

Curriculum vitae

Personal information

Name Dr. Reinhold Müller-Käfer
Address Hinderdorf 22a, CH-4424 Arboldwil
Date of birth November 2nd 1956



Employment

since 12/2021 part-time as project manager and senior expert for Tillotts, free-lance as consultant for QA/QM and as deputy of QP for several companies

06/2005 to 11/2021 at Tillotts Pharma AG in Ziefen (Switzerland), Head of Quality Control (lab with up to 10 persons), from February 2007 assistant to QP and project manager for approval of main product in Japan (until October 2009), from March 2009 Head of QC with additional QA functions, since July 2012 also deputy of QP; since June 2015 Senior Manager (PQR, new products, projects, cleaning validation and external laboratories), since May 2016 deputy of QP again and also deputy for head of QC, since 2018 Senior Manager Projects (internal and external projects and for new products in contract manufacturing including food supplements)

07/2002 to 05/2005 free-lance in pharma consulting (Parexel) and public library (IT projects)

11/2000 to 06/2002 at RCC Ltd. in Itingen (Switzerland), Study Director for Pharmaceutical Quality Control and Stability Studies (group with 5 persons)

08/1989 to 05/2000 at Hoffmann-LaRoche AG in Basel, Pharmaceutical Quality Control and Assurance (head of different laboratory groups with up to 14 persons in service, development and routine, also QA functions)

Education

10/1988 to 07/1989 searching for employment, basic training in computer knowledge

11/1983 to 09/1988 Studies for Ph.D. at Max Planck institute for solid state research in Stuttgart: synthesis and analytics of rare earth compounds, X-ray powder diffractometry at very low temperatures (liquid helium down to 5 K)

10/1976 to 10/1983 Studies in chemistry at the universities of Siegen and Stuttgart, optional subject: food chemistry; diploma thesis in inorganic chemistry

07/1975 to 09/1976 Military service (15 months basic service in the army)

04/1963 to 05/1975 School, Abitur (highschool diploma)

Training list

Seminars and courses in analytical, GMP, and IT nearly each year (available on request), last training as “responsible person for narcotics (BTM Germany)” in 2021.

Congress Visits

- 1990 103rd SASP Congress in Basel
- 1993 Conference CANAS '93 in Oberhof (Germany)
- 1994 Conference “6th Int. Solid Sampling Colloquium” in Amsterdam
- 1994 Symposium “Pharma Quality Assurance with NIR” in Frankfurt/Main
- 1995 Conference “XXIX Colloquium Spectroscopium Internationale” in Leipzig
- 1995 Conference “Laser techniques in analytical atomic spectrometry” in Berlin
- 2001 Conference “Global Stability Testing” in Amsterdam
- 2005 Conference “Impurities in Drug Substances and Drug Products” in Vienna
- 2009 3rd GMP conference in Heidelberg (ECA)
- 2011 Conference “Consequences of the amendment to Directive 2001/83/EC” in Berlin (ECA)

Special knowledge and experience

- Quality management
- Analytics: both inorganic and organic methods, especially for residues and stability of pesticides and biocides (according to CIPAC, OPPTS)
- Staff: management of diverse groups up to 14 persons, recruiting of new staff and integration of the groups, training courses in analytics and GMP
- Work in project teams:
 - internally in different groups (analytical and organisational projects)
 - IT: new LIMS, DOCUMENTUM and ELO (workflow/document management systems)
 - as head of central analytics service for other divisions (vitamins, diagnostics)
 - externally in expert groups: anorganic trace element analytics (1990 to 1995); monography for Ph. Eur. about NIR spectroscopy (1995); Basel excipients working group (1995 to 1997)
- Project management
 - ”NIR spectroscopy” (1993 to 1995):
 - “Japanese business alliance” (from mid of 2007): project management and coordination of all work related to preparation and filing of NDA (in 2008), answering of questions from PMDA, preparation of audits, marketing approval in October 2009
- Product Quality Review (PQR): establishment of reporting system and compilation since 2006
- Continued process verification (CPV): establishment of system (calculation of process capability Cpk based on CAQs and CPPs)
- Information technology: profound knowledge of usual operation systems and software (MS Office including Access and Project) as well as of software tools, good knowledge of networks, advanced knowledge of relational databases, ERP systems and LIMS

Languages: German native speaker, English business fluent, French good in speaking and writing

Arboldswil, 02/05/2023