Implications on Site Inspections
According to ISO 13485:2003
(Customer / Product Focus)

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Inspection Cycle (planned)

• Application
• Dossier review (QM documentation part)
• Evaluation of readiness for inspection (stage 1)
  a. Desktop of additional documentation (Certificates, recent audit reports, quality procedures, SOP, summary of sold product...)
  b. Stage 1 inspection (1 inspector day to inspect state of QMS implementation, facility, competence of staff, critical suppliers incl. outsourced activities, internal audit and management commitment / review)

• Initial (Stage 2) Inspection*
• Follow up (confirm implementation of CAP); if required
• Surveillance (annual reporting)
• Re-Inspection

* 2 rounds of CAP
Process Overview

Application

Prioritise?

Abbreviated PQ

PQ Process

Approved Product?

Lab Evaluation

Stop
Abbreviated PQ Process

- Info pack
  - Prepare, plan
    - Abbreviated Inspection
      - Compliant? (<6 MNC)
        - Y
          - 2 rounds CAP
            - Y
              - Terminate
            - N
              - N
        - N
          - Terminate

PQ Process (Dossier Review)

- Stage 1
  - Ready for Inspection
    - Y
      - Plan
      - Stage 2 Inspection
        - Compliant? (<6 MNC)
          - Y
            - 2 rounds CAP
            - Y
              - Terminate
            - N
              - N
        - N
          - Compliant? (<6 MNC)
            - Y
              - 2 rounds CAP
            - N
              - N
  - N
    - (Seek techn. assistance)

- Recommendation for PQ
  - Dossier Screening
    - Dossier Review
      - List of questions
        - Compliant?
          - Y
            - 2 rounds CAP
            - N
          - N
            - Terminate
Abbreviated Inspection Procedure

• **Input:** Information pack to prepare and plan efficient inspection

• **Information pack:**
  a. Product (version, photos, certificates)
  b. Description of product
  c. Manufacturing site (certificates)
  d. Ask the manufacturer to have the documents that support the regulatory approval available onsite

• **Calculation of abbreviated inspection time**
  • MDSAP MDSAP_AU_P0008_Audit_Time_Calculation_Procedure
  • MDSAP_AU_F0008.1_Audit_Time_Calculation_Spreadsheet
## Changes and Improvements

<table>
<thead>
<tr>
<th>Changes to be implemented</th>
<th>Advantages</th>
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<tr>
<td>Adopt the IMDRF MDSAP (International Medical Device Regulators Forum; Medical Device Single Audit Program)</td>
<td>Internationally harmonised, transparent Documents in public domain, adopted by 4 IMDRF members (FDA, ANVISA; TGA, HC)</td>
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<td>Introduce decision points (milestones)</td>
<td>Transparent process</td>
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<tr>
<td>Establish readiness for inspection (desktop document review, i.e. Stage 1)</td>
<td>Harmonised, transparent, Inspection planned, once the QMS has been fully implemented</td>
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<td>Clear timelines for follow up actions</td>
<td>Transparent process, clear expectations Reduce time to PQ decision</td>
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<td>Defer to technical assistance for deficient systems</td>
<td>Enhance efficiency of inspections, plan follow-up inspections when the QMS has been fully implemented</td>
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Implications

• Reduced onsite time (e.g. stage 1 remote document review; abbreviated PQ), improved transparency

• Predictable and efficient (plan, report, corrective action, follow up inspection or technical assistance if needed)
Thank you