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Website: <http://www.totzke-scientific.com>  
Born: July 6<sup>th</sup> 1965 in Cologne (Citizenship: German)

## **Work Experience**

Since November 2008 self-employed      Freelance Writer and Consultant  
Medical Affairs & Communication

October 2004 – October 2008 employed at  
*HPM Healthcare Project Management SA, Geneva, Switzerland*

January 2005 – October 2008:              Head of Medical Writing (4 direct reports)  
& Management board member

**Key accountabilities:** Build-up of the Medical Writing department, leadership and management of the team, including responsibility for profit and loss; bidding; scientific consultancy; statistical analysis; publication management; supervision of key projects (>40 CTD and >20 publication projects); participation in HPM's strategy planning.

October – December 2004:                  Project Manager Medical Writing

**Key accountabilities:** Reviewing, editing and writing of documents in compliance with GxP and current guidelines for regulatory bodies (e.g., Common Technical Documents (CTDs), Clinical Expert Reports/Statements (CER/CES), trial protocols and reports, Risk Management Plans, IMPDs, Safety Reports; narratives and causality assessments) as well as for the public domain (manuscripts for peer-reviewed journals, registries/websites; investigator and marketing brochures).

April 1999 – September 2004 employed at  
*MDS Pharma Services Central Laboratory, Hamburg, Germany*

June 2001 – September 2004:              Scientific Director (11 direct reports)

**Key accountabilities:** Set-up of new analytical techniques according to GLP-, NCCLS-, and FDA-guidelines: check of feasibility, capacities, profitability; supervision of the validation; data analysis; writing of Validation/Analytical Reports and SOPs; scientific support to internal departments and to clients (technical information on methods; medical/clinical significance of lab tests and results); member of the global scientific committee on the harmonisation of analysis procedures.

April 2000 – May 2001:                      Senior Project Manager (4 direct reports)

April 1999 – March 2000:                    Project Manager (1 direct report)

**Key accountabilities:** Set-up, supervision and management of all central lab actions in a clinical trial according to GCP, the study protocol and sponsor's requirements: set-up of the database; writing of in- and external instruction documents as well as design of the blood collection kits for investigators; presentations of study specific procedures on investigator meetings; supervision of the delivery of lab material to and the pick-up of samples from the investigators, medical review and release of lab results, coordination of affiliate laboratories in South America, South Africa, Australia, and Asia.

**Research Experience**

December 1998 - February 1999                      Postdoctoral Research Associate  
*Institute of Zoology, Dept. Ethology, University of Vienna, Austria (Prof. Dr. J. Dittami)*

**Research topics:** Behavioural changes before and during onset of different variants of spongiform encephalopathy (BSE; CJD) in Rhesus monkeys (EU-project in collaboration with *G. Eder*, Immuno AG Vienna, *A. Aguzzi*, Zürich, and *J. Collinge*, London). Winter ecology of birds in reed beds; control mechanisms of winter fattening in bearded tits (in collaboration with *F. Bairlein* (Wilhelmshaven)).

October 1992 – October 1998 employed at  
*Institute of Avian Research, Wilhelmshaven, Germany (Prof. Dr. F. Bairlein)*

August 1996 – October 1998                      Postdoctoral Research Associate  
*(DFG Ba 816/12-1)*

**Research topics:** Control mechanisms of the migratory fattening in passerine birds; evaluation of similarities to mammalian obesity by means of glucose tolerance and hormone response tests. Collaboration with *I. Schmidt* (MPI, Bad Nauheim) on the effects of leptin on birds.

October 1992 – July 1996                      Research Assistant

**Research topics:** Validation of heterologous immunoassays for the evaluation of hormone levels in birds (in collaboration with *A. Hübinger*, Diabetes-Forschungsinstitut, Düsseldorf); seasonal variations of blood metabolite and hormone levels in a migratory bird species (*Sylvia borin*); influence of food shortage on seasonal hyperlipemia and hyperglycemia; influence of thyroidal and pituitary effectors on fattening. Supervision of a project concerning the influence of fasting on blood composition in herring gulls (in collaboration with *O. Hüppop*, Helgoland).

