knoell

MEDICAL DEVICES

BIOLOGICAL EVALUATION WITH CHEMICAL & TOXICOLOGICAL CHARACTERISATION



Strategies for assessing biological safety of your medical devices



The product range of medical devices is very broad. From wound dressings, via dental materials, respiratory devices to long term implants – whatever device you have, we will support you to get it safely on the market.

Take advantage of our range of services

- Compilation of a biological evaluation *plan* Material characterisation, data gap analysis, strategy development, testing recommendations
- Study concept management and study monitoring
 Testing for extractable/leachable substances, biological testing
- Compilation of a biological evaluation *report* Toxicological risk assessment of extractable/leachable substances, conclusion on the biological safety
- Zoonosis risk assessment for materials of animal origin
 Manufacturing process investigation, literature search for relevant pathogens, conclusion on zoonosis risk



Think globally, act locally. Contact us: meddev@knoell.com