

MDSAP Transmittal Number: AO 2025-06

Transmittal Date: 2025/08/01

Title: Announcement of pilot program allowing Medical Device Organizations (MDOs) to participate in MDSAP

Purpose: The purpose of this transmittal is to inform MDSAP Regulatory Authorities (RAs), Auditing Organizations (AOs), Official Observers and Affiliates Members the start of a voluntary pilot program allowing eligible Medical Device Organizations (MDOs) to voluntarily participate in and apply for MDSAP certification.

The pilot will start on August 1st, 2025, and will have a duration of 1 year. Additional information is available in the procedure MDSAP AU P0038.001 Eligibility of Medical Device Organizations (MDOs) to apply for MDSAP certification (attached).

Approver: Tracey DUFFY, RAC Chair

Effective Date: 1 August 2025

Distribution: RAs, AOs, Observers, Affiliates, Website

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