November 1991 – August 1992                      Research Assistant  
*Institute of Biochemistry, Deutsche Sporthochschule (DSHS), Cologne, Germany*  
*(Prof. Dr. M. Donike)*

**Research topics:** Evaluation of the relevance of pituitary hormone and creatinine concentrations in the urine of athletes for doping analysis; routine chemical preparation of urine samples preceding GC/MS analysis for the detection of steroids.

**Education**

2007                      ECPM diploma in 'Pharmaceutical Medicine',  
University of Basle, Switzerland

1996                      Dr. rer. nat. (PhD), University of Cologne, Germany

1991                      Diploma in Biology (MSc), (Zoology, Botany, Biochemistry, Genetics),  
University of Cologne, Germany

1987                      Prediploma in Biology (BS), University of Cologne, Germany

1984                      Abitur; Candidate *Stiftung des Deutschen Volkes*

**Vocational Training**

- *EMWA Professional Development Program*, since 2005, European Medical Writer Association (EMWA)
- *Action Leadership Program*, 2003, Niagara Institute
- *Fachkunde Strahlenschutz*, 1993, University of Hannover

**Expertise/Therapeutic Areas**

- Clinical Research, Pharmaceutical and Laboratory Medicine
- Good Laboratory and Clinical Practice (GLP and GCP)
- Biosafety: EBSA-delegate; familiar with animal experimentation even under Biosafety Level (BSL) 3 and 4 conditions; certified to supervise the work with radioactive isotopes
- Oncology, Pain, Endocrinology, Metabolism, Nutrition, Osteoporosis, Osteoarthritis, Zoology (see publication list)

**Technical Skills and Personal Traits**

- MS Office, SPSS, SigmaPlot
- Well versed in common analytical and laboratory techniques
- Languages: German (native), English (fluent), French (advanced)
- ambitious and persistent (experienced marathon and ultra marathon runner)

**Teaching and Expert Experience**

- Contribution to zoological lectures at the University of Vienna
- Instruction and supervision of graduate and undergraduate students and trainees
- Referee for a number of scientific journals (*Austral Ecology*, *Canadian Journal of Zoology*, *Comparative Biochemistry & Physiology*, *Contemporary Clinical Trials*, *Functional Ecology*, *Journal of Comparative Physiology*, *Journal of Ornithology*, *Journal of Zoology*, *Zoology*)

**Personal References**

Available upon request.

**Publications (as main author)**

- Totzke U (1995): Klinisch-chemische Charakterisierung und erste Befunde zur endokrinen Regulation der zeitlichen Fettdeposition der Gartengrasmücke (*Sylvia borin*). *J. Ornithol.* **136**: 363 (Abstract).

- Totzke U (1995): Validierung heterologer Immunoassays zur Bestimmung von Hormonen des Energiestoffwechsels an Kleinvögeln. *J. Ornithol.* **136**: 363-364 (Abstract).
- Totzke U, Bairlein F, Hübinger A (1996): Variations of plasma metabolites and hormones during migratory fat deposition of the garden warbler (*Sylvia borin*). *Verh. Deutsch. Zool. Ges.* **89.1**: 191 (Abstract).
- Totzke U (1996): Klinisch-chemische Charakterisierung und Befunde zur endokrinen Regulation der zeitlichen Fettdeposition der Gartengrasmücke (*Sylvia borin*). *Dissertation Universität Köln*.
- Totzke U, Bairlein F, Hübinger A (1997): The fat deposition of migratory birds: metabolic changes as in human type-IIb-diabetes? *Exp. Clin. Endocrinol. Diab.* **105**, Suppl. 1: 29 (Abstract).
- Totzke U, Hübinger A, Bairlein F (1997): A role for pancreatic hormones in the regulation of the autumnal fat deposition of the garden warbler (*Sylvia borin*)? *Gen. Comp. Endocrinol.* **107**: 166-171.
- Totzke U, Hübinger A, Bairlein F (1998): Metabolic and hormonal adaptations in the garden warbler (*Sylvia borin*) during the premigratory fat deposition. *Biol. Cons. Fauna* **102**: 346 (Abstract).
- Totzke U, Hübinger A, Bairlein F (1998): Glucose utilization rate and pancreatic hormone response after oral glucose loads are influenced by the migratory condition and fasting in the garden warbler (*Sylvia borin*). *J. Endocrinol.* **158**: 191-196.
- Totzke U & Bairlein F (1998): Implications of food supply and fattening in the migratory garden warbler (*Sylvia borin*). *Ostrich* **69**: 385-386 (Abstract).
- Totzke U & Bairlein F (1998): The body mass cycle of the migratory garden warbler (*Sylvia borin*) is associated with changes in plasma metabolite levels. *Comp. Biochem. Physiol.* **121A**: 127-133.
- Totzke U (1999): Grenzen der äußerlichen Depotfettmengenschätzung bei Zugvögeln. *J. Ornithol.* **140**: 253 (Abstract).
- Totzke U & Bairlein F (1999): Ähnlichkeiten bei der Fettdeposition für den Zug und für den Winter? *J. Ornithol.* **140**: 244 (Abstract).
- Totzke U, Hübinger A, Korthaus G, Bairlein F (1999): Fasting increases the plasma glucagon response in the migratory garden warbler (*Sylvia borin*). *Gen. Comp. Endocrinol.* **115**: 116-121.
- Totzke U, Fenske M, Hüppop O, Raabe H, Schach N (1999): Influence of fasting on blood and plasma composition in herring gulls (*Larus argentatus*). *Physiol. Biochem. Zool.* **72(4)**: 426-437.
- Totzke U, Hübinger A, Dittami J, Bairlein F (2000): The autumnal fattening of the long-distance migratory garden warbler (*Sylvia borin*) is stimulated by intermittent fasting. *J Comp Physiol B* **170**: 627-631
- Totzke U & Kuyas C (2005): Non-frozen transports of whole blood samples do not cause relevant bias for global coagulation tests in clinical trials evaluating the drug safety. *Contemp. Clin. Trials* **26(4)**: 488-502.

