NOTES:

1. This working document is intended to be utilized when assessing the requirements of the Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program. Findings related to this program shall reference the Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program requirement only with a notation to the specific GLP requirement. Any findings related to GLP should be reported to PJLA headquarters to communicate with the FDA.

2. Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist.

3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.

4. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.

5. Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."

6. If, at any time, the assessment team requires assistance in the interpretation of the requirements, contact the PJLA office immediately.

Organization Name:	
Address:	
Telephone:	
E-mail:	
Web Address:	
Assessment Location (If different):	
Assessment Number:	
Assessment Date:	
Assessors(s):	

Assessment	Yes	No	Comments/Policy/Record
Testing Facility Management 21 CFR 58.31			
Are there procedures in place for management to show appropriate responsibilities and involvement in the following areas:			
A) Assigning and replacing study directors			
B) Control of study director workload (use the Master Schedule to assess workload).			
C) Establishment and support of the Quality Assurance Unit (QAU), including assuring that deficiencies reported by the QAU are communicated to the study directors and acted upon.			
D) Assuring that test and control articles or mixtures are appropriately tested for identity, strength, purity, stability, and uniformity.			
E) Assuring that all study personnel are informed of and follow any special test and control article handling and storage procedures.			
F) Providing required study personnel, resources, facilities, equipment, and materials.			
G) Reviewing and approving protocols and standard operating procedures (SOPs).			
H) Providing GLP or appropriate technical training			
Objective Evidence for this area of compliance should be presented in the form of a organizational chart highlighting the roles and responbilities of staff onsite and offsite of the testing facility.			
Study Director 21 CFR 58.33			

Assessment	Yes	No	Comments/Policy/Record
What is the study directors involvement in the study and testing on a day to day basis?			
Is the study director immedently informed of any problems that may effect the integrity or quality of the lab activities?			
Are there procedures in place that include the following:			
1) The study director assures the protocol and any amendments have been properly approved and are followed?			
2) The study director assures that all data are accurately recorded and verified?			
3) The study director assures that data are collected according to the protocol and SOPs?			
4) The study director documents unforeseen circumstances that may affect the quality and integrity of the study and implements corrective action?			
5) The study director assures that study personnel are familiar with and adhere to the study protocol and SOPs?			
6) The study director assures that study data are transferred to the archives at the close of the study?			
Quality Assurance Unit QAU 21 CFR 58.35			
Does the test facility has an effective, independent QAU that monitors significant study events and facility operations, reviews records and reports?			
Does the test facility have the following:			
a) Maintenance of a master schedule sheet.			
b) Maintenance of copies of all protocols and amendments.			
c) Scheduling of its in-process inspections and audits.			
d) Inspection of each nonclinical laboratory study at intervals adequate to assure the integrity of the study, and maintenance of records of each inspection.			
e) Immediately notify the study director and management of any problems that are likely to affect the integrity of the study.			

Assessment	Yes	No	Comments/Policy/Record
f) Submission of periodic status reports on each study to the study director and management.			
g) Review of the final study report.			
h) Preparation of a statement to be included in the final report that specifies the dates inspections were made and findings reported to management and to the study director.			
I) Inspection of computer operations.			
This section of the 21 CFR should only be utilized for in vivo testing Animal Care 21 CFR 58.90			
Is animal care and housing adequate to minimize stress and uncontrolled influences that could alter the response of test system to the test article?			
Are there adequate SOPs covering environment, housing, feeding, handling, and care of laboratory animals?			
Are cages, racks, and accessory equipment cleaned and sanitized, and appropriate bedding used?			
Is feed and water samples collected at appropriate sources, analyzed periodically, and that analytical documentation is maintained?			
Are animals of different species, or animals of the same species on different projects, separated as necessary?			
Are daily observation logs kept to record for animals reported as dead or having external gross lesions or masses?			
Are animals appropriately identified based off of dose groups and corresponding housing unit?			
Is treatment for animals authorized by the study director?			
Are newly received animals isolated?			
Are newly received animals appropriately identified?			
Are newly received animals appraised and evaluated of their health?			
Does the facility have an Institutional Animal Care and Use Committee (IACUC)?			
Does the laboratory have a pest control procedure?			
Are the chemicals used for pest control documented?			
Are there documented individuals in charge of pest control?			

Assessment	Yes	No	Comments/Policy/Record
If pest control is contracted, does an individual from the facility accompany the exterminator at all times?			
Testing Facility Operations 21 CFR 58.81			
SOP Evaluation:			
Are current SOP's available at all workstations?			
Are SOP's found in the facility clear, complete and easy to follow?			
Are SOP's found in the facility authroized by key individuals?			
Have changes to SOP's been properly authroized and dated?			
Does the facility keep records of past versions of SOP's?			
Are there procedures to familarize employees with current SOP's?			
Does the facility have SOP's detailing how to ensure the quality and integrity of data?			
Does SOP's pertaining to the integerty of data include input (data checking and verification), output (data control) and an audit trail covering all data changes?			
Does the faility maintain historical file of outdated or modified computer programs or hard copy files?			
Are current SOP's reviewed periodically?			
Do current SOP's represent the actual procedures in use?			
Can personal be observed utilizing current SOP's in the facility?			
Conduct of the Nonclinical Laboratory Study 21 CFR 58.130			
During the evaluation of the laboratory operations, facilities, and equipment were the following verified to show conformity with protocol and SOP requirements for:			
a) Test system monitoring.			
b) Recording of raw data (manual and automated).			
c) Corrections to raw data (corrections must not obscure the original entry and must be dated, initialed, and explained).			
d) Randomization of test systems			
e) Collection and identification of specimens.			
f) Authorized access to data and computerized systems.			

Assessment	Yes	No	Comments/Policy/Record
Storage and Retrieval of Records and Data 21 CFR 58.190			
Does the facility retain raw data, documentation, protocols, final reports, and specimens?			
Has the delegation of duties to other individuals in maintaining the archives occurred?			
Are archived material retained or referred to in the archive indexed to permit expedient retrieval?			
Does the archives index make specific reference to other locations where raw data and specimens are retained?			
Is access to the archives is controlled?			
Do environmental controls minimize deterioration?			
Are there are controlled procedures for adding or removing material?			
Are there any unexplained or prolonged removals of data or specimens?			
Are environmental conditions suitable for areas of the facility where data and backup copies are stored?			
Are records indexed in a way that allow access to data stored on electronic media?			
To which compacity does facility have to copy electronic media and keep in an electronic form?			
Report names and identifying numbers of both copying equipment type and electronic medium type:			
Provide a brief summary of the facility's report preparation procedures and their retention and retrieval of records, reports, and specimens.			