

Job Title	Senior Expert Quality Management Systems (QMS)
Position Type	Full time (preferable)
Job Description	
<p>Who are we?</p> <p>Dr. Regenold GmbH specialises in development, regulatory and market access. Founded in 1994 we have helped many clients progress their product developments by providing scientific and regulatory advice through to gaining regulatory approval and marketing authorisation both nationally and internationally. In 2001 we founded regulanet® which is a network of independent regulatory companies and consultancies with representation in over 90 countries throughout the world. In order to service the increasing importance of medical devices Dr. Regenold GmbH has an associate company, CEplus GmbH, which specialises in internationally regulatory affairs for medical devices and in vitro diagnostics including combination products, companion diagnostics and medical apps. We are based in south west Germany near Basel, Switzerland and have a personalised approach to business and our clients, preferring to conduct our business through recommendation, referrals and repeat business. Our team members are from several different countries which makes Dr. Regenold GmbH a lively and diverse place to work.</p> <p>What we offer:</p> <p>As a Senior Expert QMS you will have the opportunity to work on different projects within our Quality Management Team and you will be involved in various tasks, such as:</p> <ul style="list-style-type: none"> • Development and improvement of Quality Management Systems for our customers • Supporting launches and implementation of Quality Management Systems • Performing of trainings for customers (on/offsite) • Application Management for the required licences (wholesale dealers licence, manufacturing licence, import licence, notification as pharmaceutical entrepreneur) • Performing Mock inspections at the customers' site • Preparing and consulting customers for authority inspections • Coordination of customer inquiries and needs together with our regulanet® partners • Performing audits on behalf of our customers <p>Skills/Qualifications:</p> <ul style="list-style-type: none"> • Bachelor or Master degree in a life Science related field, otherwise education with a proven track record in above mentioned tasks • Several years' experience in development, implementation and maintenance of Quality Management Systems • Used to work in a regulated environment especially in GDP, having also experience in GCP would be preferable • Flexibility to immerse into various client approaches and to develop tailor-made systems • Excellent written and oral communication skills in German and English <p>Are you interested?</p> <p>If you possess above mentioned skills please send your application including cover letter, curriculum vitae and references to our human resources team at perspectives@regenold.com</p>	