**Publications (as co-author)**

- Bairlein F & **Totzke U** (1992): New aspects on migratory physiology of trans-Saharan passerine migrants. *Ornis Scand.* **23**: 244-250.
- Büdinger L, Neuser N, **Totzke U**, Merk HF, Hertl M (2001): Preferential usage of TCR-V $\beta$ 17 by peripheral and cutaneous T cells in Nickel-induced contact dermatitis. *J. Immunol.* **167**: 6038-6044.
- Lim K & **Totzke U** (2004): Die Integration des Problem-based Learning in die Ausbildung zum Physiotherapeuten. *Z. Physiotherapeuten* **56**: 33-41.
- Dittami J, Meran I, Bairlein F, **Totzke U** (2006): Winter patterns of foraging, fat deposition and corticosterone differ between Bearded and Blue Tits: Is this an expression of egalitarian or depositic winter flocks? *J. Ornithol.* **147 suppl**: 158 (Abstract).
- Lopatka L, **Totzke U**, Schmid A, Käufeler R (2007): Die Traubensilberkerze in der Behandlung menopausaler Beschwerden – Ergebnisse einer Therapiebeobachtung mit Cimifemin<sup>®</sup> uno. *J. Menopause* **14(2)**: 16-21.
- Steinmetz HT, Hellmich M, Neise M, Aldaud A, Lerchenmüller C, Tsamaloukas A, Fandel F, Weiligmann C, **Totzke U**, Schmitz S (2007): Prediction of the responsiveness to treatment with erythropoiesis-stimulating factors - a prospective clinical study in patients with solid tumors. *Oncologist* **12**: 748-755.
- Haschke-Becher E, Vockenhuber M, Niedetzky P, **Totzke U**, Gabriel C (2008): A new high-throughput screening method for the detection of chronic lymphatic leukemia and myelodysplastic syndrome. *Clin. Chem. Lab. Med.* **46(1)**: 85-88.
- Steinmetz HT, **Totzke U**, Söling U, Groschek M, Mittermüller J, Schweigert M, Tesch H, Nawka S, Schmitz S, Tsamaloukas A (2008): Hemoglobin levels that trigger ESA treatment decisions for cancer associated anemia – examination of practice in Germany. *Curr Med Res Opin* **24(10)**: 2751-2756.
- Haschke-Becher E, **Totzke U**, Afazel S, Johansson T, Schwarz M, Ladurner G, Wild C (2009): Implementing clinical decision rules for the usage of liquor diagnostics in hospitalised neurology patients reduced costs without affecting clinical outcomes. *Int J Technol Assess Health Care* **25(2)**: in press
- Steinmetz HT, **Totzke U**, Tsamaloukas A, Schweigert M, Mittermüller J, Nawka S, Tesch H, Groschek M, Söling U, Hellebrand E, Schmitz S (submitted): Rationales, strategies, objectives and effectiveness of anemia treatment in cancer patients – results on common practice from the German Cancer Anemia Registry (CAR). *Curr Med Res Opin*.

