Simplicity and ease-of-use in Risk Management

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A perfect world ?

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Implementing a risk based approach as per ISO 14971

- Will deliver a knowledge base for
  - Design Control,
  - Process Validation,
  - Sampling Plans,
  - CAPA,
  - Complaints, ...
- Enables fast decisions and will set the right priorities
- Ensures compliance internally and externally

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All we need is just .....

Risk management File

Risk Analysis on Product level

Risk Analysis on Process level

Risk Analysis on System level

Usability File

Risk management Owner

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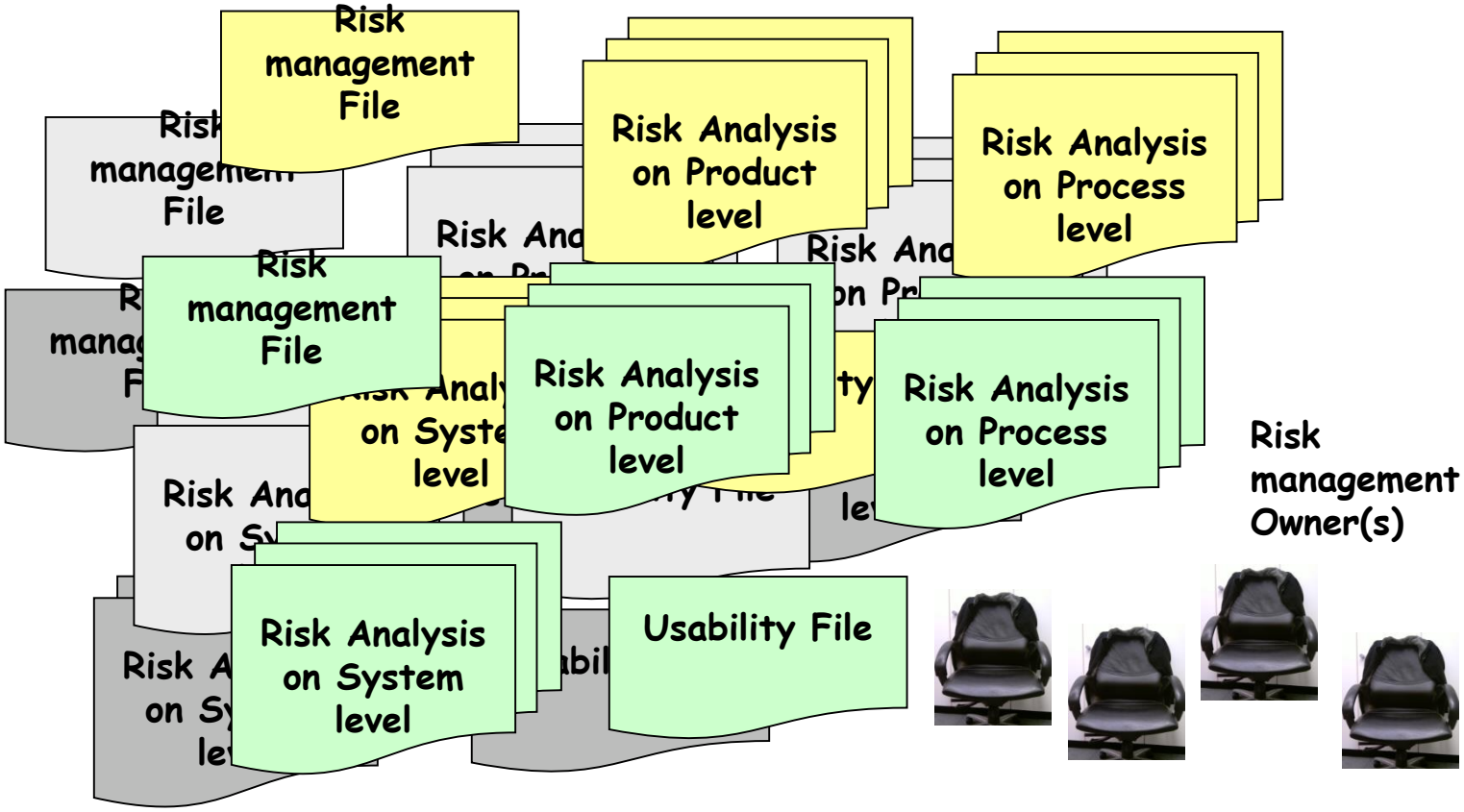
Do you have more than product?



