

# MDSAP RAC

## Medical Device Single Audit Program Regulatory Authority Council

### Project Team Work Item (PTWI) Proposal/Approval

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

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