

## Success Story: Billev Pharma ApS

### Billev Pharma is READY! for Article 57

Billev Pharma needs to be on the forefront to provide the best regulatory services for their clients. This is the reason why Billev Pharma is now among the first in the pharmaceutical industry to provide services including collecting, managing, and submitting data to the EMA according to Article 57 by using READY!



**Peter de Mayo Billev, M.Sc. Pharmacy:**

"Billev Pharma is working in a very complex environment. With our many years of experience in this field, constantly developing, we cover most areas of the pharmaceutical sphere such as human medicines, veterinary vaccines, herbal medicines and clinical trial applications. With READY! we are staying at the forefront of finding ways to comprehensively help our clients."

### How is Billev Pharma using READY! ?

Billev Pharma has a large number of clients and they work hard to provide them with services in all regulatory procedures as well as in pharmacovigilance. This environment is very complex to manage, also, they have to provide their clients with up-to-date information about the status of their products, activities and regulatory documents.

They finished the implementation of READY! in July 2011. Since then they have stored regulatory information in READY!. The solution is helping them to manage information about products, regulatory activities, tracking electronic submissions and safely archiving documents. They also use READY! for time registering to be able to produce monthly reports for invoicing.

READY! has recently been upgraded to be in line with the Article 57 requirements. The transition was easy, as Nanokinetik has upgraded the database part of the solution to include additional information as required by the EMA. **READY! is now a complete solution for managing regulatory processes. As a result of using READY! Billev Pharma has gained higher productivity, compliance and the ability to manage Article 57 submissions to the EMA on behalf of their clients.**



**Ulrikke Lynge Jensen, M.Sc. Pharmacy:**

"READY! has become an integral part of our business. We can easily access all information about products, documents and regulatory activities. The solution is very user-friendly, and our staff likes using it. It is helping us to organize and plan our activities, and enables us to be compliant with regulations, including Article 57."

### About Billev Pharma

*Billev Pharma ApS was established in 1978 as a consultancy providing services in Regulatory Affairs. As Regulatory Affairs have become more diversified it has been important to create a staff with broad experience in all aspects of the field from classical pharmaceutical knowledge of product quality to biochemistry, pharmacovigilance and language skills.*

*Over the years, Billev Pharma ApS has been at the forefront in providing assistance with all new types of applications. Starting with pure national applications all over Europe to concertation, MRP to DCP and now e-CTD and Article 57.*

*Billev Pharma has always helped their clients both in the difficult initial phases of these procedures through to more routine phases later on. In 2007 Billev Pharma established an office in Ljubljana, Slovenia, in order to help our clients obtaining authorisations at a higher speed in this part of Europe. Over the years Billev Pharma has built a network with local experts around Europe enabling them to cover all known, as well as unforeseen, problems of national and global character.*

**Billev Pharma ApS**

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