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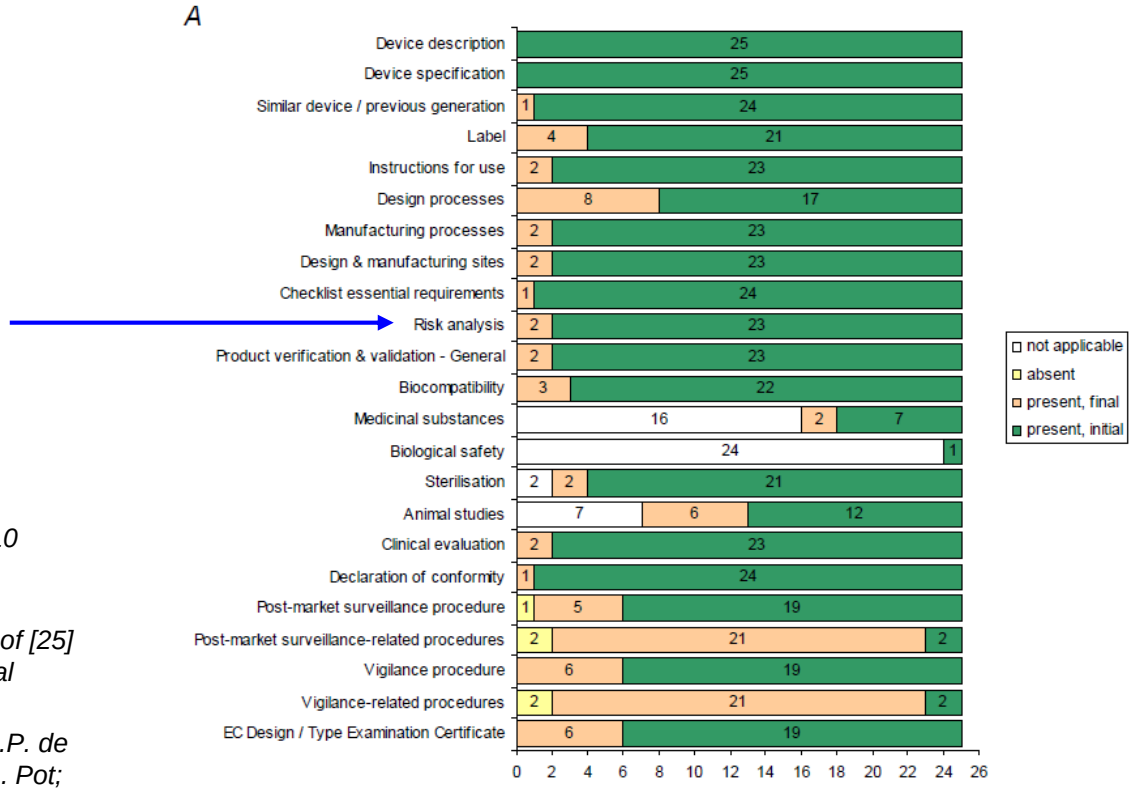
What are the consequences?

- Risk Management Documents are available....



RIVM report 360050021/2010

Assessment of technical documentation of [25] Class III medical devices

B. Roszek; A.C.P. de Bruijn; J.W.G.A. Pot; A.W. van Drongelen

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What are the consequences?

