

# Regulatory Affairs for Herbal Products

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Admission to the health market for herbal medicinal products or food is subject to many complex statutory requirements and demands highly specialised know-how. With more than 15 years of successful experience in this field, PhytoLab can offer you comprehensive support throughout the marketing authorisation and registration procedures for herbal medicinal products and homeopathic medicines, and assistance in all regulatory aspects of herbal health products. We can help you to draw up the right strategy for a successful registration process and develop concepts for the validation of existing products on your behalf.

phyreg® enables us to be a reliable partner for you with respect to all regulatory issues relating to herbal medicinal products and foodstuffs.

- National and EU procedures
- Project coordination
- Individual dossiers
- Life Cycle Management

## National and EU Procedures

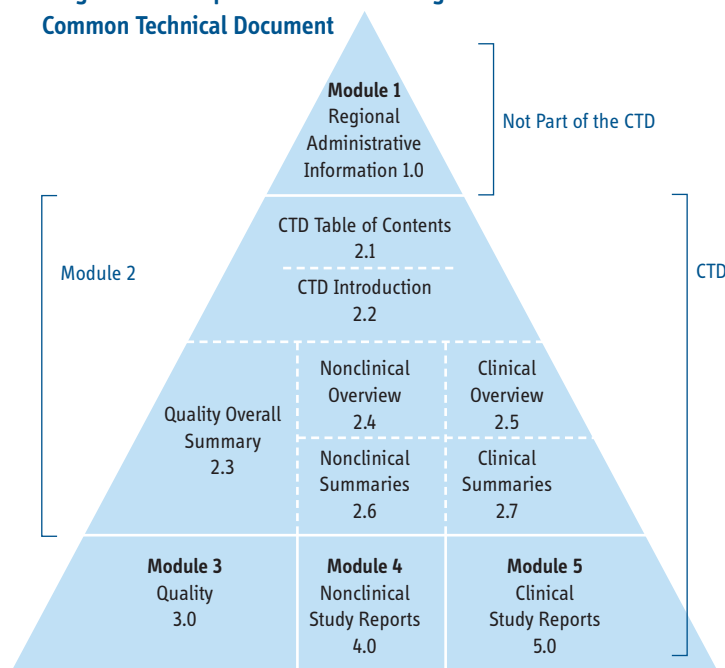
Irrespective of whether you want to register a medicinal product just in Germany or throughout the EU, whether you are aiming to register a drug on the basis of „well-established use“ or as a traditional herbal medicinal product, or you wish to apply for an attractive claim for your plant-based food supplement: PhytoLab offers you the support you need.

In EU procedures, choosing the right Reference Member State (RMS) can be just as crucial as exact scheduling. Important aspects should be reconciled in scientific advice procedures with the responsible authorities within the framework of Mutual Recognition Procedures (MRP) or Decentralised Procedures (DCP) during the preliminary stages, particularly where phytopharmaceuticals are concerned.

We offer comprehensive assistance with respect to preparing for this scientific advice, as well as conducting it and following it up. Relating to traditional herbal medicinal products, Directive 2004/24/EC (THMPD) offers a means of remarketing formulations in long-standing use. It does stipulate, however, that evidence of the quality, safety and traditional use of the

herbal medicinal products must be provided. We verify the registration capability of your products on your behalf. Based on our extensive pool of reference literature and product-specific research, we compile documentary evidence of traditional use and join forces with our medicinal scientists to document the plausibility of your products' efficacy.

## Diagrammatic Representation of the Organization of the CTD Common Technical Document



Nowadays, nutrition is much more than merely the ingestion of food. Health related and disease risk reduction claims in connection with food have therefore been regulated by the European Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods. The members of our team of food chemists and nutritional scientists advise you on all issues concerning the laws relating to food, draw up expert opinions and help you with applications for health or risk reduction claims.

#### **Project Coordination**

We have been supporting our customers throughout all phases, from the idea for a product right through to the registration process, for more than 15 years now. We can offer you advice on choosing the right raw materials, establish contact with suitable contract manufacturers, coordinate the production and storage of stability batches and network all of the parties concerned to ensure that your projects run smoothly from start to finish. You can therefore be certain that all registration documents are ready on time and that deadlines imposed by the authorities are met. If you wish, we can also assume responsibility for the entire planning, scheduling and coordination of your registration projects.

#### **Individual Dossiers**

PhytoLab does not supply dossiers „off the peg“. The dossiers that we prepare on your behalf are tailored to the specific characteristics of your individual products. They are exactly tuned to your needs and reflect both the regulatory requirements and the current state of the art in scientific terms. The Common Technical Document (CTD) has been the mandatory format for all marketing authorisation and registration applications for medicinal products since 2003. It is not always necessary to reformat the dossiers of drugs which have already been registered, but we do recommend that they should be adjusted in accordance with the latest requirements in the event of any major changes. We can draw up complete dossiers or individual CTD modules for you as required. We also take your individual layout specifications into consideration.

#### **Life Cycle Management**

Registration is just one of the many stages in the life cycle of your product. There is still much to be done after successful registration and marketing authorisation: requirements must be met, extension deadlines observed, Periodic Safety Update Reports (PSUR) must be initiated and submitted on time. Variations of testing procedures, packaging materials, the package leaflet or long-term stability must be recorded in the CTD and communicated to the responsible authorities by means of variation procedures. PhytoLab supports you in the maintenance and updating of your registrations and marketing authorisations, taking a weight off your shoulders by offering reliable deadline control and tracking. We give you advance notice of new laws and changes to statutory requirements and help you to plan the measures in order to safeguard the long-term marketability of your products.

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