XENDO
SOLUTIONS FOR LIFE SCIENCES

CONSULTANCY | PROJECTS | INTERIM MANAGEMENT | AUDITING & TRAINING

SOLUTIONS FOR LIFE SCIENCES

BREXIT SERVICES

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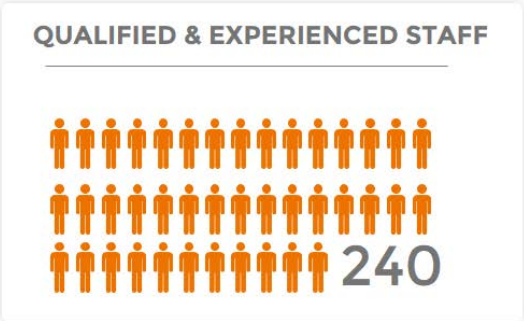
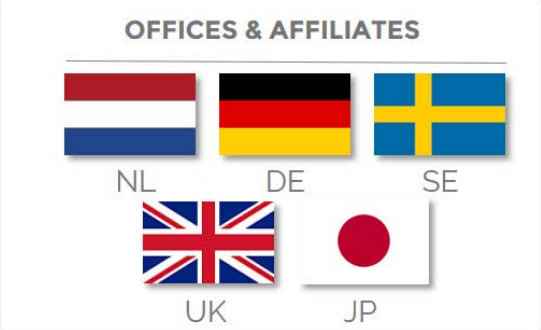
Xendo is a leading consultancy organisation in the fields of (bio)pharmaceutical products, medical devices and healthcare. Thanks to our multi-disciplinary, knowledge-driven approach, Xendo can deliver a broad palette of services to the life sciences industry, applying the right colour to projects we participate in. For over 25 years we have successfully completed thousands of national and international assignments for start-ups as well as for the largest, established multinational companies and organisations. Our 240 experienced and highly educated professionals offer their expertise ranging from strategic advice and project management to auditing, operational support and training; providing a full-colour spectrum.





OUR PALETTE OF SERVICES

- PRODUCT DEVELOPMENT
- QUALITY MANAGEMENT & LEAN SIX SIGMA
- REGULATORY AFFAIRS
- QUALIFICATION & VALIDATION
- ENGINEERING & FACILITY SUPPORT
- PHARMACO VIGILANCE

BREXIT

Besides the administrative issues at hand caused by the Brexit, there will be specific matters to be dealt with in the pharmaceutical industry. A few examples:

- need for companies to have an EU QPPV
- need for an EU local affiliate,
- change of Reference Member state/Rapporteur role if UK is the RMS or Rapporteur
- organise shipment and import of medicines from the UK to EU
- increased local responsibilities of the MHRA which have to be secured into British Law
- risks for continuity in several areas that can be compromised.

There is a definite need to look into specific matters regarding Quality Assurance, Regulatory Affairs and Pharmacovigilance; all of which are regulated in the current framework. As a leading consultant in these fields, we are offering our services to life sciences companies to make sure they are Brexit-ready.

COMPLETE SPECTRUM

The spectrum of our expertise areas is as broad as the range of clients we work for, enabling us to support the varied needs and wishes of the Life Science industry. Whether they are a (bio)-pharmaceutical or medical device company, a start-up or multi-national, a hospital or a pharmacy, a manufacturer or a laboratory, we match their colour. Thanks to the fact that Xendo is located Leiden, close to Amsterdam, we can support companies with logistic issues related to scientific advice meetings or hearings at the EMA besides our complete content-related support.

QUALITY ASSURANCE & QP

EU QP, EU GMP, IMPORT TESTING & RECERTIFICATION

Quality Assurance and the role of the Qualified Person are stipulated in EU legislation so there will be changes regarding the accompanying functions and responsibilities if the role is executed from the UK. Like most countries, the UK has some specific requirements for QPs in view of national legislation and it is most likely that this will not change on a national UK level. According to EU rule (and communicated by the EU Commission and EMA) companies who have their QP located in the UK, need to locate a QP residing in the EU (EEA) for batch release.

If there will be no mutual recognition agreement (MRA) between the UK and EU, products will be imported from the UK into the EU, where at the moment products can be distributed freely in UK and EU. Import without an MRA requires retesting and recertification of the batches. This will be a significant economic burden to pharmaceutical companies.

RELATED AREAS OF EXPERTISE

QUALITY ASSURANCE & RISK MANAGEMENT

We assist in guaranteeing quality and compliance throughout your organisation. In order to prepare for future developments following Brexit, we can support you in optimizing your Risk Management strategy in terms of quality, safety, and efficacy of your Quality Management Systems. Besides providing you with services that ensure the compliance and efficiency of your organisation, we also provide support with:

- GxP & ISO Audits
- Mock inspections
- Gap analyses
- Quality & Change management (deviations, CAPAs & complaint handling),
- Internal audits
- Supplier selection & Vendor Management
- Implementation of regulatory updates.
- Management reviews

GOOD DISTRIBUTION AND MANUFACTURING PRACTICES (GDP & GMP)

To ensure that your product is shipped and stored properly and that patients can rely on a safe and effective product, our GDP specialists help you optimise your distribution processes. They can provide you with up-op-date information regarding Brexit on the supply chain and they can support you to remain compliant under these post-Brexit circumstances. Our services also include the adoption of the role of the Responsible Person (RP).

