

Technical Bulletin

Certification of Suitability

European harmonization efforts began more than 25 years ago and entailed all facets of business, commerce, trade and the manufacture of products, including medicinal products. Bringing together the requirements of the 29 member countries for the approval of a medicinal product proved to be one of the most difficult parts of harmonization. The objective of the Council of Europe Public Health Committee (CEPHC) was to establish standardization by which to unify approval of medicinal products for marketing in Europe.

In 1993 the CEPHC adopted a procedure for the Certification of Suitability (CoS) of monographs of the European Pharmacopoeia. Prior to the European Commission's resolutions which created CoS, drug manufacturers wishing to market product in Europe faced the arduous task of obtaining approval from each individual country, and each country had its own ideas about what constituted sufficient quality, safety and efficacy. The certification process standardized the definition of sufficient quality, safety, and efficacy of a substance and deemed it suitable for use in medicinal products.

Unfortunately, in the interim, the discovery of Bovine Spongiform Encephalopathy (BSE), and the epidemic that ensued, further complicated the standardization effort with regard to medicinal products. As our knowledge of BSE grew, our understanding of the mechanism by which it occurred increased. We also became aware of other similar manifestations of the disease in humans and other animals. To encompass all forms of the affliction the term Transmissible Spongiform Encephalopathy (TSE) is now used.

In regard to BSE/TSE risk in medicinal products, the divisions between individual European country requirements were even more dramatic and constantly changing.

The CEPHC therefore amended the CoS resolution to specifically address the growing TSE concerns. The Council combined two existing guidelines and made them into a new form of the resolution. Because of the new resolution, information formerly provided by SAFC Biosciences in the form of questionnaires was no longer sufficient for our customers' needs. The resolution now requires the submission of a complex dossier with expert reviews.

The lengthy process of dossier submission and approval benefits SAFC Biosciences' customers in many ways. Once a CoS is gained, the product is said to have been assessed for the possible risk of contaminating medicinal products with TSE. The risk has been determined to be low enough that the product is acceptable for pharmaceutical manufacturing use in Europe. The dossier information provided by a submitting company details procurement, cleaning, processing, testing, auditing and traceability of said product. It is this precise detail that enables the reviewers to make an assessment. CoS approval covers 29 member countries of the European Union. The cost of not providing a CoS to our clients could mean losing the European theater for product sales.

SAFC Biosciences is pleased to announce that it has been granted Certificates of Suitability for many of our serum products.

To obtain a copy of a desired certificate or for more information about this subject or other SAFC Biosciences' products and services, please contact Technical Services.

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