Combination Products Coalition

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VIA ELECTRONIC SUBMISSION

November 14, 2022

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

Re: Docket No. FDA-2022-D-0795; Computer Software Assurance for Production and Quality System Software - Draft Guidance for Industry and Food and Drug Administration Staff

Dear Sir or Madam:

The Combination Products Coalition ("CPC") welcomes the opportunity to provide comments on FDA's document "Computer Software Assurance for Production and Quality System Software" (the "draft guidance").

The CPC is a group of leading drug, biological product, and medical device manufacturers with substantial experience and interest in combination product issues. One of our top priorities is to work collaboratively with FDA on issues affecting combination products and digital and software products to advance our common mission: providing the best possible health care to patients. Our diverse, cross-industry membership permits the CPC to bring a special, broad, and unique perspective to these issues.

The CPC greatly appreciates FDA's efforts to provide this draft guidance which helps to establish Agency expectations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. Our coalition represents members developing a range of products including combination products with embedded software and software as a medical device (SaMD) applications which may be labelled for use with drug or biological products. These products may require software and automated data processing systems for development, production, and maintenance and therefore our industry has a vested interest in the Agency's expectations regarding production and quality system software.

The CPC's comments on the draft guidance are captured below. The comments are organized by topic along with a discussion and rationale for our proposed change (if applicable).

Comments Regarding Applicability of Draft Guidance to Pharmaceutical and Drug-Primary Mode of Action Combination Product Production and Quality System Software

The preface of the draft guidance lists only CDRH and CBER as the Agency centers that have endorsed the content of the document. Additionally, the introduction section of the draft guidance limits the scope of the content to "computer software assurance for computers and automated data processing systems used as part of **medical device** production or the quality system" (emphasis added).

The draft guidance document provides considerations for computer software assurance and providing objective evidence to fulfill regulatory requirements found within 21 Code of Federal Regulations (CFR) Part 820, and specifically 21 CFR Part 820.70, *Production and Process Controls*. As the Agency is aware, drug and biologics regulations provide separate but similar provisions for computer systems used in production and process controls, for example within 21 CFR Part 211.180 *General requirements* and 21 CFR Part 211.68 *Automatic, mechanical, and electronic equipment*.

Despite having very similar computer system validation provisions between the medical product quality system requirements, the Agency has chosen to focus the draft guidance only on medical devices. The CPC believes that the tenants and considerations proposed by the Agency in the draft guidance are equally applicable to computerized and automated systems used in production and quality systems for drugs, biologics, and combination products.

This request is consistent with other comments provided by the CPC requesting increased inter-center coordination on new software and digital guidance. The CPC continues to respectfully request that the Agency centers collaborate more closely on the final version of the draft guidance to provide meaningful information regarding the applicability of the draft guidance to computerized systems that are used in production and quality system processes for drugs, biologics, and combination products.

The CPC greatly appreciates FDA's efforts to provide this proposed guidance and the opportunity to comment on elements which impact combination product manufacturers.

Yours truly,

Bradley Merrill Thompson,
On behalf of the Combination Products Coalition