

Consolidated version of

## **Swedish Board for Accreditation and Conformity Assessment's (SWEDAC) Regulations (STAFS 2008:4) on the introduction of the OECD principles of Good Laboratory Practice (GLP)**

With amendments up to and including STAFS 2014:11

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### **Scope**

**Section 1** These regulations apply to bodies that are already approved or are applying to be approved as GLP laboratories by SWEDAC. Such bodies perform or intend to perform non-clinical studies in accordance with the principles of Good Laboratory Practice (GLP). The studies will be used as the basis for safety assessments. *(STAFS 2014:11)*

### **Definitions**

**Section 2** The definitions set out in the regulations (1991:93) on the introduction of the OECD principles of Good Laboratory Practice apply in these regulations.

### **Requirements for approval**

**Section 3** A body that wishes to be approved as a GLP laboratory must submit a written application to SWEDAC.

**Section 4** A GLP laboratory must comply with the requirements of Annex 1 of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances<sup>1</sup>.

**Section 5** A GLP laboratory that contracts a phase of a GLP trial to another laboratory must ensure that it is also approved as a GLP laboratory.

### **Inspection**

**Section 6** *has been repealed by (STAFS 2014:11).*

**Section 7** Inspection of a GLP laboratory normally takes place with two-year intervals. Additional targeted inspections may be initiated by the relevant authorities.

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<sup>1</sup> (OJ L 50, 20.2.2004, p. 44–59, Celex 32004L0010).

**Section 8** A GLP laboratory is required to assist SWEDAC in its inspection.

### **Revocation**

**Section 9** If a GLP laboratory no longer meets the requirements in these regulations, approval as a GLP laboratory will be withdrawn.

### **Other provisions**

**Section 10** *has been repealed by (STAFS 2013:12).*

**Section 11** SWEDAC may, in individual cases and if there are special reasons, grant exemptions from the application of these regulations.

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STAFS 2008:4

These regulations come into force on 1 July 2008, when the Board's regulations (STAFS 1999:6) on the introduction of the OECD principles of good laboratory practice (GLP) shall cease to apply.

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STAFS 2013:12

These regulations come into force on 1 January 2014.

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STAFS 2014:11

These regulations come into force on 1 January 2015.