



NRS

NORPHARM REGULATORY SERVICES

“Experience Excellence”

What we offer

REGULATORY / QUALITY ASSURANCE SERVICE & USER TESTING

Assistance and advice with QA issues including

- Preparation of applications for Marketing Authorisations for medicinal products in the European Union
- Comparison 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
- Compilation of SPC/Leaflet and Mock ups
- Regulation strategy including advice on individual country requirements to ensure rapid and successful authorization of dossiers
- Translations
- Licensing of Medicinal products via the National, MRP or DCP Procedures
- Management of applications
- Submission and management of variations
- Submission and management of Renewals
- Preparation of pharmacovigilance system including preparation and compilation of all necessary SOPs
- Preparation of PSURs
- Preparation of Environmental Risk Assessment reports

Assistance with QA issues including:

- Auditing of third party manufacturers, packers and API suppliers
- Strategic advice with regard to finding the perfect manufacturing partners
- QP Release services for EU imported products

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User Testing Service

- Readability Testing and review of the package Leaflet
- Efficient service
- Fast Turnaround
- Competitive pricing

Readability testing on Package Leaflets for medicinal products is now a legal requirement as directed in EU legislation Article 59 (3) and 61 (1) of Directive 2001/83 as amended by Directive 2004/27/EC.

This states that consultation with target groups is necessary to ensure that the package leaflet of a medicinal product is legible, clear and easy to use.

Consultation with patient groups is now required for all new applications. Certain EU authorities (such as the UK and Ireland) have also set deadlines whereby all package leaflets for marketed products must be the subject of consultation with the target patient groups.

We can save you money by assessing your leaflets for suitability for Bridging Reports

- The MHRA Guidance indicates that although all Package Leaflets (PL)s must reflect the results of consultation with patient groups (user testing) not every leaflet needs to be the subject of a separate test. The said guidance infers that such PLs may be able to rely on testing applied to PLs for similar products.
- NRS will assess your package leaflet's suitability for bridging to your previously tested package leaflets thus saving you money.
- Avail of our strong regulatory and QA background.

“fast turnaround and professional service guaranteed at all times”