Animal Sera, Animal Sera Derivatives and Substitutes Used in the Manufacture of Pharmaceuticals: Viral Safety and Regulatory Aspects

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This publication provides an up-to-the-minute account of current practices and policies concerning the use of animal-derived products in the manufacture of biopharmaceuticals.

For the first time, different views and concerns of pharmaceutical industries, academic experts, suppliers of serum and other animal products, and the relevant regulatory agencies are described in one single volume. It focuses mainly on current perceptions of the risks posed by contamination of biopharmaceuticals with viruses or other infectious agents from animals and how these risks can be managed. Issues covered include all aspects of the supply chain from animal management through sourcing, collection and processing of animal products to the latest technology for the detection and inactivation of contaminating agents. Approaches towards the elimination of animal products from the manufacturing process are also examined.

This book succeeds in clarifying many of the technical and regulatory questions surrounding the use of animal products. Professionals concerned with sourcing raw materials, process development, quality assurance and control and regulatory affairs will find it a valuable reference and a great help in dealing with the special challenges posed by these materials.

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