

DI RENZO SRL

PHARMACEUTICAL COMPANIES AND REGULATORY AFFAIRS

Di Renzo Regulatory Affairs was founded in 1985 by Sante Di Renzo, a chemist and psychologist with a long-term experience in Farindustria and in the pharmaceutical field.

Our company benefits from a highly professional working staff of about 40 people, including a large technical staff, and offers regulatory services in the field of medicinal products for human and veterinary use, medical devices, biocides, cosmetics, food supplements, dietetic products, homeopathic remedies, medicinal gas products, phytotherapy products. We offer advice on and preparation of local documentation for MRPs, DCPs, national registrations, variations, renewals and MA transfers. For the national phase, we are able to deal with the pricing dossiers and advice on reimbursement issues for Italy as well as to negotiate the price with the Italian Pharmaceutical Agency. We offer advice on preparation of the technical dossiers to obtain CE certification of medical devices and offer support on the registration of biocidal products.

We have units that deal with Pharmacovigilance, drug traceability, scientific information and transformation of medicinal dossiers into eCTD format. We avail ourselves of mother tongue translators for the translation of scientific texts from/to English and German and if necessary we provide asseveration of the same at the tribunal. We cooperate with International consulting firms with long-standing experience and with the main GLP accredited analysis laboratories.

We are part of European networks of regulatory consultants. Our main office is situated in a strategic position in the centre of Rome, not far from the Ministry of Health, the Italian Pharmaceutical Agency and the Istituto Superiore di Sanità. In order to offer a more comprehensive and effective service, we will soon have offices in Milan and London.

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