

Title: Senior Human Factors Consultant – Medical Products

Agilis Consulting Group is one of the fastest growing human factors firms serving the pharmaceutical and medical device industry (www.agilisconsulting.com). We help clients develop safe and user friendly medical products and devices that clear regulatory agencies fast while helping to improve the quality of life for users. We are seeking a technically talented practitioner who has a passion for quality and enjoys working with a selective client base on an interesting variety of medical products and devices in a team environment. If you love what you do and are looking for a different environment in which to do it – this may be the right fit.

This is a full-time position where the individual works in a remote location of their choice enjoying flexible hours and endless ‘casual Fridays’ when not with clients or other professional situations. Approximately 25% US and international travel is required.

The ideal candidate has a master’s degree or PhD in human factors engineering or a related field. Preference will be given to the candidate with experience in the medical industry and in particular, successfully clearing medical devices/combination products through the CDRH/CDER/FDA human factors process. Experience with other international medical regulatory guidance documents and processes is desired. Experience outside of medical with a strong focus on risk to the user may also be considered.

The Senior Human Factors Consultant is responsible for:

- Leading the execution of human factors consulting projects for multi-national and start-up companies. Compliance with regulatory agencies especially FDA is mandatory.
- Design, development, implementation, moderation, data analysis, and report writing of formative and validation usability studies.
- Participation as a consultant-team member working with other like-minded professionals with a passion to support our clients and provide safe and effective medical products and devices to professional and lay users.

Agilis is small enough so you will always know your value and big enough so you will never be bored. Salary plus bonus and benefits are negotiable and this position reports to the Director of Human Factors. Sanitized work and writing samples as well as references will be requested from candidates. For more information all prospective candidates should contact Stan Caplan at 585-442-0499 or staffing@usabilityassociates.com.