



ABOUT

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

ATEN's responsibilities is to support the Quality Control Laboratory activities and ensure that all tested quality parameters are within the shelf life specifications for commercial products and oversee the stability profiles of launched products.

AL TEN ACTIVITIES

AL TEN's support is to provide the relevant stability reports to health authorities as well as participating in answering questions that may arise.

- Determine which tests are needed in any given stability study
- Setting up and starting stability studies (commitment, supportive, post-approval, follow-up)
- Determine whether results generated are within previous trends
- Reviewing Stability Protocols and reports
- Pulling out samples and delivery to the correct laboratories
- Delivering reports for Submission
- Reviewing clients documentation
- Supporting clients by assessing whether a product is fit for consumption after a temperature excursion

STANDARDS & TOOLS

- Stability expertise with good knowledge of ICH guidelines
- Microsoft Office
- SAP
- Chromeleon



1 FTE



2018 - 2023



Switzerland (Stein)



Time & Material

AL TEN ADDED VALUE

- ▶ Participated in the submission of two drug products. Both approved by various Health authorities
- ▶ Implemented cost saving method for sample pullout
- ▶ Part of HART (Health Authority Response Team)
- ▶ Responsible for the stability of 5 products and oversee all products on stability