**Publications with acknowledged contributions**

- Scheiffarth G, Wahls S, Ketzenberg C, Exo KM (2002): Spring migration strategies of two populations of bar-tailed godwits, *Limosa lapponica*, in the Wadden Sea: time minimizers or energy minimizers? *Oikos* **96(2)**: 346–354.
- Bairlein F (2002): How to get fat: nutritional mechanisms of seasonal fat accumulation in migratory songbirds. *Naturwissenschaften* **89(1)**: 1-10.
- Kunz I, Meier KM, Bourson A, Fisseha A, Schilling W (2008): Effects of rimonabant, a cannabinoid CB1 receptor ligand, on energy expenditure in lean rats. *Int. J. Obesity* **32(5)**: 863-870.

- Haschke-Becher E, Brunser O, Cruchet S, Gotteland M, Haschke F, Bachmann C (2009): Urinary D-lactate excretion of infants receiving *Lactobacillus johnsonii* with formula. *Ann. Nutr. Metab.* in press

### **Scientific lecture & poster presentations**

(for titles not mentioned, see abstracts under publications)

- 127<sup>th</sup> Annual Meeting *DO-G*, Wilhelmshaven, Germany, 21.-26.9.1994 (2 poster)
- 89<sup>th</sup> Annual Meeting *DZG*, Oldenburg, Germany, 27.5.-1.6.1996 (lecture)
- 41<sup>st</sup> Symposium *DGE*, Lübeck, Germany, 6.-8.5.1997 (lecture)
- *Max-Planck-Institut für Verhaltensphysiologie*, Andechs, Germany, 24.2.1997 ('The migratory fattening of the garden warbler (*S. borin*) - a zoophysiological phenomenon of medical interest?')
- 1<sup>st</sup> Meeting *EOU*, Bologna, Italy, 28.-30.8.97 (poster)
- *Konrad-Lorenz-Institut für vergleichende Verhaltensforschung*, Austrian Academy of Sciences, Vienna, Austria, 17.12.1997 ('Body mass cycles in birds and their interrelationship with intermediary metabolism')
- 22<sup>nd</sup> *IOC*, Durban, South Africa, 17.-22.8.98 (poster)
- 131<sup>st</sup> Annual Meeting *DO-G*, Jena, Germany, 7.-11.10.1998 (1 poster, 1 lecture)
- 133<sup>rd</sup> Annual Meeting *DO-G*, Leipzig, Germany, 19.-25.9.2000 (poster)
- 14<sup>th</sup> Spring Meeting *EMWA*, Malta, 17.-21.05.2005
- 18<sup>th</sup> European Meeting *DIA*, Paris, France, March 2006
- 15<sup>th</sup> Spring Meeting *EMWA*, Lyon, France, May 2006
- 24<sup>th</sup> *IOC*, Hamburg, Germany, 13.-19.8.2006 (poster)
- 19<sup>th</sup> European Meeting *DIA*, Vienna, Austria, 26.-28.3.2007
- 9<sup>th</sup> Autumn Meeting *EMWA*, Basle, Switzerland, 1.-3.11.2007
- 20<sup>st</sup> European Meeting *DIA*, Barcelona, Spain, 3.-5.3.2008
- Annual Meeting of the German, Austrian, and Swiss Societies for Haematology and Oncology (*DGHO, ÖGHO, SGMO, SGH*), Vienna, Austria, 10.-14.10.2008

### **Professional Memberships**

- TIPPA, The International Publication Planning Association (2008 - current)
- SWAPP, Swiss Association of Pharmaceutical Professionals (2007 - current)
- DIA, Drug Information Association (2006 - current)
- EMWA, European Medical Writer Association (2005 - current)
- EBSA, European Biosafety Association (2000 – 2004)
- DO-G, Deutsche Ornithologen-Gesellschaft (1997 – 2008)