Di Renzo® Regulatory Affairs

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DI RENZO REGULATORY AFFAIRS
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In 1985, *Di Renzo*® Regulatory Affairs began its regulatory consulting for medicines for human and veterinary use, food supplements, Presidi Medico Chirurgici (PMC) and then biocides, medical devices, In Vitro Diagnostics (IVDs), cosmetics and a range of other related services.

As a result of the development of national and international standards, ever increasing business needs, and thanks to the technical-scientific and administrative structure which *Di Renzo*® Regulatory Affairs has adopted, more and more companies are entrusting *Di Renzo*® Regulatory Affairs with numerous activities that were previously performed in-house.

Di Renzo® Regulatory Affairs collaborates with an international network of regulatory agencies and consulting firms in all countries of the European Union and the main non-European countries.

Areas of interest

- **Regulatory Affairs**
  - o Medicinal products for human use
  - o Medicinal products for veterinary use
  - o Food supplements, Food for Specific Groups (FSG), Foods and Novel foods
  - o Cosmetics
  - o Medical Devices (MDs) and In Vitro Diagnostics (IVDs)
  - o Presidi Medico Chirurgici (PMC) and Biocides
- **Vigilance**
  - o Pharmacovilance for medicinal products for human use
  - o Surveillance and vigilance for MDs and IVDs
  - o Cosmetovigilance
  - o Foodvigilance and phytosurveillance

- **Scientific information and advertising**
- **Clinical trials (regulatory aspects)**
- **Quality Services**
- **Audits**
- **Legal and notary services**
- **Translations**
- **Publications in the Italian Official Journal**

REGULATORY AFFAIRS

Medicinal products for human use

- **Feasibility studies** for business projects
- **Update** on national and international regulations
- **Due diligence**, **gap analysis** and preparation of chemical, clinical and pharmaco-toxicological **expertise**
- Preparation of applications for marketing authorizations for **national**, **Mutual Recognition**, **Decentralized** and **Centralized** procedures initiating from either Italy or another EU country
- Preparation of dossiers in **CTD** and **eCTD**
- Preparation of **variations**, **extensions**, **transfers** of ownership and marketing authorization **renewals**
- Drafting, check and translation of Summaries of Product Characteristics (**SmPCs**), **labels** and Package Information Leaflets (**PILs**) in accordance with current regulations
- **Readability Test** for the Package Information Leaflet (PIL)
- Preparation and check of **artworks** for immediate, secondary packaging and PILs
- Drug **traceability**, application of **optical antifraud stickers** and **serialization**
- Consultancy and preparation of **price dossiers** and pricing **negotiations**
- Request for Certificates of Pharmaceutical Product (**CPPs**) and other documents required for export and their **relevant legalization**
- Regulatory consultancy on **parallel imports**, for importations due to drug shortage and for direct importation
- Technical and administrative regulatory consultancy: **homeopathic** products, medical gases, radiodrugs, and allergens
- Advice to obtain and extend **manufacturing** and **importation authorizations** for active substances or finished products sites
- Classification and submission of essential and non essential **changes** for manufacturing sites: preparation, submission, document drafting
- **Course on regulatory affairs** dedicated to manufacturing sites for importers as well as manufacturers of active substances and medicines
- Course on regulatory affairs for MA Holders
- Submission of **ASMFs** of APIs and dossiers of starting materials to the EDQM for the **registration, renewal and variation of CEPs**
- Requests for **GMP certificates**
- Support in the registration, management and maintenance of data and information in the EMA platforms and portals (**IAM**, **SPOR-OMS** e **PLM-PMS**)

- Assistance in obtaining authorization for the **storage of medicines** (distributors)
- Assistance in the procedures related to **narcotic drugs** and drug precursors
- Regulatory advice during all the steps for the development of **orphan drugs**, from the obtaining of the initial orphan designation to the marketing authorization

Medicinal products for veterinary use

- **Feasibility studies** for business projects
- Regulatory **updates**
- Preparation of applications for marketing authorizations for national and European procedures
- Preparation of **variations**, **extensions**, **transfers** of ownership and **renewals** of marketing authorizations
- **Due diligence**, **gap analysis** and preparation of chemical, clinical and pharmaco–toxicological **expertise**
- Translation and update of Summaries of Product Characteristics (**SmPCs**), **labels** and Package Information Leaflets (**PILs**) in accordance with current regulations
- Preparation of **artworks** for immediate, secondary packaging and PILs
- Request for **GMP certificates**, Certificates of Pharmaceutical Product (**CPPs**) and other documents required for export and the relevant legalization
- Consultancy on new applications, renewals and variations of manufacturing authorizations for **active substances** or **finished products**
- Revision of the labels and the composition of animal **feed for veterinary use** in accordance with current legislation

