



# Safety of Herbal Products

**phy** | **guard**  
Guarding the Safety of Herbal Products

# Guarding the Safety of Herbal Products

PhytoLab has been providing professional services relating to the development, marketing authorisation and analysis of herbal health products for more than 10 years now. Our activities have been focussed on one main objective right from the beginning, and that is ensuring maximum safety and security for our customers' products. Today, more than 400 companies in the pharmaceutical and food industries trust in the expertise and capabilities of PhytoLab, one of Europe's leading laboratories.

**phyguard** is a unique PhytoLab product safety and security package that is tailored to the needs of your products and includes:

- R&D consulting
- Pharmacovigilance
- Benefit/risk assessment
- Periodic Safety Update Reports (PSUR)
- Expert reports

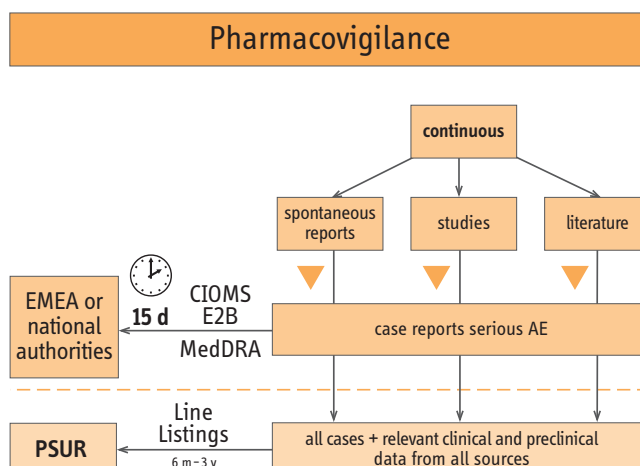
## R&D consulting – Safety first

“Safety first” is the key phrase for the development of new products as far as PhytoLab is concerned. At the very beginning of a project, our experts sift through the more than 30.000 titles that make up our library and search the scientific online databases for any information which may be relevant to the safety of your product, identifying potential risks according to contaminants, adulterants or toxic compounds. PhytoLab makes sure that risk management already begins during the development phase of your product. We can also coordinate toxicological or pharmacological studies on your behalf, in cooperation with acknowledged GLP-accredited laboratories.

## Pharmacovigilance

Like all drugs and medicines, herbal medicinal products (HMPs) have to comply with the requirements of European pharmacovigilance directives and regulations. Regular international bibliographic research, MedDRA encoding of adverse drug reactions, electronic reporting of cases to competent authorities and Periodic Safety Update Reports (PSURs) constitute the key factors for compliance with these requirements. Keeping abreast with pharmacovigilance regulations is a challenging goal for medical and regulatory experts and last but not least the quality assurance (QA) personnel.

A competent medical assessment of drug safety information is just as essential as formal compliance with regulations and directives, however, and a proper assessment of HMPs requires a sound knowledge of the specific aspects of herbal quality. PhytoLab builds on a unique combination of medical and phytopharmaceutical excellence to provide you with an in-depth evaluation of the scientific and regulatory aspects of any information that may be relevant in terms of the safety of your products.



## **Benefit/risk assessment**

The right balance between benefits and risks is the very basis of every medicinal product. But science changes and so might the assessment of the benefits or risks associated with your product. In an increasingly stringent regulatory environment with greater competition in the markets, the importance of product-specific safety and efficacy data is growing all the time. Based on an in-depth benefit-risk assessment we identify the potentials of your products and can coordinate safety and efficacy studies in cooperation with acknowledged institutes and leading experts.

## **Periodic Safety Update Reports**

Now that the review of European pharmaceutical law has been fully implemented, Periodic Safety Update Reports (PSUR) have gained crucial importance in the regulatory life cycle management of herbal medicinal products. While ongoing pharmacovigilance focuses on adverse events from case reports or clinical studies, the PSUR encompasses preclinical data, e.g., on genotoxicity, as well. PhytoLab either compiles your herbal PSUR on the sole basis of bibliographic references or includes your proprietary data from studies and spontaneous reporting.

## **Expert reports**

Every marketing authorisation application for a herbal medicinal product requires a Common Technical Document (CTD), irrespective of the application level – full, bibliographic or traditional. PhytoLab offers you clinical and pre-clinical CTD modules and formulates the wording of the Summary of Product Characteristics (SPC) and printed packaging materials. In the event of legal disputes with the authorities or competitors, PhytoLab's officially recognised experts will put their regulatory and scientific excellence at your disposal.

For food products containing herbs or herbal preparations the scientific substantiation of safety and claims is gaining increasing attention from regulators and consumers. PhytoLab is an accredited laboratory according to ISO 17025 and 93/99/EWG and is prepared to handle all questions relating to the safeguarding of herbal food and food supplements.

PhytoLab GmbH & Co. KG  
Dutendorfer Straße 5 - 7  
91487 Vestenbergsgreuth  
Germany  
Tel.: +49 9163 88-216  
Fax: +49 9163 88-456  
[welcome@phytolab.com](mailto:welcome@phytolab.com)  
[www.phytolab.com](http://www.phytolab.com)