...FREEDOM TO EXPLORE YOUR REGULATORY NEEDS

IVOWEN LIMITED

REGULATORY AFFAIRS SPECIALISTS

Established in **2002**

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ABOUT IVOWEN LIMITED

IVOWEN LIMITED WAS CO-FOUNDED IN 2002 BY MAJELLA RYAN TO CATER TO THE GROWING NEEDS OF GENERIC PHARMACEUTICAL COMPANIES IN THE FIELDS OF REGULATORY AFFAIRS CONSULTANCY AND PROJECT MANAGEMENT.

Ivowen Limited is committed to providing expert advice on Regulatory Affairs and Project Management to the generic pharmaceutical industry. Ivowen Limited can provide regulatory affairs support as consultants to human and veterinary pharmaceutical companies based in the European Union, EU accession states and worldwide on the successful development and timely registration of their products in the EU and other markets.

Ivowen Ltd are part of a pan-European network of consultants, (EuDRAcon) and can therefore provide local support and services across the EU and EEA. We are proud to have worked with multinational companies as well as small start-up companies helping them to achieve their goals.

MEET THE TEAM

MAJELLA RYAN

ALICE D'ALTON

AUDREY BUTLER

NANDA NAIK

EMILY FLETCHER

MARIAN WINDER

MARY CANNING

IVOWEN LIMITED

REGULATORY AFFAIRS SPECIALISTS

We invite you to meet the team who can help you to achieve your goals.

The team at Ivowen Limited has extensive experience in the areas of Pharmaceutical Regulatory Affairs and Pharmacovigilance. Our individual team members bring diverse expertise together to solve our clients' unique problems. Our combined experience spans over 20 years in the generic pharmaceutical industry and covers all dosage forms including tablets, capsules, solutions, suspensions, as well as creams, parenterals and other sterile products with a strong emphasis on regulatory strategy.

Our team has experience managing complicated projects in multiple Member States and has therefore established strong working relationships with regulators throughout Europe. We can provide expert advice in all areas of product development, regulatory strategy, dossier preparation and MA submission through to national phase registration. We can support your license registrations by advising on the need for variations post-approval. We can also provide expert pharmacovigilance advice pre and post-approval including the provision of QPPV services. Ivowen Limited has an extensive range of training options available which can be tailored to your company's needs.

PHARMACEUTICAL REGULATORY AFFAIRS SERVICES: HUMAN & VETERINARY MEDICINAL PRODUCTS

NATIONAL PROCEDURES

Ivowen Limited is well versed in the preparation and submission of applications for national marketing authorisations or licences in all EEA states. We would liaise with the Health Authority on your behalf to answer any queries arising from the application.

Regardless of the outcome of the UK exit from the EU, Ivowen can assist you in all aspects of UK registration. We liaise with the MHRA regularly and can also advise you on how best to update your current MR, DC or CP licences to take account of Brexit.

MUTUAL RECOGNITION, DECENTRALISED AND CENTRALISED PROCEDURES

- A Mutual Recognition Procedure (MRP) is used when your company wishes to market the same medicinal product in more than one country in the EU and where you already have a licence in at least one EU MS.
- A Decentralised Procedure (DCP) is used when your company wishes to market the same medicinal product in more than one country in the EU and where you do not already have a licence in any EU MS.
- The Centralised Procedure (CP) is available to use for generic applications. The CP gives the Marketing Authorisation Holder (MAH) a Community Authorisation which allows the MAH to market in all MSs of the EU and EEA on one licence/MA.

Ivowen Limited has a wealth of experience in preparing and submitting dossiers using the MRP, DCP and Centralised Procedures. We also provide the following services:

- A full gap analysis/dossier audit prior to submission.
- Preparation of Clinical Summaries and Overviews, Non-Clinical Summaries and Overviews and Quality Overall Summaries (formerly Clinical, Pre-Clinical and Pharmaceutical Expert Reports).
- Comparisons of the Summary of Product Characteristics (SmPCs) of the originator products in target markets to identify all areas of potential contention between the Health Authorities in the markets of choice.
- Advice on how to meet individual country requirements to ensure a rapid and successful assessment of your dossier.
- Organisation of translations of relevant sections of the application, as well as mock-up compilation, User Consultation testing and bridging reports.
- Environmental Risk Assessment reports, ICH Q3D impurity risk assessment.
- eCTD building and submission.
- Ivowen Limited can manage all aspects of the procedure independently or in liaison with your own Regulatory Affairs department.
- Ivowen can act as MAH for your product until you find a local distribution partner to transfer the licence to.

