RA consultancy services

PhaRA can take ownership of specialised regulatory activities and deliverables for pharma and biotech companies, or even function as a fully-staffed EU or BENELUX regulatory affairs department (eg, act as head of Regulatory Affairs for start-up companies or provide a ‘virtual’ regulatory department for small/medium-sized companies). We advise on drug development and regulatory strategies, submit your applications, run your procedures, liaise with health authorities.

We can prepare for EMA or national scientific advice, orphan drug designation (ODD), pediatric investigation plan (PIP), clinical trial application (CTA), marketing authorisation application (MAA), including strategic advice, regulatory scientific writing, and procedural support (CP/DCP/MRP) for initial filing or during life cycle management.

Areas of special interest include early phase development, infectious diseases, immune inflammatory diseases, (immuno)oncology, vaccines, and other unmet medical need areas.

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