CDRH Pilot Activities

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VCIP – Voluntary Compliance Improvement Program Pilot

Status	NOT ACTIVE
Description:	Pilot allows a manufacturing site to self-identify compliance issues and correct the issues before FDA inspection is performed.
Assessment:	FDA Compliance Audit
Cost:	No additional cost to manufacturer
Modifications:	FDA would allow one year to implement corrections before inspection.

MDSAP – Medical Device Single Audit Program

Status	ACTIVE PROGRAM
Description:	The program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturing site that satisfies the relevant requirements of the regulatory authorities participating in the program. ***Participating Countries***: USA, Canada, Brazil, Japan, and Australia
Assessment:	• MDSAP recognized third party compliance audit • Performed annually • Audit report and findings available to all participating countries • Satisfies the site audit requirement for all participants but does not satisfy specific requirements for some countries or regulatory bodies.
Cost:	Manufacturer is responsible for costs of the audit
Modifications:	• FDA accepts results for routine surveillance inspections • Allows the manufacturing site to leverage one audit to fulfill requirements for multiple regulatory organizations ***Benefit:*** • Reduces the burden and disruption of audits required by multiple regulatory body. • Auditor provides more detail and guidance on findings

PMA CtQ – PMA Critical to Quality Pilot

Status	PILOT
Description:	• The pilot allows a PMA device manufacturer meeting the participation criteria to engage on new PMAs early in the review process and identify their critical to quality requirements, the relevant controls, and supporting data. • The pilot objectives are to provide a focus and engagement on quality attributes earlier in the review • Limited to 9 participants
Assessment:	FDA Compliance Audit
Cost:	No additional cost to manufacturer
Modifications:	Pre-approval inspection is waived for manufacturing site responsible for the product who demonstrates a focus on identifying critical to quality attributes and effective controls ***Benefit:*** Early engagement with the manufacturing review team and accelerates the premarket approval by waiving premarket inspection and performing a post-market inspection after 6 months to 12 months.

CfQ – Voluntary Medical Device and Product Quality Pilot

Status	PILOT
Description:	• The pilot focuses on using a maturity appraisal to drive continuous improvement and organizational excellence at a medical device manufacturing site. • The enrolled site will participate in a maturity appraisal conducted by the CMMI Institute and commit to early engagement with CDRH and submission of objective pulse metrics established during the appraisal to monitor improvement and progress
Assessment:	• Third-Party Quality System Maturity Appraisal performed by certified team • Performed annually during pilot • Requires submission of baseline performance metrics during appraisal and resubmission of the metrics as progress monitor at established intervals through the pilot year. • Requires commitment for feedback into appraisal process and pilot
Cost:	Manufacturer is responsible for costs of the audit ($17K – $35K) plus travel costs
Modifications:	• Manufacturing site uses appraisal in lieu of surveillance audit • Can be applied to US or Foreign Sites but only fulfills FDA Regulatory requirements • Additional confidence and transparency allows FDA to streamlined 30-Day Notices submission reviews, Site changes, and PMA Manufacturing Sections ***Benefit:*** • Reduces the burden and disruption of audits and focuses on shifting resources to innovation and improvement • Waives pre-approval inspection for PMA Originals • Allows streamlined submissions and accelerated review and approval • Appraisal team provides feedback on what is succeeding, what has opportunity for improvement, what is or is not driving value for you customers or business based on your business objectives.

Digital Health – FDA Pre-Cert Program

Status	PILOT
Description:	• This program development pilot for Software as a Medical Device (SaMD) that focuses on assessing the culture of quality and organizational excellence of a software organization, identifying common validation principles, and identifying key performance indicators/metrics centered around excellence principles that FDA has established as part of demonstrating patient safety, product quality, clinical responsibility, cybersecurity responsibility, and pro-activeness. • The objective of the pilot is to develop an appraisal methodology that can identify excellence metrics that are common across manufacturers and incorporate the unique challenges of software development. This will be used to develop an a streamlined accelerated review and clearance paradigm for this software and digital health technologies. • Limited to 9 participants.
Assessment:	• No Assessment • FDA Site Visit and Engagement. The site visit is not a compliance audit or inspection. • Requires participation in developing of baseline metrics or KPIS for the excellence principles as part of the pilot commitment
Cost:	No additional cost to manufacturer
Modifications:	• In this pilot, the selected participants are key to helping identify and exercise the types of engagement, metrics, and relevant KPIs. ***Benefit:*** • Allows software experts and manufacturers to be part of developing what the critical elements of the Pre-Cert program will be. • Creates a regulatory approach that can rapidly adjust and focuses on driving excellence not compliance • Develops the Pre-Cert model which enables the agency to streamline and accelerate clearance or approval of digital health technologies.

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Thank You!


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