Food supplements, Food for Specific Groups (FSG), Foods and Novel foods

- **Feasibility studies** for business projects
- Preparation of the **scientific rationale** for supplements containing herbal preparations (botanicals)
- Conformity assessment of **labelling** and **composition**
- Assistance with Food for Specific Groups (FSG), including Food for Special Medical Purposes (FSMP)
- Assistance on **nutritional and health claims** in accordance with the Regulation (EC) no. 1924/2006
- Authorization procedures of novel foods at the European Commission
- Development of **artworks** for the packaging material
- **Notification** procedure with the Italian Ministry of Health of food supplements and other foods subject to notification
- Assistance in the notification procedures for the marketing in most EU countries
- Evaluation of advertising material and drafting of brochures and leaflets
- Feasibility studies for the biological certification of food supplements
- Assistance with registration of companies as Food Business Operator (FBO) in Italy
- Assistance with the uplaod of products to the main databases, including: Farmadati Italia, Codifa and CSF Sistemi

Cosmetics

- **Feasibility studies** for business projects
- Consultancy in order to comply with the provisions of **Regulation (EC) no. 1223/2009**
- Review of the **technical and administrative documentation** provided by the company
- Conformity assessment of labelling
- Preparation of **artworks** for cosmetic packaging
- Preparation of **data sheets** on the toxicological characteristics of cosmetic ingredients
- Preparation of the **safety assessment** of cosmetic products
- Preparation of the **Product Information File** (PIF)
- Entering data into the **European Cosmetic Products Notification Portal** (CPNP)
- Evaluation of suppliers and **audits** by technicians at manufacturing companies
- Request for Free Sale Certificates (**FSCs**) and the relevant legalization
- Evaluation of advertising material

Medical devices (MDs) and in vitro diagnostic medical devices (IVDs)

- **Feasibility studies** for business projects
- Advice on Italian and European **regulations** in force in Italy, in the EU, and in some non-EU countries
- Assumption of the role of **Authorized representative** for extra-EU companies
- Assumption of the role of **UK Responsible Person** (UKRP)
- Revision and verification of the **compliance** of technical documentation for the registration of products in Italy, in the EU, and in some non-EU countries
- Registration of manufacturers, importers, authorized representatives, and system/procedure packs producers in the **EUDAMED** economic operators module in order to obtain the single registration number (**SRN**) or actor ID.
- Registration of medical devices in the relevant EUDAMED form
- Notification of MDs and IVDs in the **Database/Repertorio** of the Italian Ministry of Health and in other EU Member States
- **Registration of manufacturers** of custom-made medical devices
- Preparation of technical files for **CE marking**
- Drafting of **Clinical Evaluation Plan** (CEP) and **Clinical Evaluation Report** (CER)
- Contacts with the **Notified Bodies** and consultations for obtaining the CE marking
- Contacts with **qualified laboratories** to conduct tests on products
- Assumption of the role of **Quality Assurance** (QA)
- Assumption of the role of **Person responsible for regulatory compliance** (PRRC)
- Regulatory activities related to the **import**/ **export** of MDs and IVDs
- Request for Free Sale Certificates (FSCs) and relevant legalization
- Verification and assistance with the **authorization of advertisements**

Presidi Medico Chirurgici (PMC) and biocides

- **Feasibility studies** for business projects
- Information on the Italian legislation on PMCs
- Advice on the regulations in force and on the evolution of the legislation on biocidal products, in particular on the **transition** period for PMCs-biocides
- Verification of the inclusion of the active substances in the **Union list** in order to classify the product as a PMC/biocide/product of free sale or otherwise, in accordance with current regulations
- Verification of the requirements for **registration** in certain EU and non-EU countries
- Assistance in the preparation and submission of the **registration dossier** to the Italian Competent Authorities and relevant authorization process for a **PMC**
- Assistance in the preparation of the dossier for the manufacturing authorization for PMCs and the relevant **authorization procedure** at the Italian Ministry of Health
- Preliminary assessment, preparation and submission of the dossier for the **authorization of a biocidal product** and assistance throughout the entire authorization process
- Identification of **studies** to be performed (chemical-physical, toxicological and eco-toxicological and efficacy studies, etc.) in accordance with the product type (PT) of interest, the active ingredient and the intended use of the product
- Contacts with qualified laboratories for product testing
- Preparation and verification of PMC and Biocide **labels** in compliance with regulatory requirements
- Request for Free Sale Certificates (**FSCs**) for PMCs and relevant legalization
- Development of **mock-ups** of labels and **logos**, graphic design of **brochures**, data sheets and **advertising materials**
- Preliminary assessment of **advertisement material** for PMCs and requests for the appropriate authorization from the Italian Ministry of Health
- European notification into the ECHA portal (PCN)

