Del Corno & associati s.r.l.

Regulatory Affairs

And

Pharmacovigilance Services

Sede Legale ed Operativa
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The regulatory activity of a company is of primary importance in a highly regulated industrial sector such as the pharmaceutical one, and is essential for business development and lyfecycle management.

Del Corno & associati can offer a partnership both in terms of the more traditional lifecycle management and in product development, thanks to the experience gained at national and international level.

Del Corno & associati is an independent regulatory consultancy company active in the sectors of strategic consultancy for pharmaceutical companies, staff training, collaborating directly or indirectly with various national and multinational companies

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Del Corno & associati, thanks to its experience in the sector, can offer a wide range of services to companies including:

- **Preparation of m 3 Quality Overviews and Quality Overall summaries (m 2.3-3, m2.4-2.6, m2.5-2.7)**

Del Corno & associati prepares m3 and deals with the drafting (medical writing) of various dossiers in compliance with European regulations.

The activity is carried out both for innovator products and for generic products..

- **Product development**

- The company has participated in the development of innovative, generic or "generic plus" products for human use. **Del Corno & associati** can manage or monitor the complete development of the product by selecting the most appropriate development companies, laboratories and production facilities as well as CRO for the realization of appropriate clinical studies, with transparent selection procedures aimed at product quality. We can assist the preparation of a registration strategy and project management.

- **Lifecycle management (variations – renewals)**

Del Corno & associati, can provide support in identifying the national or international registration strategy most suited to the product. This includes the complete development of a product, as well as targeted projects such as setting up variations, renewals.

In detail, the following services can be performed :

- Support in the request for Scientific Advice with the reference authorities: from the preparation of documents to the management of the procedure with the authorities, including participation in the meeting
- Accreditation at regulatory bodies and the Public Administration (power of attorney), also for foreign companies
- Support for start-up activities: SIS Code, AIFA applications (fees and AIFA Front End)
- Support in national and community registration of medicines, through:
    - Preparation of the registration dossier (Forms 1-5) in CTD format, e-CTD, conformity assessment for the check-in phase;
    - Management of the procedure and contacts with the local Authorities, preparation of the response documents during the assessment phase, support up to obtaining the MA
    - Preparation of national publications in the Official Journal.
- Support in the maintenance of drug approvals, such as:
    - Preparation of modules and quality, pre-clinical and clinical overview (Modules 3, 4 and 5) to support quality and safety variation requests, renewals and line extensions;

- Evaluation, preparation, filing and follow-up of administrative, quality and safety changes, line extension, MA renewals;
    - Re-formatting of files in CTD, e-CTD format.
    - Due diligence: in-depth study of the regulatory documentation of the Company's medicinal products, to report any scientific, technical and documentary problems, in order to support and optimize the product portfolio strategies of the Company
    - Gap-analysis dossier
    - Support in the preparation of the dossier for registration of medicines in Extra-EU Countries
    - Drafting and translation of Product Information documents
    - Support to companies in compliance with Bilinguism
    - Support to companies for the fulfillment of the communication to Farmastampati
- Evaluation of regulatory compliance of medical and scientific information material for ethical and OTC drugs (Healthcare advertising)

Manufacturing sites:

- Support in requests for authorization / extension to production / import
- Production / import registration applications
- Support to GMP certificates requests
- • Qualified Person replacement / addition
- • Procedural follow-up
- • Certificates of free sale (CLV): requests and legalization

• Certificate of pharmaceutical product (CPP): request at AIFA, sworn translation, endorsement at the Consulate

- **CCDS editing, Readability -PIL user testing-**

According to the legislation, the readability of the leaflet is a mandatory activity for the preparation of the registration dossier. Del Corno & associati has developed a suitable and consolidated procedural *know-how* for the realization of *User testing*.

- **ACCESS - Reimbursement applications**

After the release of the marketing authorization the product can be included in the reimursability list of the NHS botha t national and regional level. The study of the best access strategy is supported through the close collaboration with partner companies specialized in the analysis of the access requirements both to the PTN and PTOR

- **eCTD**

Del Corno & associati can transfer and/or maintain your dossier in *eCTD* and provide advise for the implementation of the eCTD in your organization through the use of *eCUBE* of the SASI partner company, validated software that also allows the document management of the files.

Del Corno & associati is accredited by AIFA for the registration of pharmaceutical products, a service offered for Italian or foreign companies.

- ## Medical devices

Del Corno & associati offers advice on compiling technical files and updating them. The company is accredited for entering data in the national database and the Directory also on behalf of foreign companies.

We provide the service for the authorization of public advertising with the Italian Moh.

In view of forthcoming MDR we are preparing adequate procedures for MD vigilance.

- ## Food supplements-Food for Special Medical Purposes and cosmetics

Del Corno & associati deals with products belonging to these categories and carries out the input in the Italian ministerial databases (Portale alimenti) and in the EU CNPN

We provide services for the self control of authorizations related to public advertising of food supplements and FSMPs.

- ## GDP Good distribution Practices

Del Corno & associati has been involved and got experience in the implementation of a QS relevants to GDPs, with the relevant SOPs to have in place for MAH, Distributors and Importers.

PHARMACOVIGILANCE

Del Corno & associati, can offer a wide range of services to companies in compliance with the EU GVPs and locally to the Legislative Decree 219/06 and subsequent updates and with the new "Regulation" of Pharmacovigilance (Dir. 2010/84; Reg. 520/12; Decree. Min Sal. of 30 April 2015), including:

- Consultancy for the establishment of an adequate **Pharmacovigilance Quality System**
- Preparation of the **Pharmacovigilance System Master File (PSMF).**
- Registration of the Company to the **National Pharmacovigilance Network** and release of access codes.
- Registration of the Company to**Eudravigilance** and acquisition of **a MedDRA** license according to the structure of the Company.
- Monitoring and iinput of **ICSRs** in Eudravigilance
- Population and update of **XEVMPD.**
- Validated pharmacovigilance **database for ICSRs**: Del Corno & Associati has adopted the Max Application **SafetyDrugs** database; the software is validated and in compliance with international requirements regarding software validation for the pharmaceutical industry
- **Signal detection** through **Business Intelligence** software **integrated with the SafetyDrugs database**
- Pharmacovigilance **training**
- Preparation/revision of the Pharmacovigilance Agreements (**SDEA**) with Italian and foreign third parties.
- Planning, preparation and submission of **Periodic Safety Update Reports** (PSURs / PSUSA)
- Preparation and review of **Risk Management Plans** (RMPs)
- Screening of indexed **literature**, MLM and local literature, with reconciliation according to targeted procedures.

The PV structure is constantly audited by PV auditors.

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