

DRUG DEVELOPMENT, REGULATORY & CLINICAL RESEARCH CONSULTANCY

RSA Consulting provides specialist management consultancy services to the Life Sciences industry (pharma, biotech, generics and medical devices). It deploys the highest calibre specialists (in-house and external) to deliver top quality solutions giving customers value for money in all key functional areas (R&D, Clinical Research, Sales & Marketing and Manufacturing) whether strategic or operational, at the corporate or the executive level.

Clinical & Pre-Clinical Outsourcing

Assisting clients in placing projects with CROs, including planning, benchmark costing, negotiating formal agreements and budgeting.

Providing detailed quantitative and qualitative advice on individual CROs, including objective assessment of resources, capabilities and standards.

Providing project and team management in clinical research/clinical IT.

Providing access to information from our comprehensive database of CROs (clinical, pre-clinical, regulatory, analytical and toxicology).

Drug Development

Supporting project management of development programmes.

Planning of development programmes on a strategic or operational level.

Carrying out feasibility studies, obtaining expert opinions, assembling panel of experts to develop study concepts, advising and recommending CROs.

Consulting on clinical trial supplies and formulation development.

Business Intelligence/ Market Strategy/Due Diligence

Conducting market surveys, market analysis, market demand, competitive intelligence, appraisals of product fit and optimisation.

Techno-commercial due diligence on medicinal product, technology or company.

Regulatory Outsourcing Services

Providing regulatory services (Regulatory CROs and Regulatory Consultants) including streamlining the submission process from the original study documents to final delivery at the regulatory bodies worldwide:

Advising on every aspect of e-submissions – from strategy and process design, to training and the systems build and advising on appropriate software.

Providing eCTD ready templates so you can be assured that your documents are e-submission ready at creation time.

Making your legacy documents eCTD ready with document transformation software.

Providing full publishing services (complying with ICH and regional guidelines) for your e-submissions in eCTD, NeeS, hybrid or even paper format.

Expert Resources

Our resources in development include professionals covering:

- Clinical Project Management
- Medical Writing
- Regulatory Affairs
- Pharmacovigilance
- Statistics
- Data handling
- Quality Assurance Audits and Inspections

Email:
Patricia.Lobo@theRSAGroup.com

or call her on:
+44 (0) 1707 282028

www.theRSAGroup.com

