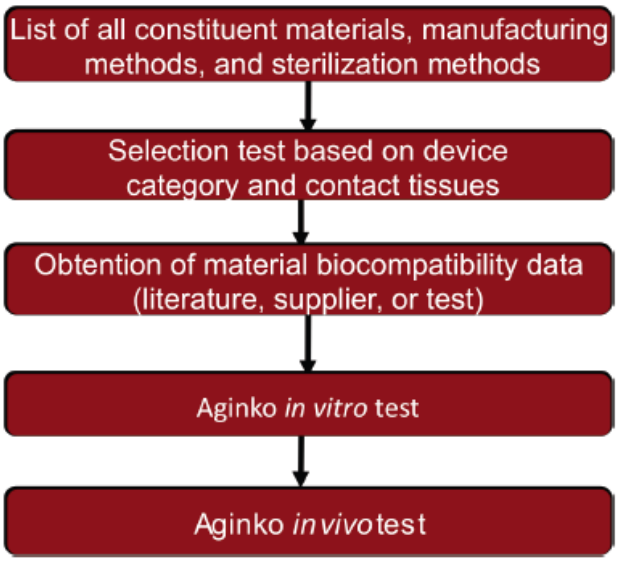
AGINKO Research

Biocompatibility Testing

European and North American standards for biocompatibility testing are similar but not identical. European requirements are based on ISO 10993. The US FDA has substantially adopted ISO with some differences in specific testing requirements. For tissue and bone implants, including engineered tissues and scaffold, a series of evaluation tests are required to assess biological effects. All testing in support of regulatory submissions must meet GLP standards.

Test	ISO	FDA	Description
Cytotoxity	x	x	In vitro assay
Sensitization	x	x	Murine local lymph node assay (LLNA), Megnuson-Klingman test
Irritation	x	x	Intracutaneous injection of test material
Systemic Toxicity	x	x	
Acute (<24h)			Intravenous Rabbit endotoxin and pyrogen test
Subacute Subchronic (more than 24h and less than 10% of animal lifespan)			Intravenous Intraperitoneal Single or multiple exposure
Chronic (>10% animal lifespan)			Supplemental test
Subchronic Toxicity	x	x	IP dosing, long follow-up
Genotoxicity	x	x	Ames test, Chromosomal Aberration Assay, Mouse Micronucleus Assay
Implantation	x	x	Test for local effects after implantation
Carcinogenicity	x	x	Supplemental test
Biodegradation	x	x	



Preclinical Research Testing Services

AGINKO Research AG
Route de l'Ancienne Papeterie
1723 Marly - SWITZERLAND - Email: welcome@aginko.com -Tel: +41 31 331 76 79 - Fax: +41 41 560 80 53