PHASE 3 ~ DESIGN FOR MANUFACTURING

Deliverable 12 ~ Biocompatibility Evaluation

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable12

INSTRUCTIONS. Complete a biocompatibility evaluation for your device. Your evaluations are due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

Purpose

The Food and Drug Administration (FDA) uses a range of biocompatibility test data to evaluate medical devices before clearing or approving them for marketing. An *initial biocompatibility evaluation identifies: 1) issues that need to be addressed to qualify a "new" device and 2) some of the non-clinical tests which may be used* to document the device's safety, effectiveness, and clinical utility before submission to the FDA.

The biocompatibility evaluation will be used later in the regulatory review (a phase 5 deliverable) and in a master file (i.e., set of documents providing detailed information on manufacturing protocols and procedures) for the preparation of premarket approval applications (PMAs), investigational device exemption (IDE) applications, or premarket notifications (510(k)).

Critical Information

Biocompatibility evaluation involves the ***full characterization of all device materials in contact with tissue and/or body fluids***. To accurately identify these materials, the material specifications from the manufacturer, and qualitative and quantitative information concerning all constituent materials used in the manufacturing should be provided.

Note, a biocompatibility statement is useful only when it is considered in the proper context. A statement such as "propylene is biocompatible" lacks precision and can lead to misunderstanding. ***Any statement of biocompatibility should include information on the type of device, intended conditions of use, degree of patient contact, and the potential of the device to cause harm***. You should ***avoid using the term "biocompatible"*** without clearly identifying the environment in which it is used and any limitations on such.

Biocompatibility is generally demonstrated by testing device materials, and their leachable chemicals, using toxicological principles. Biocompatibility testing may not be necessary if a material has a long history of use in currently marketed devices. If there is sufficient knowledge about the biocompatibility/toxicity of every constituent of the device, then it need not be subjected to further biocompatibility tests. However, ***you need to provide sufficient evidence to establish that further biocompatibility testing is not necessary***. You may submit information and data available in publications or from other legitimate sources which show that the material is non-toxic in biological tests.

If a device or its materials are found to be NOT biocompatible, you should attempt to find an alternate material that is.

An important principle in the safety assessment of medical devices is that a ***material that was found to be safe for one intended use in a device might not be safe in a device intended for a different use***. Accurate characterization is an essential step in selecting a material for a medical device

Biocompatibility Evaluation: A Step toward FDA Regulatory Review

The biocompatibility evaluation should address the following points:

- A general description of the device and its intended use
- Degree of body contact
    - Noncontact (direct or indirect
    - Surface device (skin, mucosal membranes, breached or compromised surfaces)
    - External communicating device (blood path indirect, tissue/bone/dentin communicating, circulating blood)
    - Implant device (tissue/bone, blood)
- Duration of body contact
    - Limited (< 24 hours)
    - Prolonged (24 hours - 30 days)
    - Permanent (> 30 days)
- The chemical nature of the constituent materials for contact
- A review of available biocompatibility data for each material component
- A justification for the tests conducted to evaluate biocompatibility
- Previous clinical experience with each material—including their relevance to the safety evaluation of the current device—should be discussed

It is essential that all factors be fully documented.

Biocompatibility evaluation forms the basis for understanding the composition of your medical device and its potential for an adverse biological effect when the device is put into use. This document should ***provide sufficient information to allow evaluation of the potential success of your medical device, at least with regard to its biocompatibility properties***.