



Global Harmonization Task Force

Working Towards Harmonization in Medical Device Regulation

Training Seminar on Risk Management

**Summary Technical Documentation STED and
Risk Management**

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This can be a short & relaxing presentation

Risk Management

All day you hear about this topic

STED

You may not want to hear about this topic

Your choice:

This could be a short & relaxing presentation

Risk Management (ISO 14971:2000)

All day you hear about this topic

STED (GHTF SG1 N011R17)

You may not want to hear about this topic

Your choice:





OK, we'll talk about STED first ...

Summary

Technical

Documentation

**So, gentle(wo)men, it is a
SUMMARY**

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Summary

Technical

Documentation

**So, gentle(wo)men, it is a
SUMMARY, and not:**



STED (http://www.ghrf.org/sg1/inventorysg1/pd_sg1_n011r17.pdf):

- Developed by GHTF → all medical devices
- Format to support conformity assessment process
- Intended for all risk classes
- Beneficial for regulators AND industry

if used properly...

STED ...

Contains

- Description of manufacturer, device & intended use
- Overview of proof that device fulfils Essential Principles (EP: <http://www.ghtf.org/sg1/inventorysg1/sg1-n20r5.pdf>)
- And that's all ...



F.F.M.

STED ...

Proof that device fulfils Essential Principles:

- Risk analysis/management
- Design verification and validation
- Clinical information/investigation

And perhaps a few more details

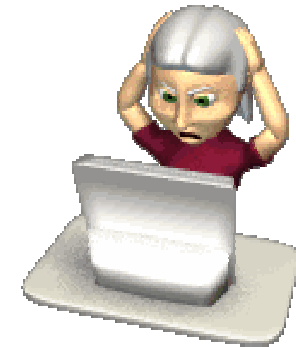
- Labelling, certificates, declarations, ...

STED & risk management ...

Now we come to the heart of today's story:

Risk analysis/management

Can you have full Risk Management details in a STED ???



STED & risk management ...

Can you have full Risk Management details in a STED ???

Clearly, you can't ...

But what then **CAN** you do ?

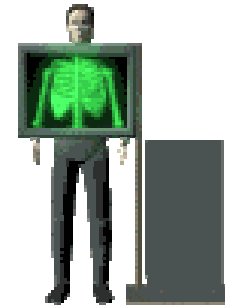
What will do the trick ?



STED & risk management ...

What is the problem ?

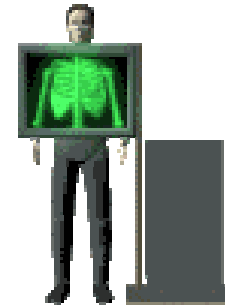
- Risk management dossier is BIG
- No prescribed format
- Links to many other documents
- Decisions made by manufacturer
- How to interpret all information?



STED & risk management ...

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- Decisions made by manufacturer
- (**How to**) interpret all information?



STED & risk management ...

So what now ?

For the manufacturer

- Include process description in STED dossier
- Give actual RM process data for the device

For the regulator

- Verify that RM process **IS** in place



STED & risk management ...

Ah, I see the point ... in combining RM and QMS:

- One audit
- One certificate

software ??



There are a few attention points

- RM must cover **all** life cycle phases

i.e., manufacturing, materials & component procurement, use, design changes, CAPA, disposal and maintenance (*tricky* !)

- RM is “never” complete

STED & risk management ...

Messages

- RM: key element in the process
- RM: “naturally” part of QMS
- BTW, STED must become a success
- All parties must “behave” and work ...
- ... to learn and to achieve convergence





Thank you for your attention !!