VARIATIONS

Variations are any change to the licensed details following approval in any Member State. Ivowen Limited can prepare variations to your licence for you. We can also give you advice on what supporting data you would need for a particular variation, review the data as it becomes available and answer any questions that the Health Authority may have on your application.

RENEWALS

Marketing authorisations/licences for human and veterinary medicinal products will have unlimited validity. However, the marketing authorisation must be renewed at least once within five years of approval and must be placed on the market within three years of approval.

- Ivowen Limited can prepare renewal applications and or review your data in preparation for a renewal application.
- Ivowen Limited can also advise you about Sunset Clause exemptions and submit them on your behalf.

PHARMACOVIGILANCE

Ivowen offers a wide range of pharmacovigilance consultancy services with the necessary tools and expertise to assist marketing authorisation holders and applicants in monitoring the safety of their medicinal products and meeting regulatory reporting requirements during marketing authorisation application and post-approval. We partner with our clients from start to finish, focusing on their needs while developing effective strategies and producing high quality and timely deliverables and outputs. With a wealth of experience in pharmacovigilance and medical affairs, we can create tailor-made service packages based on the individual client's pharmacovigilance requirements.

AGGREGATE REPORT WRITING

- PBRER (and response to PSUSA), PSUR, Addendum Clinical Overview, DSUR and RMP preparation and maintenance.
- Literature review and analysis, safety evaluations and risk-benefit assessments conducted as required.
- Submission via EMA repository if required.

MEDICAL AFFAIRS

- Full product review and harmonisation projects, tailored to specific client needs.
- Creation of product-specific supporting documentation for maintenance and update of Company Core Data Sheet, local product updates, safety variations, e.g. Clinical Overviews, Non-Clinical Overviews, Clinical Expert Statements.
- Management of RFI/RtQ from Agencies.

CONSULTANCY SERVICES

- Audit preparation and support for both internal and externally driven regulatory authority inspection.
- Generation of CAPA report post-audit and development of implementation timelines and plan.
- PV department set-up support to ensure compliance with regulatory requirements.
- Tailor-made training including pharmacovigilance procedures and processes, GVP modules, Aggregate Reports, RMPs, Literature review etc.

OTHER SERVICES

- Signal management
- Literature screening, review and analysis in accordance with GVP Module VI
- PSMF creation and maintenance as per GVP Module II
- SOP/WIN/Template creation and/or review as required
- QPPV provision

- Clinical trial support from case processing to expedited/periodic reporting of SAEs/SUSARs as needed
- Processing of ICSRs
- Registration with EudraVigilance
- Reporting via EudraVigilance

PAEDIATRIC INVESTIGATION PLANS (PIPS) AND PAEDIATRIC USE MARKETING AUTHORISATIONS (PUMAS)

The Paediatric Regulation entered into force on 26 January 2007. As it is an EU Regulation, it is applicable in all Member States as of that date.

Depending on the type of medicinal product there is a staggered entry into force of obligations relating to the development of medicinal products for use in children.

- Ivowen Limited can advise on the requirements for a PIP for all products.
- Ivowen Limited can prepare and submit the PIP/ PUMA for your company.
- Ivowen Limited has access to qualified medical personnel who are familiar with PIPs and their requirements.

Please contact Ivowen Limited to discuss your particular requirements.

CERTIFICATE OF SUITABILITY (CEP)

- The European Directorate for the Quality of Medicines (EQDM) is the body responsiblefor granting CEPs to active pharmaceutical ingredients which are monographed in the European Pharmacopoeia.
- An active pharmaceutical ingredient manufacturer may apply to the EQDM for a CEP for any chemical entity which has a monograph in the European Pharmacopoeia.
- The EQDM also issues CEPs for any product with a possible associated TSE risk.
- Ivowen Limited can provide advice on how to prepare your submission for a Certificate of Suitability for your drug substance.
- Ivowen Limited can review the data that you are planning to submit to obtain a Certificate of Suitability.
- Ivowen Limited can prepare your submission for a Certificate of Suitability.

ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD)

Ivowen Limited has the following capabilities:

- Use of fully ICH compliant eCTD software.
- Preparation of fully eCTD compliant dossiers prepared from either electronic or paper source files.
- Baseline dossiers for conversion of your old dossiers to fully eCTD compliant dossiers.

REGULATORY STRATEGY

As regulatory affairs consultants, one of our prime areas of expertise is in regulatory submission strategy planning.

