



BSI Standards Publication

Biotechnology — Ancillary materials present during the production of cellular therapeutic products

Part 1: General requirements

National foreword

This Published Document is the UK implementation of [ISO/TS 20399-1:2018](#).

The UK participation in its preparation was entrusted to Technical Committee BTI/1, Biotechnologies.

Attention is drawn to the fact that during the development of [ISO/TS 20399-1:2018](#), the UK committee voted against its approval.

The UK committee recognizes the advances made through the development of the ISO/TS 20399 series. However, in the opinion of the UK committee, there remain concerns relating to potential misunderstanding and limitations caused by the introduction and use of certain terminology in this document regarding the risk assessment of ancillary materials.

The UK committee advises users to be aware that, while it believes the meanings to be effectively the same, the term 'raw material' (RM) – rather than the term in this document, 'ancillary material' (AM) – is more consistent with terminology used by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The UK committee notes that raw materials are an integral part of any manufacturing control strategy and that to what degree raw material quality needs to be controlled, and how critical any one raw material is, can differ considerably from product to product. The UK committee also notes that the principle of selecting appropriate-quality raw materials does not differ between cell-based products and other medicines; it is the risk assessment that is distinct.

Furthermore, the UK committee notes that this document makes no reference to specific qualities or features of raw materials, the understanding of which would be necessary – in the UK committee's opinion – in order for users to undertake a risk assessment. It is also the UK committee's opinion that the document does not contain any specific recommendations for addressing risks arising from adventitious agents from standard raw material treatments that can impact the raw material's quality.

The UK committee believes that the introduction of the term 'animal-derived component free' (ADCF), and the use of multiple levels of ADCF (see Subclause 5.2.2), poses the potential risk that a user may not ask appropriate questions about the source of a raw material in cases where a supplier claims that the raw material is compatible with, for example, ADCF level 1. The UK committee believes that this document has potential limitations through suppliers not using terminology consistently and thereby introducing an unacceptable level of risk to both manufacturers' investment and patient safety.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Part 1: General requirements

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Partie 1: Exigences générales



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