



Curriculum Vitae

Personal information **Martin Umhang**

Work experience

Oct 2024 - present: Senior Quality Assessor Biologics at Swissmedic, Bern, Switzerland: Review of CTD Module 3 documentation. Technical co-lead of quality assessment activities for Biologics, support to quality assessors for complex cases and critical requests. Harmonization of decisions within Swissmedic quality assessment and internationally.

Feb 2022 - Oct 2024: Quality Assessor Biologics at Swissmedic, Bern, Switzerland: Review of CTD Module 3 documentation for marketing authorization applications and variations to approved biotechnologically manufactured Drug Substances and Drug Products.

Aug 2019 - Dec 2021: Associate Director/Team Lead QA Operations in Mammalian Manufacturing at Lonza AG, Visp, Switzerland: Leading a team of QA managers in the start-up phase of a single-use mAb manufacturing unit. Defining quality requirements for the GMP manufacturing of clinical and commercial drug substances produced using mammalian cells.

Mai 2018 - Jun 2019: Senior Manager QA Drug Substance, Deputy Team Lead QA Raw Materials and SME Cleaning Validation at Siegfried Ltd, Zofingen, Switzerland. Guidance and training of new team members, implementation of continued process verification concepts.

Mar 2014 - Apr 2018: Manager QA Drug Substance, Deputy Team Lead QA Raw Materials and SME Cleaning Validation at Siegfried Ltd, Zofingen, Switzerland: QA release of intermediates and APIs. Review and approval of changes and deviations associated to the clinical and commercial manufacturing and testing of APIs.

Mar 2011 - Nov 2013: QC Lab Manager BioPharma at Lonza AG, Visp, Switzerland: Project lead for the development, implementation and validation of analytical methods for drug substances. Evaluation of analytical results for release of APIs. Documentation and investigation of incidents in collaboration with the quality assurance and production departments.

Education and training

Feb 2007 - Feb 2011: PhD in Plant Biochemistry, ETH Zürich, Switzerland: Purification and biochemical characterization of plant enzymes involved in starch metabolism. Next generation sequencing of non-model plant species for genome and transcriptome analysis.

Jan 2006 - Jan 2007: Research assistant, ETH Zürich, Switzerland: Supervision of bachelor and master students, cloning of *Arabidopsis thaliana* genes and promoter regions.

Aug 2001 - Nov 2005: MSc in Biology, University of Bern, Switzerland: Heterologous expression, purification and characterization of enzymes involved in starch degradation

Additional information

Publications

Projects

Memberships

Other Relevant Information