



U.S. Food and Drug Administration
Protecting and Promoting Public Health



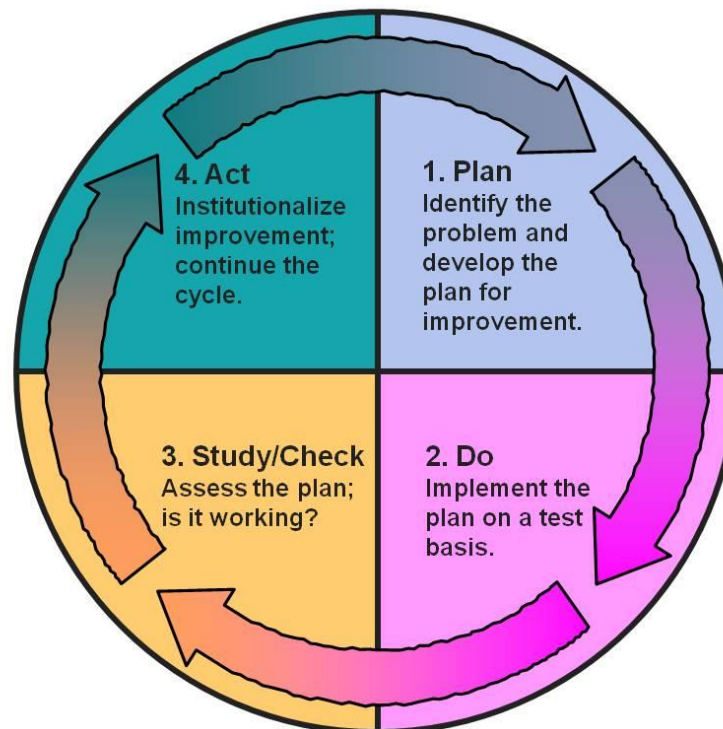
OIR Quality Management Update

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ISO 9001:2015

The Deming Wheel (or PDCA Cycle)




Scope

All OIR-owned processes, procedures, work instructions, forms, and templates related to

- Medical device premarket, surveillance, and compliance
- CLIA
- EPRC
- MQSA
- Digital Health
- Program Management Office



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Policy and Operations	OIR SWIFT	Training Records						
OIR SWIFT Home	<input type="checkbox"/>	Document Title	Applies to	Subject Area	Document Type	Keywords	Doc ID	Effective Date
OIR SWIFT Documents		OIR Document Control SOP	OIR	Quality Management Program	SOP	Document Control	05000 v1.01	3/4/2016
Advanced Search								
Change History Search								
Change History List								
Document Change Requests								
Make a Request		SWIFT Approvers	OIR	Quality Management Program	Supporting Document	Document Control, Approval	05001 v1.01	5/27/2016
Multiple DCR Entry Datasheet View								
Pending DCRs		OIR SOP Template and Instructions	OIR	Quality Management Program	Template	Document Control	05002 v1.00	2/22/2016
DCR Log								
DCR Log Search		OIR WI Template and Instructions	OIR	Quality Management Program	Template	Document Control	05003 v1.00	2/22/2016
Document Preparation								
DCTD Drafts		ISO 9001-2015 Process Traceability Form and Instructions	OIR	Quality Management Program	Template	ISO 9001	05004 v1.00	2/22/2016
DIHD Drafts								
DMD Drafts		OIR Controlled Document Approval Record Form and	OIR	Quality Management Program	Form	Document Control, Approval	05008 v1.00	2/22/2016



Training Records Site

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2016-2017 Strategic Priorities

**Establish a National Evaluation System for
Medical Devices**

Partner with Patients

**Promote a Culture of Quality and
Organizational Excellence**

FY-16 Milestones

- Form team and train on ISO 9001:2015
- Create traceability matrix
- Gap analysis/ planning
- Initial inventory of processes to control
- Processes to be under document control by end of FY-16

What's Next?

- CAPA
- Process Audits
- Process Improvement
- ISO 9001 to Baldrige

Contact

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