SCHEDULE 3

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

PART 5

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SERA

8. Without prejudice to any other requirements to keep records, the licence holder shall keep the following durable records relating to the production of sera readily available for inspection by a person authorised by the licensing authority, and shall ensure that those records are not destroyed for a period of five years from the date when the relevant production occurred—

(a) as to the cultures used—

(i) the source from which the culture was obtained,

(ii) the nature of the material from which the culture was isolated,

(iii) the date of the isolation, and

(iv) evidence of the identity and specificity of the culture;

(b) as to the procedure used in the immunizing of animals—

(i) the method of preparing the culture or antigen used for immunization,

(ii) the dosage and methods employed in administering the culture or antigen, and

(iii) the time in the course of immunization at which blood is withdrawn for preparation of the serum; and

(c) the results of any tests which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulations revoked by S.I. 2012/1916 Sch. 35