November 14, 2022

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

In Re: Draft Guidance – Computer Software Assurance for Production and Quality System Software (Docket No. 2022-19763).

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) submit these comments related to the draft guidance on *Computer Software Assurance for Production and Quality System Software*. Our comments will focus on three key areas: the risk-based approach that the guidance takes to computers and automated data processing systems, cross-referencing examples, and validation of certain software.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 6,000 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

Risk-based approach. In general, the AATB and TPG note and appreciate that this guidance document continues to promote a risk-based approach, as did the January 2002 guidance "*General Principles of Software Validation."* The 2002 guidance, from the outset, states that "based on the intended use and the safety risk associated with the software to be developed, the software developer should determine the specific approach, the combination of techniques to be used, and the level of effort to be applied." The draft *Computer Software Assurance* guidance extends that approach to computers and automated data processing systems.

Cross-referencing examples. While the appendices provide specific examples (e.g., Appendix A describes a computer software assurance example for a nonconformance management system and Table 2 includes a column devoted to a risk-based analysis), the AATB and TPG note that cross-referencing to that information in the base text, and adding additional specificity throughout the document, may be helpful for manufacturers. For example, ***adding additional information regarding the decision-making process for manufacturers, such as the advantages and disadvantages of using scripted vs. unscripted testing, would help ensure manufacturers are choosing appropriate validation strategies.***

Validation. The document states that "in general, software used as part of production or the quality system falls into one of two categories: software that is used directly as part of production or the quality system, and software that supports production or the quality system." Manufacturers must validate both categories of software, but the draft guidance acknowledges that second category, or the software that supports production or the quality system, "often carries lower risk, such that under a risk-based computer software assurance approach, the effort of validation may be reduced accordingly without compromising safety." In addition, the draft guidance notes a third category – general business software and software for establishing or supporting infrastructure that does not need to be validated. The document then goes into a discussion related to the intent of the software in determining the specific category (and the resultant validation).

We appreciate that the Agency makes a distinction between the three levels of risk for these various tools and the effort for validation, and that the guidance provides examples of testing methods for high-risk and low-risk features, functions, and operations. Specifically, the guidance states that "for high-risk software features, functions, and operations, manufacturers may choose to consider more rigor such as the use of scripted testing or limited scripted testing, as appropriate, when determining their assurance activities. In contrast, for software features, functions, and operations that are not high-risk, manufacturers may consider using unscripted testing methods such as ad-hoc testing, error-guessing, exploratory testing, or a combination of methods that is suitable for the risk of the intended use." We note, however, that the guidance also states "supporting software, as referenced in Section V.A., often carries lower risk, such that the assurance effort may be reduced accordingly. Because assurance activities used 'directly' in production or the quality system often inherently cover the performance of supporting software, assurance that this supporting software performs as intended may be sufficiently established by leveraging vendor validation records, software installation, or software configuration, such that additional assurance activities (e.g. scripted or unscripted testing) may be unnecessary." ***Given this information, it would be helpful to have further details from the FDA regarding the specific instances in which it may be unnecessary to perform additional assurance activities for low-risk software.***

Additionally, the AATB and TPG note that example 3 from Appendix A, related to business intelligence applications, focuses on "a commercial business intelligence solution for data mining, trending, and reporting." Instead of validating reporting software, manufacturers should validate the report itself (this is akin to validating a spreadsheet instead of the software that was

used to create the spreadsheet; in this case, we believe it's the spreadsheet that should be validated, not the software).

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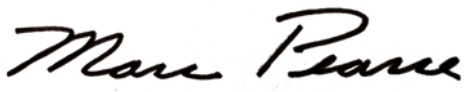
We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that you deem appropriate.

Respectfully,



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