VIGILANCE

Pharmacovigilance for medicinal products for human use

- Assumption of the role of European Qualified Person for Pharmacovigilance (**EU-QPPV**) – including the availability of a Deputy
- Assumption of the role of **Local Contact Point for Italy** – including the availability of a Deputy
- Management of the entire pharmacovigilance quality system and assumption of the role of pharmacovigilance quality Responsible Person
- Periodic training for internal staff of MA Holders/Italian Affiliates on pharmacovigilance and operational procedures
- Periodic pharmacovigilance **training** for **medical sales representatives**
- Screening for adverse reactions in EudraVigilance and case management
- Conducting **pharmacovigilance audits**
- Periodic verification of Italian and international scientific **literature** for medicines and active ingredients
- Medical evaluation of adverse drug reactions (**ADRs**)
- **Follow-up** management
- **Data Entry** and **Quality Control** of the **ICSR** in the safety database
- Submission of ICSRs to Competent Authorities (**Eudravigilance**)
- Safety data exchange with business partners and English translation of Italian ICSRs in **CIOMS** and/or in XML format according to the E2B standard
- Insertion and updates of medicines in the EMA database Extended EudraVigilance Medicinal Product Dictionary (**XEVMPD**)
- Data update, review and upload into the **PMS** database
- Preparation of the Periodic Safety Update Report (**PSUR**)
- Preparation of the Risk Management Plan (**RMP**)
- Preparation and maintenance of the Pharmacovigilance System Master File (**PSMF**)
- Drafting, review and updating of safety agreements for the exchange of information (Safety Data Exchange Agreements - **SDEA**)
- Periodic review of **safety data**
- **Signal** Detection and Validation
- **Back log** of ADR reports and uplaod into the safety database
- Due Diligence of Pharmacovigilance documentation in case of MA transfers

Surveillance and vigilance for MDs and IVDs

- Devicevigilance activities, with assumption of the role of **vigilance responsible** person
- Management of **incident reports** to the Competent Authorities
- Consultancy in the phase of investigation and preparation of corrective actions (**FSCA**)
- Activities of **post marketing surveillance** and Post-Market Clinical Follow-up (**PMCF**): implementation of the MDR and IVDR requirements
- Drafting of **PSURs** and other **PMS** documents
- Development of **PMCF** surveys
- Trend analysis

Foodvigilance and phytosurveillance

- Management of **post-marketing foodvigilance** and of **phytosurveillance** in Italy and Europe

Cosmetovigilance

- Assumption of the role of **Contact Point** for the Italian and European Authorities
- Managing cosmetovigilance and **post marketing surveillance** in Italy and in the European Union

Scientific information and advertising

- Assumption of the role of **Responsible for the Scientific Information** of medicinal products for human use
- Assistance with the **Scientific Information** of medicines and submission to the Italian Medicine Agency (AIFA)
- Request of authorisation for **conferences** and **congresses**
- Assumption of the role of **ACC Contact Person** (Conferences and Congresses Authorization)
- Request of registration of Pharmaceutical Sales Representatives by the Regions to access health facilities
- Assistance to obtain **certification** according to the Farmindustria guidelines on Scientific Information
- Evaluation of **advertising** material to the public related to human **OTC** medicines, no-prescription veterinary medicines, **PMCs**, **medical devices** and **IVDs**, authorization requests to the Ministry of Health and authorization procedures
- Graphic design of artworks of **brochures** and **advertising materials** and collaboration in the preparation and maintenance of **websites**
- Assistance with promotional materials in other EU countries

Clinical trials

- Regulatory consultancy and assistance for the authorization of **interventional and observational clinical trials** for medicinal products, medical devices and food supplements
- Review of documentation and technical assistance in the submission to the Competent Authorities and **Ethics Committees**
- Data entry into the Clinical Trials Information System (**CTIS**) and into the National Register for Observational Studies
- Translation of the **dossiers**, clinical **protocols**, **informed consent** and other documents to be included in the Clinical Trial Application (CTA)

Quality Services

These consulting activities are addressed to companies and institutions wishing to comply with the necessary requirements for the **achievement of ISO 9001** and **ISO 13485**, **ISO 22716**, **GXP** (GMP, GDP).
In this area the following services are provided:

- Preparation of the corporate **organization chart**
- Preparation of **Job Descriptions**
- Preparation of the **Quality Manual** or evaluation of that already in use at the Client site
- Preparation of Standard Operating Procedures (**SOPs**) and optimization of management procedures for all areas of regulatory activities
- Review of **technical agreements** and execution of audits at suppliers
- Assumption of the role of **Quality Assurance**
- Contacts with **Certification Bodies**
- Support to Clients on the implementation of the **quality system** in accordance with ISO standards
- Preparation of registration system to ensure the compliance with procedures and manuals
- Context assessment and Context analysis drafting
- Assessment and drafting of the risk assessment matrix

Audits

Remote and on-site audits at the following facilities:

- **Manufacturing sites** of active pharmaceutical ingredients (APIs) and finished products, in Italy and in other European or non-EU countries
- **Companies and suppliers** of medicines, medical devices, food supplements, PMCs, biocides, cosmetics
- Companies offering services of clinical trials, pharmacovigilance, regulatory affairs
- **Warehouses**, **distributors**, **wholesalers**

Publications in the Italian Official Journal

- Electronic **publication** services for **listings** in the Official Journal of the Italian Republic

Legal and notary services

- **Legal and Public Notary assistance** in the regulatory sector
- Collaboration in the preparation of **contracts** for the purchase and sale of products
- Elaboration of **expertise** on legal issues related to regulatory activities

Translations

- **Scientific translations** from/into the following languages: Italian, English, Spanish, French, German, Russian and other languages
- **Sworn translations**
- Sworn translation into German of leaflets and labels and upload to the **Unifarm** database (bilingualism) for the Italian market

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