- Risk Management Documents are poor in quality

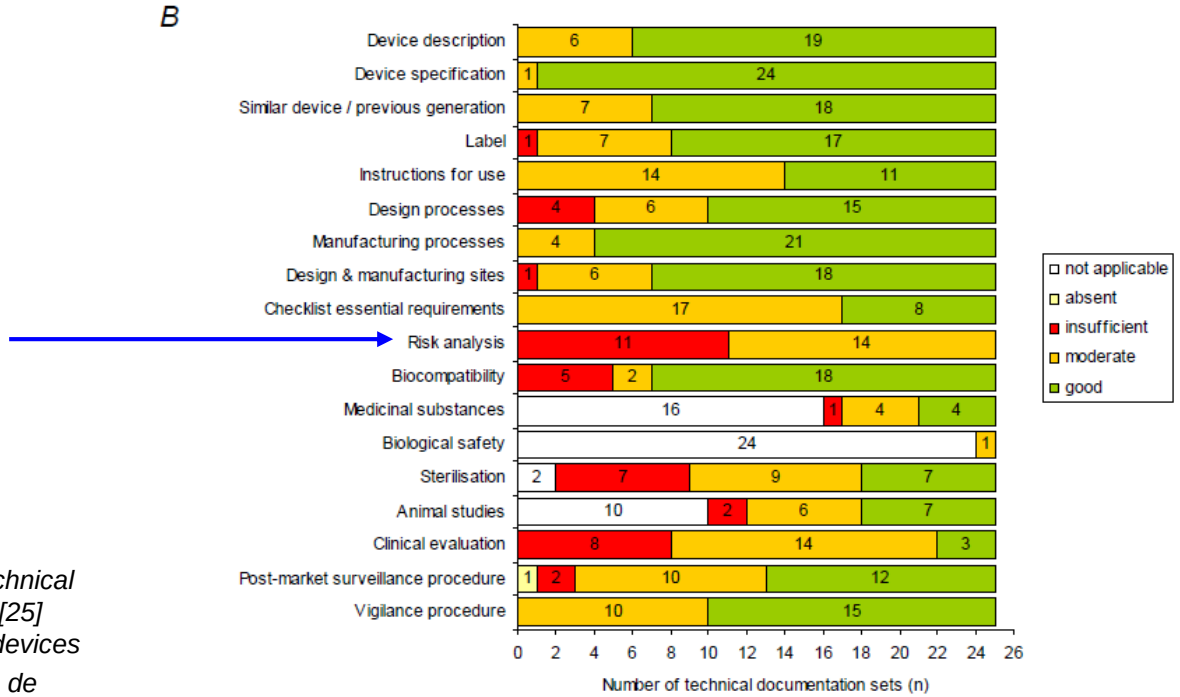

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Figure 2. Availability (A) and quality of technical documentation (B) of Class III medical devices 'Present, initial' means present after initial request and 'present final' means present after the final request.

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What went wrong in Medical device companies since implementation in 2000?

- In many companies Risk Management was most often implemented for compliance reasons
- Focus was given to documentation and risk assessments and evaluations were formalised in excel templates or word files
- Time spent for copy/paste, formatting and PowerPoint Engineering was exceeding the time spent to think about the content itself

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What went wrong in Medical device companies since implementation in 2000?

- Symptoms of insufficient implementation are
  - 100+ pages of FMEA for simple disposables
  - Inconsistencies between documents,
    - Different severities for the same harm
    - The same failure modes in design and process leading to different harms
  - Extreme levels of details or “helicopter” FMEA’s only
  - Low participation in Risk Analysis meetings
  - Low frequency of updates

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What‘s the value added?

		Riskanalysis (FMEA)								
Titel: Process FMEA-Extrusion		**Author**								**reviewed**
										reviewed
		previous revision	N/A							**reviewed**
	Process-FMEA	**Revisions**	1				**Date:**	12.11.2008		
Component or process step	**Potential failure**	**Potential effect of failure**	**Potential Cause of failure**	**Current controls**	**Occurrence**	**Severity**	**Detectability**	**RPN**	**Recommend-ation**	**resp**	**completed**
Extrusion	malfunction of extruder	Products out of spec	technical defect	Maintenance Calibration Work Instruction Training	2	4	2	**16**	n/a	n/a	n/a
	Wrong material	product too hard	human error	LHR Incomming inspection Training Work Instruction	1	2	5	**10**	n/a	n/a	n/a

100+ pages FMEA ... and where is the patient?

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Did you ever observe something like this?

Product FMEA

Product function	Potential Product Failure	Harm / Hazardous situation	Severity (S)	Potential cause of failure
Sealing	Sterile barrier sealing too small	sterile packaging opens - infection	9	width of bags too small

Process FMEA

Process / Step #	Process function	Potential Process Failure	Harm / Hazardous situation	Severity (S)	Potential cause of failure
5	Sealing	Meachanical defect of fixture damages sealing	loss of sterile barrier leading to non sterile product - infection	8	tooling worn due to thermal stress

The patient will not be injured less because it was just the process and not the design.