To market in more than one territory in the EU, a pharmaceutical company must use either the centralised or the decentralised procedures (either MRP or DCP) to register a product.

Part of the process is harmonising the generic product Summary of Product Characteristics (SmPC) across all territories, even though the originator SmPC may not be harmonised.

- SmPC Comparisons.
- Ivowen Limited can liaise with Competent Authorities prior to submission on SmPCs, reference products, quality issues, etc.
- Ivowen Limited can help your company to devise the best route for product approval in all markets in time for patent expiry.
- Ivowen Limited can advise your company on whether an application for a Paediatric Investigation Plan (PIP) is required or not. Ivowen Limited can also prepare PIPs, waivers to PIPs and PIP deferrals for your company in conjunction with clinical experts with expertise in various therapeutic areas.
- We can also advise on individual countries national requirements, such as EFG status in Spain, the MHRA SmPC fragmentation, samples for Hungary, etc.

TRAINING

In any pharmaceutical company it is the responsibility of the Regulatory Affairs department to ensure that your product has received approved Marketing Authorisations for each product in each territory on the target date. Due to the complexity of the EU system for Marketing Authorisation applications, it can take years of practice to get your staff to a level of competency to achieve this goal every time.

Ivowen Limited can provide your company with specialised Regulatory Affairs training, tailored to your specific needs. We specialise in generic pharmaceutical medicinal products and their registration and this involves an in-depth understanding of the commercial and marketing requirements of generic pharmaceutical companies.

Regulatory Affairs training is not just for your Regulatory Affairs team! Each company is a compact unit made up of interdependent departments. The success of any company rests on knowing its target markets and getting a quality product to these markets on time in a cost effective manner.

Each department in a company is dependent on each other to provide the expertise and experience necessary to achieve the company's goals.

However, this cannot be done without the input, data and support of the following departments and people:

- Patents
- Research and Development
- Analytical
- Quality Assurance
- Pharmacovigilance
- Quality Control
- Stability
- Production
- Logistics
- Sales and Marketing
- Administration

Ivowen Limited can provide Regulatory Affairs Overview Training to all interested parties. This will provide an insight into what Regulatory Affairs do, why they do it, how they do it and what they need from other departments to make it work.

Also included is comprehensive specialised training in all aspects of the EU legislation and in the MRP/DCP/CP and eCTD system for registering medicinal products in the EU, which is our speciality.

TRAINING INCLUDES:

- Full text notes including suggested wording for certain sections of the dossier
- Case studies tailored to your level of knowledge
- All relevant and current guidelines for each section

PROJECT MANAGEMENT

Project management is the process of planning, organising, and managing tasks and resources to accomplish a well-defined objective, usually within constraints on time, resources, or cost.

Ivowen Limited can offer:

- Management of development projects from initiation through to licence approval.
- Preparation of Project Plans with Critical Path, Milestones, Resource and Budget Allocation.
- Set-up and support of Project Management systems within a company.
- Liaise with experts on your behalf.

COMPLIANCE

The purpose of regulatory compliance is to provide a controlled link between documentation submitted to regulatory authorities in support of marketing authorisations and documentation that is utilised by the company's Operations/Production and QA departments. A regulatory compliance system is a formal, documented system which will ensure that the product is always manufactured and released in line with the Good Manufacturing Practises (GMP), technical agreements and currently licensed particulars. Ivowen Ltd can assist with a range of Compliance services as follows:

- Provide expert advice on the set-up of a Compliance System in your company. Moreover, we can support your new team with the Change Control Procedures that need to be implemented as part of a Compliance System.
- Prepare the necessary SOPs to manage a compliance system including the introduction of compliance audits to monitor the system.
- Review or prepare job descriptions for personnel currently involved in documentation control.
- Provide the necessary support to the compliance team by carrying out external system audits on a regular basis.
- Provide updates on all regulatory changes and developments in the EU that may impact on your company in relation to compliance.

MEDICAL DEVICES

Ivowen Limited offer the following services to the Medical Device Industry:

- Classification Strategy
- Notified Body Selection
- Technical File Preparation
- Submission/Correspondence – Meeting Attendance
- European Authorised Representative Services

We would be delighted to meet with you to discuss how we can add value to your business.

Please contact us:
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Co. Tipperary
Ireland

Ivowen Limited is:
Committed to providing expert advice on Regulatory Affairs and Project Management to the generic pharmaceutical industry, enquire here!

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