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

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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

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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

60601TurboRM Features

- 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 form 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

Summary

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