



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.**