Joanne Hulbert

Director - Global Regulatory Affairs, Europe, Asia-Pacific, Africa

Joanne Hulbert has over 18 years of regulatory experience. Since joining the industry she has been able to gain in-depth experience in the areas of regulatory affairs, product development, clinical trials, pharmacovigilance, and quality assurance (GCP, GVP, IP-GMP and Regulatory). She specializes in managing all the regulatory aspects of global clinical trials, MAAs and providing a broad range of regulatory strategy and consultancy for pharmaceuticals, biologicals, medical devices, and advanced therapies. Joanne Hulbert has led a wide variety of regulatory projects, including CTAs (phase I to phase IV), management of MAAs through the national, centralized, decentralized and mutual recognition procedures (over 20 within the EU), post-approval/lifecycle activities, requests for product designation/reclassification, development of product labeling and Patient Information Leaflets (PILs), PIL user testing, and corporate due diligence activities. She has also been involved in the preparation and writing of all sections of the IMP and MAA dossiers, including CMC information, Risk Management Plans, nonclinical and clinical summaries and overviews. Ms Hulbert has worked in a variety of therapeutic areas and technologies ranging from known active products to biological and GMOs and from oral dosage forms to topicals and transdermals.

About PRA Health Sciences

PRA Health Sciences (PRA) is one of the world’s leading global contract research organizations, or CROs, providing outsourced clinical development services to the biotechnology and pharmaceutical industries. Side-by-side with clients, PRA strives to move drug discovery forward to help develop life-saving and life-improving drugs.

PRA has therapeutic expertise in areas that are among the largest in pharmaceutical development, including oncology/hematology, CNS (neurology/psychiatry), cardio-metabolic diseases, inflammation/immunology, infectious diseases, rare diseases, respiratory, and biosimilars.

Since 2000, PRA has performed more than 3,100 clinical trials worldwide and has worked on more than 100 marketed drugs across several therapeutic areas. With more than 11,000 employees worldwide, PRA's global clinical development platform spans 70+ offices across North America, Latin America, Europe, South Africa, the Middle East, Asia, and Australia.