



Company Profile

GRS is a **specialist regulatory affairs consultancy** based in the UK offering resource, support, advice and solutions to life science companies worldwide. Our client base ranges from start-ups through to multi-nationals such as GlaxoSmithKline. We have built up a global network of several thousand consultants and associates. Our professionals are all very experienced with many of them being leaders in their own field. As a direct result of the high calibre of our professionals, we are able to provide strategic advice (thinking 'outside the box') as well as ensuring compliance with all the current and relevant rules and regulations. Due to demand, we have established specialist teams in the following areas:

- pre-clinical
- early stage development (product and/or company) offering strategic advice
- GxP (Good Practice quality guidelines and regulations, for example: Good Manufacturing Practice)
- generic medicines
- paediatrics
- herbal and traditional medicines/natural products/botanicals
- functional foods/nutraceuticals/food supplements
- cosmetics
- Advanced Therapy Medicinal Products (ATMPs)/cell therapies/biologics/biosimilars
- medical devices/diagnostics/combination products
- stem cells/regenerative medicine

In addition, through strategic alliances we can offer

- full pharmacovigilance service (including medical information)
- eCTD templates and publishing
- medical device design and manufacturing support
- a full clinical trial service (adults and paediatrics)
- Patient Information Leaflet (PIL) Readability Testing
- web-based solutions to centrally manage operations
- commercialisation of healthcare, biotech and pharmaceutical technologies/products

Our specialists include ex-FDA and ex-MHRA employees, food scientists, herbal experts, toxicologists, world renown stem cell scientists, pre-clinical advisers, Qualified Persons (QP), medical experts and validators (with many authoring papers in their particular field of expertise). Our personnel are experienced in all types of submissions and are comfortable in advising on the best route to market.

With our worldwide network of consultants and regulatory specialists, GRS is well placed to support companies with emerging, novel technologies from stem cell therapy through to borderline products (including medical devices, biomarkers and in vitro diagnostics). We do not shy away from undertaking something which is going to break new ground or be launched into other countries. We enjoy the challenges presented to get innovative products from lab to market. We have a good working relationship with key Health Authorities and through open dialogue and good communication we can readily support our innovative clients to achieve their objectives.

For more in-depth information about our service portfolio, company culture and values, please visit our website www.globalregulatoryservices.com.