November 5, 2018

Dear ISO TC 210 WG1 Chair,

The Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC), who is responsible for the oversight of MDSAP, is writing to you regarding the current status of ISO 13485:2016. MDSAP is a global regulatory quality management system audit program based on ISO 13485:2016 and was established through the International Medical Device Regulators Forum (IMDRF). MDSAP allows recognized Auditing Organizations to conduct a single regulatory audit of a medical device manufacturer to satisfy the relevant requirements of the regulatory authorities participating in the program which include the Therapeutic Goods Administration of Australia, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency, and the US food and Drug Administration. In addition, The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers to MDSAP.

We understand that ISO 13485:2016 is based on the format of the previous edition (2003) and ISO 9001:2008 and does not currently follow the ISO High Level Structure (ISO HLS) as outlined in Annex SL of the ISO/IEC Directive Part 1. At the time of publication of the current version of ISO 13485 there was an agreement to conduct a systematic review within 3 years and that the next revision of ISO 13485 would consider ISO HLS. It is our understanding that the ISO HLS may not currently meet the needs of the medical device sector and revising ISO 13485 to follow the ISO HLS at this time will not only cause instability for the medical device sector but can result in fundamental changes to the requirements of ISO 13485. For example, one of the challenges with moving to the HLS is that it introduces concepts and potentially requirements (e.g. business risk) that fall outside the purview or the authority of Regulatory Authorities. Introducing such concepts and/or requirements could make it problematic for regulators that use (or plan to use) ISO 13485 as a regulatory requirement since these regulators could be seen to be over-reaching beyond their authority. This could lead to regulators needing to either exclude portions of the standard from regulatory requirements, or to develop their own version of the standard that exclude the objectionable concepts and requirements. Therefore, it is imperative that the medical device sector is engaged in any future revisions of the ISO HLS, if there is a desire by ISO TMB that the standard continue to be used for regulatory purposes.

We believe that careful consideration should be given to the need to revise the standard considering its current state and the potential impact to regulators, manufacturers, and other relevant stakeholders. In the case of ISO 13485:2016, the standard is used as a regulatory

requirement in many jurisdictions and is used as the foundational basis for the MDSAP audit model. Each new version of ISO 13485 and the ongoing transition for changes to standards and regulations create considerable challenges that often take years to implement. For example, the transition period for ISO 13485:2003 certificates will end in March 2019. With the transition period ending, many medical device manufacturers and other organizations in the medical device supply chain will have only just updated their quality management systems to the current version of ISO 13485 when this systematic review is scheduled to begin. Since the transition to the 2016 version of the standard is not yet complete, and industry and regulators only have limited experience with its application, it is unlikely that a revision at this time would deliver any meaningful technical improvements. If the goal of this revision is only to align the standard to the HLS and ISO 9001 without substantially improving the technical foundation of the standard then it could rightly be perceived as an unnecessary editorial revision which would only add costs and disruption to a highly regulated industry that is already going through some very significant changes. In addition, if changes are implemented to ISO 13485:2016, the audit model for MDSAP, which was just recently revised, will have to be completely revised, training of the Auditing Organizations will need to be conducted, and transition periods will need to be implemented leading to instability in the MDSAP at a critical time.

Furthermore, the systematic review of ISO 13485:2016 comes at a critical time where medical device regulators, manufacturers, and other stakeholders are already undergoing substantial changes to the global regulatory system which will impact MDSAP. For example:

- Health Canada is in the process of transitioning from the Canadian Medical Device Conformity Assessment System (CMDCAS) to the Medical Device Single Audit Program (MDSAP) which is an audit model based on ISO 13485:2016 and covers regulatory requirements for audits in Australia, Brazil, Canada, Japan and the USA with potential expansion to other markets.
- The US FDA has announced their intention to harmonize the US Quality System (QS) regulation for medical devices to the requirements of ISO 13485:2016, likely with an associated transition period of a few years. This decision and commitment by US FDA, represents a significant step towards global harmonization for medical device quality management system requirements.
- MHLW/PMDA is in the process of harmonizing the Japanese Quality Management System (J-QSM) to the requirements of ISO 13485:2016, with a transition period of a few years.

The consortium of Regulatory Authorities that participate in MDSAP as well as the Official Observers respectfully request that ISO maintain stability of the standard throughout the next revision as a 5-year systematic review will offer stability to a sector that is currently undergoing many transitions. By providing stability in the standard until 2024 experience can be gained in the application of ISO 13485:2016 and its use in MDSAP.

ISO's engagement with relevant stakeholders will be key to ensure standards are developed to meet regulatory needs and that any changes to standards do not have a negative impact on the medical device sector. Furthermore, as Regulators, we hope that productive engagement with ISO will help ensure our ability to fulfill our public health mission to patients and the medical

device sector through the application of international standards written for regulatory purposes. Thank you for your consideration in this matter.

Sincerely,

David Bowe

Chair MDSAP RAC 2018