Medical devices with materials of animal origin needing special attention

knoell

worldwide registration

Take advantage of our team of experts in the field of "risk assessments on medical devices manufactured utilizing materials of animal origin" according to MDR (EU 2017/745), EN ISO 22442-1, US FDA guidance and recent standards for China.

Our service at a glance

- Assessment of zoonosis risks caused by viruses, bacteria, parasites, molds, yeasts, transmissible spongiform encephalopathy (TSE) causing agents
- Assessment of supply chain and manufacturing process with regard to
  - zoonosis risk,
  - cross contamination and
  - inactivation of pathogens
- Study concept management and study monitoring for inactivation studies
- Risk analysis and evaluation of mitigation measures
- Systematic search and review of available data (e.g. scientific literature, governmental data) including regular updates
- Training on zoonosis risk assessments

Founded in 1996, knoell is an independent global service provider for biocides, chemicals, cosmetics, crop protection, food contact materials, medical devices and veterinary medicine with sites in Europe, Asia and the Americas.
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