LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guidelines on applications for authorisation to conduct toxicological and pharmacological trials for the purpose of assessing the safety of medicines (non-clinical trials)

These guidelines describe how to complete the form for application for authorisation to conduct toxicological and pharmacological trials for the purpose of assessing the safety of medicines (non-clinical trials).

Any company conducting toxicological and pharmacological trials for the purpose of assessing the safety of medicines (non-clinical trials) must be authorised by the Danish Medicines Agency, cf section 85(1) of the Danish Medicines Act.

In the following, we will refer to this type of company authorisation as a "non-clinical trial authorisation".

For information on general requirements and guidelines for application for a company authorisation, please see Guidelines on requirements and deadlines for applications for company authorisations.

For requirements to conduct toxicological and pharmacological trials for the purpose of assessing the safety of medicines (non-clinical trials), see the Danish executive order on good laboratory practice for medicinal products (in the following referred to as the GLP executive order), in Danish titled: "Bekendtgørelse om god laboratoriepraksis for lægemidler".

General guidance on the application form
In the sections below, you can find information on how to fill out Annex 1-6 of the application form.

General remarks on Annex 1
Please be aware that Annex 1 is site-specific. Therefore, the applicant must complete Annex 1 for each site conducting non-clinical trials. Specify the address of the relevant site at the top of Annex 1. In Annex 1, all activities carried out on the address must be specified.

Annex 1
Here the activities performed by the company must be indicated. The relevant items 1.1-1.9 are ticked.

Under Annex 1, the details below must furthermore be provided as relevant:

- The product types within the pharmaceutical area the company is testing (e.g. chemical or biological products, animal feed, etc.)
- Whether the company is safety testing other products than medicinal products (with a view to future marketing of medicines)
- Any other clarifying remarks

Annex 2
Annex 2 must be completed if the company has outsourced non-trial specific activities, e.g. archiving or quality assurance. The company must indicate which activities have been outsourced as well as provide the names and addresses of all companies to which tasks have been outsourced. A copy of the signed contract must be enclosed with the application pursuant to section 4(4) of the GLP executive order.

Annex 3
In Annex 3, the applicant must indicate who the company's responsible manager is. The title of the responsible manager must be stated in Danish and English.

Annex 4
In Annex 4, the name of the person responsible for the Quality Assurance Program must be provided. The responsible person for the Quality Assurance Program should be independent of the trials carried out by the company. When applying for a new responsible person for the Quality Assurance Program a CV for the candidate listing relevant practical experience, relevant courses etc. and the organisation chart for the company should be included. The responsible person for the Quality Assurance Program is expected to have practical and/or theoretical experience in the area.
If a contract has been entered into with an external party, the company must enclose a copy of the contract signed with the external party pursuant to section 4(3) of the GLP executive order.

Annex 5
Here the company must provide the name of the person responsible for the archive where the test documentation is retained. The responsible person for the archive should be independent of the management, the Quality Assurance Program and the trials carried out by the company. When applying for a new responsible person for the archive a CV for the candidate listing relevant practical experience, relevant courses etc. and the organisation chart for the company should be included. The responsible person for the archive is expected to have practical and/or theoretical experience in the area.
If a contract has been entered into with an external party, the company must enclose a copy of the contract signed with the external party pursuant to section 4(3) of the GLP executive order.

Annex 6
Here, the names of all study directors must be provided. Study director means the individual responsible for the overall conduct of the non-clinical health and environmental safety study. If contracts have been entered into with external parties, the company must enclose a copy of the contracts signed with the external parties pursuant to section 4(3) of the GLP executive order. The company can also attach a list of study directors as an appendix.

Special notes on applications to change an authorisation
If a company has changes to the contents of an application, it must be approved by the Danish Medicines Agency before the company is allowed to implement them in practice. However, standard operation procedures and the list of study directors may be changed without the authorisation of the Danish Medicines Agency.

Additional material to the application
When an application for a **new authorisation** for non-clinical trials is submitted, the following materials should be attached to the application:

- facility floor plans (or mark-up of affected buildings)
- a list of the most essential standard operating procedures
- Organisation chart
- Copy of contracts for Annex 2, Annex 4, Annex 5 and Annex 6
- CV listing relevant practical experience, relevant courses etc. for the person responsible for the Quality Assurance Program
- CV listing relevant practical experience, relevant courses etc. for the person responsible for the archive

When an application to **change an existing authorisation** is submitted, these documents are only to be enclosed if they have changed significantly.