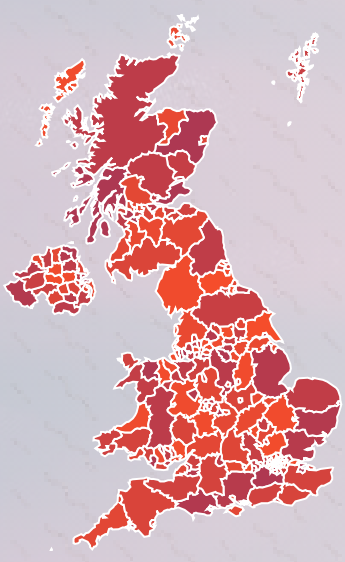
PHARMACEUTICAL CONSULTANCY SERVICES

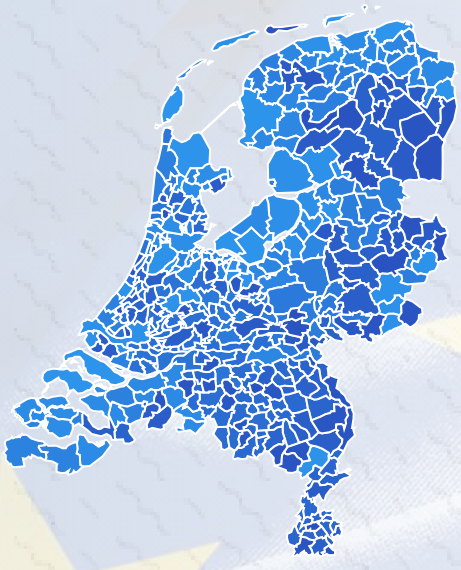
BREXIT

www.pcs-nl.com/brexit



Current political developments force British pharma companies to prepare for an uncertain future. Transferring activities to the Netherlands is an efficient and effective strategy successfully implemented by many of these pharmaceutical companies. When the Brexit negotiations have been concluded, the Marketing Authorization Holder (MAH) must be based in the European Union. Many British organization are moving their MAH to the Netherlands.

PCS (est. 1990) **is your local, Dutch partner for all Brexit preparations.** We assist British companies with MAH and PV transfers. We liaise with Dutch regulatory authorities and guide you in the submission of license applications.



The MAH is required to have a Quality Management System (QMS), including Pharmacovigilance (PV). Additionally, a Qualified Person Responsible For Pharmacovigilance (QPPV) must be based in the European Union.

1 For whom?

These services apply to the following companies (amongst others):

- British pharmaceutical organizations wanting to obtain a Dutch Manufacturing, Distribution, Controllled Drugs and Veterinary Licenses as a result of the Brexit.
- Pharmaceutical organizations that need a certified QP within the EEA.
- Pharmaceutical organizations that perform batch release and QC testing and are required to move their site(s) to the EU.
- Pharmaceutical organisations that have moved Marketing Authorisation Holder (MAH) to the EU and need a Quality Management System

2 Why?

PCS has the experience and expertise to analyse your current situation accurately and help you navigate the regulatory hurdles. Allowing you to focus on your work without being hindered by translation issues, unnecessary bureaucratic delays or confusion over the Dutch regulatory system.

Many British organisations are struggling with the Dutch regulatory inspection and licensing system. In the UK there's only the MHRA, while in the Netherlands the regulatory responsibilities are spread out over several agencies, such as IGJ, CBG-MEB and Farmatec. The links between these organisations, their requirements and functions can be confusing. PCS has been active in the Netherlands since 1990. **We know the regulatory institutions and their officers, we know the requirements and speak the language.**

We're on a clock!
Under normal circumstances the Dutch licensing authority requires 90 (ninety) days for reviewing applications. As time progresses, we expect that the amount of British companies applying for licenses will increase exponentially while the capacity of the Dutch licensing authority won't. We offer this service to help you submit your application as soon as possible without unnecessary delays.

3 Brexit Services Outline

1 Project Initiation Phase

An initial meeting between your organization and PCS to discuss your strategy, your wishes and how PCS will assist you during the transfer process.

PCS will use the information obtained during the initial meeting to map your supply chain.

With all the required information assembled, PCS will write a mitigation plan. **The PCS Brexit Mitigation Plan is your road-map to transfer your activities to the Netherlands.**

2 GAP-Analysis & Qualified Person Services

PCS will perform a GAP analysis of your GMP/GDP compliance status against EMA and Dutch regulatory requirements. Following this analysis, the Mitigation Plan will be supplemented with the results and required resources.

In case you perform batch release and QC testing in the UK, you must relocate your testing site(s) to the Netherlands. PCS will supply an **interim QP, QP training and QC laboratory guidance** if required.

3 PCS Brexit Migration Plan Implementation

Using the Mitigation Plan, the required actions for license applications are initiated and completed. PCS will liaise with local authorities to ensure the process runs as smoothly as possible. If required, PCS will adjust your QMS to reflect Dutch/EMA regulatory requirements. Additionally, PCS can supply training and QP services if not already initiated.

4 Continuous Support

Throughout (and after) your transfer of activities, PCS will offer continuous support. Our back-office can offer instant responses to queries and have a great number of tools available to help you more easily integrate into the Dutch market, **including the translation of any documents between Dutch and English.**

PCS has designated senior and junior consultants who can assist in the adjustment of your QMS through the **creation, revision or review of SOP's at low cost.** This allows you to focus your resources on the actual transfer of activities.

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