

Telecon Script

Date: April 20, 2017

Product: *Babesia microti* Nuclei Acid Test (NAT)
Babesia microti Arrayed Fluorescence Immunoassay (AFIA)

Sponsor: Oxford Immunotec, Inc.

STN: 125588, 125589

Topic: Teleconference to discuss software and cybersecurity

FDA Teleconference Participants:

Robert Duncan- OBRR/DETTD
David Leiby- OBRR/DETTD
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Lisa Simone- OBRR/DETTD
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Oxford Immunotec teleconference Participants:

Dr. Wolfgang Pieken, FDA Contact, Senior Director of Program Management
Suzanne Korreck, Imugen Senior Quality Manager
Brent Campbell, Senior Software Engineer
Katie Pomerantz, Project Specialist
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Mark Rusch, Global IT Director
Zeenita Mahajan, Data Security Manager
Scott Lemonde, Imugen Senior Network Systems Administrator
Ben Hamilton, Regulatory Manager
Mike McAndrew, Director of Program Management, Oxford

Summary of discussion- software issues:

FDA discussed the challenges reviewing the documentation provided because:

- The boundaries of the system are unclear with respect to the IT infrastructure. It is not clear what system components are dedicated to the device and where connectivity occurs with the business infrastructure and the outside world.
- To document, Oxford could start from hardware architecture already developed and include everything else that may be missing. This information should be referenced in the design control.
- Information presented in version one of some documentation that was submitted recently is different from the corresponding documentation

that was submitted in December of 2016, and it is unclear if all previous documentation is no longer valid.

- Some documents are stated to be obsolete but are referenced as valid in other documents (e.g., the risk management process).
- There are some possible risks stated in some of the design documents but not stated in others.
- The risk-based approach is acceptable in some ways but there are some areas that are inconsistent. For example, reference to the risk management standard ISO 14971 but the documentation does not align with the standard.
- The risk assessments needs to be more fully developed. Problems that could occur are not reflected in the risk documentation. In some examples discussed, the hazard and hazardous situations are not clearly identified, and probabilities are not inclusive.
- The risk documentation should include an identification of all the ways that someone could be harmed and the associated risks.
- The cybersecurity process is missing.

Oxford summarized what they heard by indicating that they need to have a better description of the software and hardware components. They will identify in each step the risk that is involved, and include an assessment of risk and the mitigation. Oxford asked that for the risk elements such as firewalls, USB, etc., what level of detail needed for the documentation to be adequate. FDA indicated that Oxford will need to think about the scope of the boundaries of the system; examining the scope of the system within the larger environment. For example, what parts of the operational technology interface with the rest of the world? These are some places where Oxford will need to look for vulnerabilities; for example, some companies disable USB devices because of the risk associated with them. FDA indicated this information depends on the scope of the system, and because Oxford did not provide the scope the FDA cannot aid them in identifying potential risks.

To conclude FDA reiterated that Oxford should approach risk at a system level, not only at the software level. FDA indicated there should be consistency and realignment of Oxford's process with ISO 14971.

With respect to software version, Oxford stated most testing has been performed for version 1.0.5.4 but they wish to ship with version 1.0.5.5 (that is in the process of implementation), and asked what FDA recommends be done. FDA indicated that a process is generally in place that a firm uses to determine what level testing should be performed, based on the magnitude of the changes made. Oxford stated that they did not have such a process in place. Oxford will need to develop a test plan for this version of software to clarify the testing required and a justification if comprehensive testing is not performed. All corresponding design documentation for the launching version of software should be provided.

FDA will provide links to the FDA Guidance on Software Validation, and for an FDA presentation about risk management in May.

To assist in the review, FDA requested and Oxford agreed to provide the following in two-weeks' time:

- An architecture diagram of the system and description of the components that can be used to assess various threats to the system.
- A decision about the risk processes that will be used to produce a new revision of the risk documentation.

Oxford indicated they will work to address FDA comments and develop documentation as recommended.

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