

# Removing New French Regulatory Burden through Document and Processing Expertise

## CASE STUDY

## ProductLife Group Takes On Template Development and Design Combined with Labelling Support

### THE CLIENT

Mylan is a United States-based company engaged primarily in the commercialisation of generic drugs. Mylan has been the leader in the generic market in France for more than 15 years.

### PROJECT SCOPE

Faced with an additional regulatory burden, Mylan turned to ProductLife Group to manage new template requirements for product information submitted in France. The requirement, issued by French regulatory authority Agence nationale de sécurité du médicament et des produits de santé (National Agency for Medicine and Health Products Safety, or ANSM), involves:

- Development of the template by using the new ANSM style sheet
- Formatting of labelling content within the template

ProductLife Group supports Mylan by supplying three data and document processing team members and four team members from the Belgium labelling platform to manage the project. The project began in late 2016 and is ongoing.

### CHALLENGES

Mylan faced a significant challenge and an additional work burden in meeting the ANSM's process requirements involving labelling documents, which require companies to provide product information in a new format. The change, which goes into effect at the end of October 2017, will require that Mylan, like all France-based life sciences companies, provide the ANSM with translations of its product information under new terms and conditions for the formatting of the new template.

Mylan needed a partner that had knowledge of and experience with the new ANSM template model, as well as expertise in the management of labelling content.

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## PROJECT DESCRIPTION

To make sure Mylan meets the requirements, ProductLife Group draws on its expert data and document processing platform team. The team formats the client's product information to the new template, ANSM 10, through a methodical process of:

- Formal document verification and processing that includes the adoption of and adherence to new styles; attention to formatting consistency; verification of the inclusion of all mandatory properties and titles; and checks to ensure the document is compliant with the required format
- Quality control processing of format and application of the new styles
- Inclusion and updating of any missing sections
- Management of any required reformatting
- Conducting of final quality control

## RISK FACTORS AND REQUIREMENTS

The company could face significant risks if its product information documents fail to meet the new ANSM requirements, including delay in the submission and, potentially, even refusal to approve the submission.

ProductLife Group has taken on much of the burden of making sure Mylan meets template requirements and submits its product information in the correct format. In addition, ProductLife Group has provided training for stakeholders to enable them to quickly solve any problems and to handle submission emergencies. ProductLife Group's development of compliance-monitoring tools also helps keep the company's product information template processes compliant.

## CUSTOMER BENEFITS

By turning to ProductLife Group for the management of ANSM requirements, Mylan took advantage of experts in the areas of the creation and formatting of complex templates as well as an experienced labelling team that ensured that content got updated accurately and thoroughly.

ProductLife Group's expertise assures the client that its product information documents meet the requirements and will not be at risk of rejection. In addition, the automation tools developed by ProductLife Group safeguard formatting consistency in the future—and without the need to revisit document processing, formatting, and quality control.

## PRODUCTLIFE GROUP SUCCESS FACTORS

ProductLife Group's teams of data and document processing and labelling experts have taken on the ANSM template burden for Mylan, thereby freeing Mylan's regulatory team to focus on other time-consuming activities.

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ProductLife Group specialises in helping international life sciences organisations more effectively get their products and therapies to market by providing those clients with functional support across all of the regulated stages of the product life cycle—from development to launch, to postmarketing.

Performing successfully for more than 20 years, ProductLife Group has an established global presence in Europe, the Middle East, Asia Pacific, Africa, Latin America, and North America. We deliver services via an innovative, platform-and-hub operating model, enabling our clients to achieve continuous improvement, increased quality, enhanced performance, reduced risk, better compliance, and overall cost benefit. That approach, combined with our collaborative, partnership-oriented culture, empowers life sciences organisations to realise the commercial potential of their own international operations.