



ABOUT

Novartis was created in 1996 through a merger of Ciba-Geigy and Sandoz. **Novartis** is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients

Cells & Genes Therapy is a new kind of therapy based on genetic reengineering where Cells or genes are reprogrammed to cure diseases such as leukemia.

Alten’s mission is to support with QA compliance for the qualification of production and laboratory devices at the new CGT facility in Stein.

AL TEN ACTIVITIES

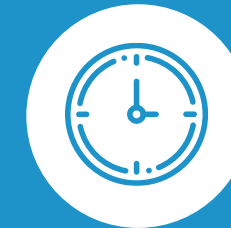
- Review and approval of qualification documentation
 - URS
 - Qualification plan
 - Qualification protocol
 - Device release
- Support the qualification team for the deviations
- Ensure the compliance of the qualification with Data Integrity, qualification regulations and local procedures
- Provide pragmatic solutions to ensure the release of the devices in respect of the timelines
- Qualification of Bioreactors, air samplers (viable and non viable), centrifuges, gases
- Environmental and Equipment Monitoring software

STANDARDS & TOOLS

- ISPE, Eudralex, FDA 21 CFR part 11
- COMOS, ESOP, Office
- 5 why’s, Yoshikawa
- Deviations, CAPA, URS, QP, IOQ



1 FTE



2021 (9 months)



Switzerland (Stein)



Time & Material

AL TEN ADDED VALUE

- ▶ Equipment qualification (IQ/OQ) within tight timelines
- ▶ Regulatory expertise
- ▶ Core competency in qualification
- ▶ Tailore made approach