



We work for
your success!

UNIVERSALJOB

Universal-Job AG • Kasinostrasse 32 • 5000 Aarau



Senior QA Expert

00023010

Company profile

Our client is a successful company in the pharma industry.

Work location

Stein

Main duties

- This role requires adherence to specific cGMP requirements and execution according to the valid SOP's.
- Maintains the Annual Inspection/Audit Schedule
- Leads and coordinates the preparation and execution of Health Authority Inspections, Customer Audits and Internal inspections
- Coordinates the timely preparation of written responses to inspection/audit reports and ensures that adequate corrective and preventive actions are defined and implemented on time.
- Compiles annually the Site Quality Plan (SQP) and regularly monitors progress of each project against the associated timelines
- Ensures that Self Inspections are executed within the company according to a predefined program and ensures follow-up of corrective and preventive actions.
- Ensures that a valid Quality agreement is in place in line with the requirements of the Global template, which clearly defines cGMP roles and responsibilities between the company and the contract giver, as well as product details and requirements.
- Ensures that all aspects of the handling, manufacturing and distribution of supplied products are in compliance with the company Quality Manual, the effective Quality Agreement, that they meet relevant cGMP regulatory requirements and are conducted according to local SOPs
- Writes / Reviews / Approves SOPs/Forms associated with above duties

Start of work

Immediately / by agreement

Education

University/academy degree in chemistry, pharmacy or equivalent

Experience and Skills

- Professional experience in quality control/quality assurance and in the manufacturing of pharmaceutical drug products
- Profound knowledge in cGMPs
- Proven track record with FDA, EMEA and other Health Authorities.
- Strong understanding of risk assessment and risk management fundamentals/tools



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- Technical understanding of pharmaceutical / biological processes
- Extensive auditing experience

Languages

English: Very good written and spoken

German: Fluent written and spoken

Are you interested? Please send your complete application documents by email.