

A wealth of new data compiled in a single source

Viral Safety and Evaluation of Viral Clearance from Biopharmaceutical Products

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Assurance that biopharmaceuticals do not contain unwanted infectious agents is a vital safety consideration in the use of these products. This can only be ensured by careful screening of the cells and other materials used in their production, and subsequent testing of the final product.

This publication reports the proceedings of an international conference which focused on the methods of how to avoid contamination of cell cultures with virus during the production process of biologicals, with the aim of providing harmonised guidelines to ensure product safety. Scientists from industry and regulatory agencies present updates on the current state of knowledge about assays for viral contamination and procedures for inactivation and removal. Risks associated with the processing of biopharmaceuticals are identified, and data on the actual experiences of testing and industrial laboratories are presented and discussed in the context of the clinical setting. Drawing together a wealth of new data, this book will be essential reading for all scientists concerned with the development, production and quality control of biopharmaceutical products.

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