You could say that GMP is in our genes. Many of our consultants are industry pharmacists and specialists who are familiar with the ins and outs of the applicable quality standards and can help you to design or adapt your product's quality and safety processes in order to minimise the risks involved in (bio)pharmaceutical production. We cover all aspects of the manufacturing process, from the starting materials and equipment to the training of staff and the release of your finished products by one of our Qualified Persons.

PHARMACOVIGILANCE

QPPV FUNCTION & THE LOCATION OF THE PSMF

Currently, the majority of the QPPV functions is located in the UK and, many of them will have to decide to either relocate abroad or find new employment. As stipulated by the European Commission (Article 8 of Directive 2001/83/EC & Article 74 of Directive 2001/82/EC PSMF) that:

"the QPPV must reside and carry out his/her tasks in the Member State of the Union (EEA)"

Companies and their EU QPPV have to take a strategic decision how to move forward. As a consequence, the location of the Pharmacovigilance System Master File must be brought in line with an eventual EU QPPV change and has to be in compliance with the Commission Implementing Regulation (EU) No 520/2012. Again, this will be accompanied by an administrative burden and costly fees because QPPV and PSMF details need to be updated through Article 57.

RELATED AREAS OF EXPERTISE

PV SYSTEM & EU NETWORK OF LOCAL PV RESPONSIBLES

Next to the individual PV tasks, Xendo provides the full PV system to customers including the use of the Argus database. To complete the PV system we also provide local PV services throughout the EU and ROW depending on the requirements and customer needs. Xendo's QPPVs reside both in the UK and within the EU and therefore will be able to fulfil all QPPV responsibilities for both the EU and the UK if required.

PHARMACOVIGILANCE SYSTEM MASTER FILE (PSMF)

Our experts are able to support companies with the set-up or transfer of a PSMF. We also conduct audits focussing on the PSMF as implemented by our clients. After such audits, we advise the clients on the accuracy and completeness of their PSMF and assist in the implementation of corrections and improvements.

REGULATORY AFFAIRS

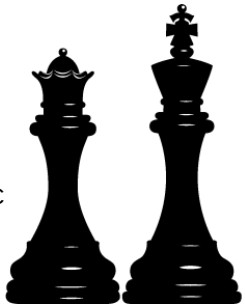
APPROVAL PROCEDURES, MARKETING AUTHORISATION HOLDERS & INTERNATIONAL COMPANIES

One area that is bound to go through an administrative ordeal is Regulatory Affairs. For about 25% of EU procedures, the MHRA is currently the (Co-)Rapporteur or RMS and simply because they will no longer be part of the EU this workload will need to be shifted to the remaining 27 countries.

All companies are recommended, for instance, to look into the transfer of EU Marketing Authorisation Holders, dertermine if there is a need for relicensing, find new (Co)Rapporteurs for existing Centralised Procedures and new Reference Member States for existing Mutual-Recognition-Procedure/DeCentralised Procedure products. All of which is most likely coupled with a huge administrative burden and accompanying costs for companies

RELATED AREAS OF EXPERTISE

REGULATORY STRATEGY & INTELLIGENCE



An overall regulatory strategy is essential for successful Brexit preparation and has the potential perspective of limiting investments in time and expenses. The procedure to follow, the regulatory environment and legal requirements are some examples of appropriate strategic considerations. We investigate historic decisions of regulatory agencies relevant to your product to anticipate on e.g. the decision which Health Authority to approach as future RMS for your products.

REGULATORY MAINTENANCE AND COMPLIANCE

The vast majority of all activities for medicinal products and medical devices relate to maintenance of existing marketing authorizations and conformity assessments and will consequently be greatly affected by Brexit. These activities have a high economic value as they are needed to assure the continuation of market access of your product. However, dealing with regulatory maintenance is often not related to the strategic regulatory focus from your regulatory team. In addition, regulatory maintenance can often result in peaks in the workload, which for many companies is already challenging to resolve in regular circumstances. In order to deal with these challenges,

Xendo can take care of your regulatory activities by means of a consolidated partnership for all maintenance activities. This would allow your regulatory affairs team to focus on other core regulatory challenges.

Results and advantages working with Strategic Maintenance Partnership:

- Dossier updated within pre-defined timelines
- Tailor-made solution to handle peaks in workload
- Efficiency through working with products in multiple countries
- Expert knowledge from consultants facilitates review of submissions
- Exchange of documents through interface
- Convenient and smooth collaboration

DATA MANAGEMENT & IDMP

Obtaining and maintaining management attention for the fact that IDMP is more than generating extra data for the regulator and realizing that it is a fundamental change to the way data are currently collected and archived, is a major challenge. Especially, with the changes due to Brexit ahead.

A great administrative burden falls upon remaining Post-Brexit EMA regulators who have to take care of the Mutual Recognition, Decentralised and Centralised Procedures for which the MHRA is currently in the lead. At the same time, the MHRA has to consider how they will migrate their own data to an IDMP environment.

Some of the major IDMP challenges are bound to be regarding efficiency and what can be achieved here; turning threats into opportunities. Our experts combine their experience from IT and business allowing them to translate technicalities into a tailor-made project to get your company Brexit-ready.

CONTACT US

For further information on Brexit developments and advice on how to prepare for upcoming changes we invite you to contact us;

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Xendo's multidisciplinary team of knowledge-driven consultants is here to get your company **BREXIT-READY**.

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