburg, M Woźniak, S Zander, F Ludwig, B Pajaziti, **A Romeike**, P Korytko (2020) Save your MTD: How to Diagnose Procedure-Related Spinal Cord Lesions after Lumbar Intrathecal Bolus Administration of Oligonucleotides in Cynomolgus Monkeys". *Int J Toxicol*, 39(6):510-517.

M Boyle, B Bennet, K Colman, A-L Frisk, B Garcia, C D Houle, **A Romeike**, R Sura, J Werner, and S A Elmore (2021) Mini review: *Publication categories in Toxicologic Pathology*, *Tox Path* 49(5):1042-1047.

C Saravanan, T Flandre, C Hodo, A D Lewis, L Mecklenburg, **A Romeike**, O C Turner and H-Y Yen (2020) Research Relevant Pathology and Diseases in Nonhuman Primates. *ILAR* 61(2-3):139-166.

R Chamanza, SW Naylor, M Gregori, M Boyle, ME Pereira Bacares, E Drevon-Gaillot, **A Romeike**, C Courtney, K Johnson, J Turner, N Swierzawski and A Sharma (2022) The Influence of Geographical Origin, Age, Sex, and Animal Husbandry on the Spontaneous Histopathology of Laboratory Cynomolgus Macaques (*Macaca Fascicularis*): A Contemporary Global and Multisite Review of Historical Control Data (in press/online May 2022)  
<https://doi.org/10.1177/01926233221096424>

## ORAL PRESENTATIONS IN TOXICOLOGIC PATHOLOGY

16<sup>th</sup> Conference of the German Society of Toxicologic Pathology (GTP), Giessen 2002:  
"Epidermotropic cutaneous T-cell lymphoma (*Mycosis fungoides*) in SD rats" **A. Romeike**,  
L. Longeart, J-L. Lenet, M. Andreu, M.T. Masson

16<sup>th</sup> Conference of the German Society of Toxicologic Pathology (GTP), Giessen 2002:  
"Endothelin<sub>A</sub> receptor antagonist-induced tubular dilatation in the rat testis" **A. Romeike**

9<sup>th</sup> Conference of Classic Examples in Toxicologic Pathology, German Society of Toxicologic Pathology (GTP), Hannover 2002: *“Endothelin Antagonists”* **A. Romeike**

33<sup>rd</sup> Annual Symposium of the Society of Toxicologic Pathology (STP), Washington DC, 2014, Career Development session on Effective Communication of Pathology results in regulatory studies: *“Communicating with Regulators: OECD peer review guidelines as a case example”* **A. Romeike**, E. Barale

French Society of QA (SOFAQ) Annual Meeting, Paris, 2015, *Peer Review of Histopathology data: Review of the OECD Guidance and Application* **A. Romeike**

Combined ACVP/ASVCP/STP Annual Meeting, Minneapolis, 2015, STP Focused Scientific session on Cutaneous Toxicity: *“Cutaneous Toxicity in Non-Human Primates”* **A. Romeike**, L. Mecklenburg

5<sup>th</sup> ESTP International Expert Workshop “Adversity of Lysosomal Accumulation” Sept 23/24<sup>th</sup>, 2016 *“Pharmacokinetics and mechanisms of PEG accumulation”* **A. Romeike**

15<sup>th</sup> European Congress of Toxicologic Pathology (ESTP) “Regulatory environment of GTMPs: Example of nonclinical development of a viral vectored therapeutic vaccine to treat human cervical cancer” August 30-2 Sept 2017, **A. Romeike**

15<sup>th</sup> European Congress of Toxicologic Pathology “Pathology Peer Review – regulatory concerns and potential consequences” August 30-2 Sept 2017, **A. Romeike**

## **POSTERS**

*“Sulfamethoxazole 4-week oral toxicity studies in FVB and XPA transgenic mice”*  
G. Hanton, **A. Romeike**, L. Longeart, P. Comby, J-P. Provost, Ph. Baneux  
Eurotox meeting, Oslo, 27-30 June 1999

*“The CEPA group : Optimization of cell proliferation studies and apoptosis assays”*  
**A. Romeike**  
Drug Safety Evaluation Global Offsite, Pfizer Global Research, Ann Arbor, MI, 2000

*“Prevalidation of a human corneal epithelium model ”*  
S. Catoire, I. Domingo, G. Couvenant, **A. Romeike**, C. Charuel, O. Blanck, N. Alépée  
PGRD Science Day, Pfizer Amboise Laboratories, France, 2003

*“Refinement in primate use: marmosets instead of macaques ”*  
S. Picavet, **A. Romeike**, Ph. Baneux  
PGRD 3Rs poster session on “Ethical Innovations”, Pfizer Sandwich Laboratories, Kent, UK, 21st September, 2004

*“The Immunotoxicology Inter-Laboratory Project (IILP): Validation of a T-cell Dependent Antibody Response (TDAR) using Keyhole Limpet Hemocyanin (KLH) in Rats”*  
S. Spanhaak, M. Desmidt, K. Cederbrant, M. Müller, M. Wing, F. Horand, F. van Och, **A. Romeike**, R. Zierz, A. Penninks

46<sup>th</sup> Annual Meeting of the Society of Toxicology, March 25-29, 2007 at the Charlotte Convention Center in Charlotte, North Carolina.

*“Recent applications of GLP Transmission Electron Microscopy in Drug Research and Development”* R. Masson, T. Lemarchand, **A. Romeike**

Annual meeting of the French Society of Toxicology, Annecy, 16 Oct 2014

*“Always know your vehicle: Unexpected nephrotoxicity and pancreas toxicity induced by a sulfuric acid-based vehicle in Cynomolgus monkeys (Macaca fascicularis)”* S.Friderichs-Gromoll, S. Korte, M.Niehoff, **A.Romeike**, T.Pfaff

14<sup>th</sup> Annual meeting of the European Society of Toxicologic Pathology, Barcelona, Sept 2016

*“Adversity of Lysosomal Accumulation” in Toxicity Studies, The Pathologists' Point of View – Results from the 4th ESTP International Expert Workshop in Barcelona, Sept. 23 – 24, 2016”*

Lenz B, Braendli-Baiocco A, Engelhardt J, Fant P, Fischer H, Francke S, Fukuda R, Gröters S, Harada T, Harleman H, Kaufmann W, Kustermann S, Nolte T, Palazzi X, Pohlmeier-Esch G, Popp A, **Romeike A**, Schulte A, Silva Lima B, Tomlinson L, Willard J, Wood C.E, Yoshida M. 36<sup>th</sup> Society of Toxicologic Pathology (STP) Annual Symposium, Montreal (Canada), 24-26<sup>th</sup> June 2017 & 15<sup>th</sup> European Congress of Toxicologic Pathology (ESTP), Aug 30- 2 Sept 2017, Lyon (France)

Saint-Germain-en-Laye, September 1, 2022

Dr. A. Romeike