Services

We provide strategic and hands-on EU and BENELUX regulatory affairs services, tailored to the client's needs and organisation. Our consultants not only have a strong scientific background and a solid regulatory technical knowledge, but also excellent project management and communication skills. By focusing exclusively on regulatory affairs, we can offer in-depth knowledge, insight, skills, and expertise covering all regulatory affairs activities during drug development and life cycle for chemical entities and biologicals.

We can either assist the client's regulatory affairs department, or operate as independent drivers of specialised regulatory activities, or even function as a fully-staffed BENELUX or EU regulatory affairs department (e.g., for US SME companies).

ALWAYS RELIABLE, RESOURCEFUL, RESPECTFUL AND REGULATORYWISE

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).

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PHARA+ talentsharing

PHARA+ offers temporary onsite staffing solutions for companies located in Belgium and the Netherlands during prolonged sickness, maternity leaves, holidays, or while awaiting a permanent hire. We complement existing resources at EU headquarters or BENELUX affiliates to cope with workload peaks or to bridge a period of uncertainty due to staff shortage by sharing our talented regulatory affairs professionals.

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RA training

PhaRA can provide inhouse RA training tailored to the client needs and organisation, e.g., train newly hired junior staff, train US clients to gain insight in the EU regulatory frame and navigate the regulatory landscape, personal coaching and assistance with specialised subject matters (e.g., first time to handle a scientific advice, prepare for an agency meeting, write a PIP, apply for orphan drug status, request a re-examination, coordinate a referral, etc.).

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PhaRA provides expert regional content on Belgium and Luxembourg for Cortellis™ Regulatory Intelligence. Clarivate Analytics professional regulatory intelligence specialists work with an international network of consultants, each with an in-depth local expertise. As a result, each Cortellis™ Regulatory Intelligence country module contains detailed and continuously updated Regulatory Summaries written by experts from the region.

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PhaRA is a recognized provider of the kmo-portefeuille for training. Through the kmo-portefeuille you can apply for grants from the Flemish government.

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