MDSAP Transmittal Number: 2025-01

Transmittal Date: 2025/28/03

Title: Release of P0036:003 Remote / Hybrid Audit Procedure

Purpose: The purpose of this procedure is to define and document the requirements for the routine ongoing use of remote (fully offsite) and hybrid (partially offsite) audits of medical device manufacturers. An audit may be eligible to be performed by remote audit or hybrid audit methods only if in compliance with all the applicable criteria.

This update supersedes the Pilot arrangements from P0036:002.

Changes include:

i) A revision of the categories of high-risk devices in 5.1a to reduce restrictions.
ii) Revision of Table 1 to describe the minimum audit methods permitted for specific site activities and audit types.
iii) Decision tree added to provide clarity of permissible audit methods.
iv) Production task 26 and Purchasing task 9 removed from 5.1c.
v) Hybrid audits can now be performed for the initial audit of a device manufacturer that is not manufacturing high risk device categories listed in 5.1a.

AOs are encouraged to contact their assigned Assessment Program Manager (APM) if they are unsure of the applicable audit method eligibility criteria described in P0036:003.

Approver: RAC Chair, Tracey Duffy

Effective Date: 2025/27/03

Distribution: AOs, RAs

Action Requested: Apply requirements and restrictions for fully remote and hybrid audits according to P0036:003.

Location of Document: BOX (restricted access)

Issued by: Andrew Bathgate (Project Lead)