



Medical Device Single Audit Program Regulatory Authority Council

Project Team Work Item (PTWI) Proposal/Approval

(Please submit PTWI Proposal/Approval to MDSAP RAC secretariat)

Project Title	[Insert Proposed Project Title]
Project Proposal Date	[Insert Date of Proposal]
Initiator(s)	[Insert Name(s) and Regulatory Authority(ies) of Proposal Initiators]
Purpose and Rationale	<u>Purpose</u> [Explain the Purpose of the Proposal] <u>Rationale</u> [Explain the Logical Basis for the Proposal Including MDSAP Benefits] <u>Alignment with MDSAP Functional Statement Objectives</u> [Explain How the Proposal will Support or Accomplish MDSAP Functional Statement Objectives]
Project Scope	[Describe Areas, Functions, and Personnel Affected and How]
General Project Plan	[Describe or Attach a Clear and Concise Initial Project Plan with Major Milestones, Deliverables, and Timelines]
Proposed Lead Project Manager	[Insert Name and Regulatory Authority of Proposed Lead Project Manager]
Proposed Sources of Expertise; or Additional Resources	[Insert Names and Affiliation of Subject Matter Experts; and/or Describe Anticipated Additional Resource Needs From Outside the Participating Regulatory Authorities]
Relevant documents (e.g. ISO, MDSAP, GHTF, etc.)	[Identify Documents that May be Affected by or Support the Proposal]
MDSAP RAC USE ONLY	
MDSAP RAC Decision (Decision represents RAC decision documented by RAC Chair or Vice Chair, where applicable)	<u>Name of Chair or Vice Chair</u> [Insert Name of Official Authorizing the RAC's Final Decision]
Decision Date	[Insert Date of RAC Decision]
Project Proposal Approved as Proposed ☐ (Identify Lead Project Manager)	<u>Lead Project Manager</u> [Identify Lead Project Manager]
Project Proposal Approved with Comments ☐ (Identify Lead Project Mgr.; provide clear and concise comments)	<u>Lead Project Manager</u> [Identify Lead Project Manager] <u>Comments</u> [Provide RAC Comments and Instructions]
Project Proposal Rejected ☐ (Provide clear and concise rationale for rejection)	<u>Rationale</u> [Provide the RAC's Logical Basis for Rejection]