Simplifying Medical Device Risk Management requirements for 60601-1 3rd Edition

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SDP Engineering Inc. 11/13/2012
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Agenda

• Introduction
• Review of IEC 60601-1:2005’s Risk management Aspects
• Application of 14971:2007 to 60601-1:2005
• IEC Guidelines
• Typical Checklist required
• Manual Process
• 60601TurboRM
• Pre requisite
• User Interface
• Project Settings
• Viewing of Audit results
• Creating Check List, Gap Lists and Document List
• Comments, Q&A
Preparing Checklists required by the Test Labs - Manual Process Steps

• Read Specifications
• Prepare company documents
• Look for required phrases and terms
• Search in documents
• Decide appropriate applicable reference
• Copy the references in document, write brief description
• Fill in the check list
• Perform this for 125 Tables – 5 to 8 entries per table

• Total time required? Make your own estimates!

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Preparing Checklists required by the Test Labs – using 60601TurboRM

• Fill in Product specific information in Setup Wizard
• Specify folder name in which all Risk Management Documents are present
• 60601 Turbo RM provides a table for you to review
• Select most appropriate references in the table
• 60601TurboRM prepares required Check List in MS Word format

60601TurboRM Reduces time required to create check list by 80% to 90%

Software Requirements

• OS: Windows based OS – XP, Win 7
• Office – MS Office 2003, 2007, 2010
• CPU: i3, i5, i7 cores
• Document Format: - MS Word, MS Excel, pdf
• Risk Management Process, Report, Plan and other RM documents
Audits the risk management documentation prepared by the company for compliance with ISO 14971:2007 standard clauses related to IEC 60601-1:2005

- A Clause by Clause audit or Complete audit
- Project Wizard collects company and product specific information
- Auto Document Name Search identifies most relevant documents i.e. Risk Management Procedure, Risk Management Plan
- For each 60601-1 clause and ISO 14971 Clause, most appropriate references are searched in documents provided in a folder
- Easy to View Audit Results with details
- Provides Page Number, Line Number, Key Reference from standards, Description of Up to few lines of Content including key reference from standards in a tabular view
- One click to open document, find reference, highlight reference for easy detailed view
- Provides Add / Delete for similar references, provides priority adjustments for check list inclusions
- Enables browsing of results by 60601-1 Clause, ISO 14971 Clause and Document Names
- Generates Checklist with items selected by reviewer
- Generates Gap List – Gap Analysis document
- Generates Document Gap List – A list of missing typical documents
- Generates Used Document List – A list of documents used for Check List
- Generates All References List – A list of all required clauses and all possible references found within company documentation
- Provides hints and help from Guidance for evaluation of Risk Management in ME Equipment.
- Check Boxes to include searched item in the check list
- Check Boxes to mark a clause N/A
60601TurboRM enables the ME manufacturer to prepare the required checklist in a time efficient way. It also enables the Agency reviewer to review all referenced documents and expedite process of approval.

• SDP Engineering’s 60601TurboRM enables device manufacturers expedite the approval submission process for Risk Management requirements of 6061-1 3rd edition

• It reduces Approval Agency’s review time for the device manufacturer’s documents and check list

• Software Demo and evaluation version – Contact don@sdpengineering.com