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Change the way we do Safety Risk Management

- Bring back common sense
- Set roles and responsibilities
- Focus and Prioritize
- Apply the right tools
- Use it !

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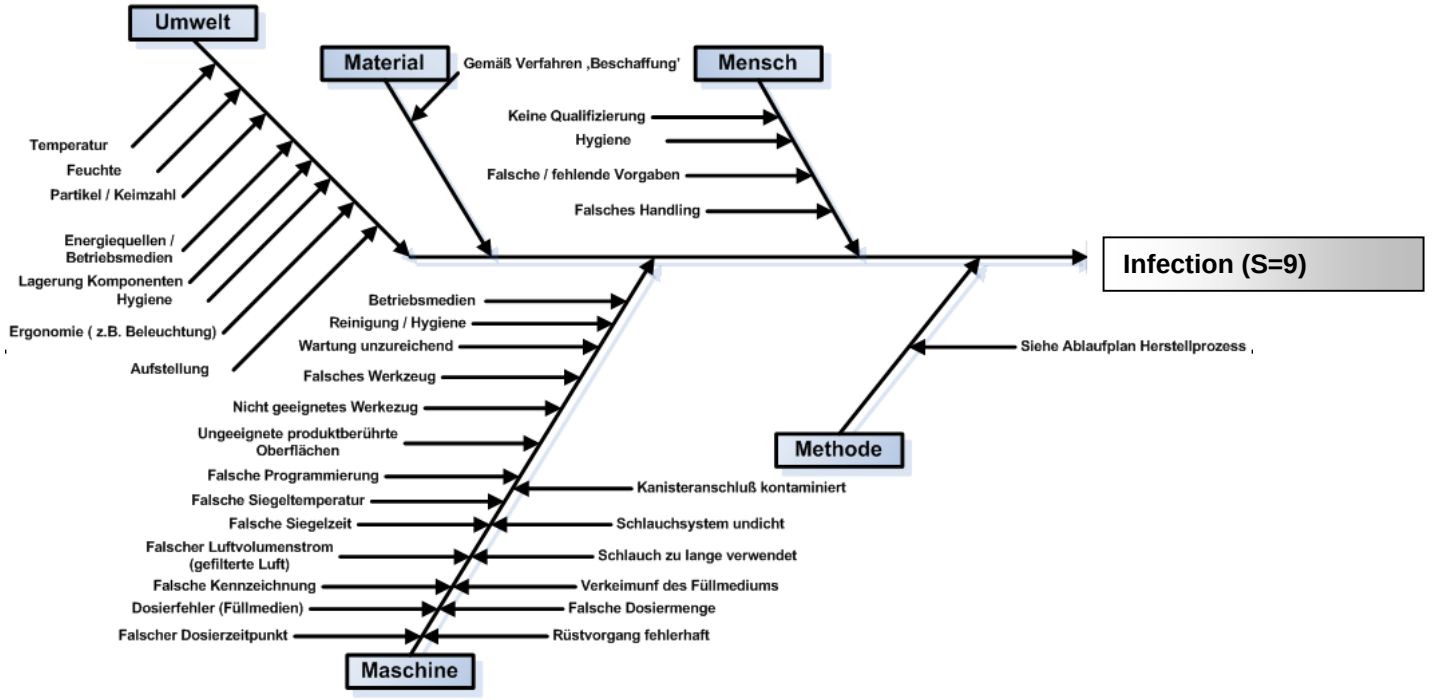
Start with the most severe harm and identify the areas causing the harm



Product and Process knowledge is key

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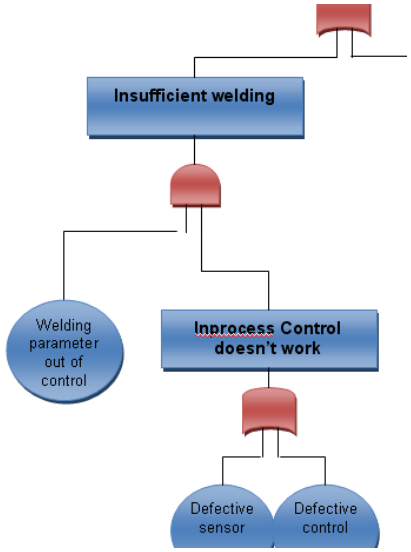
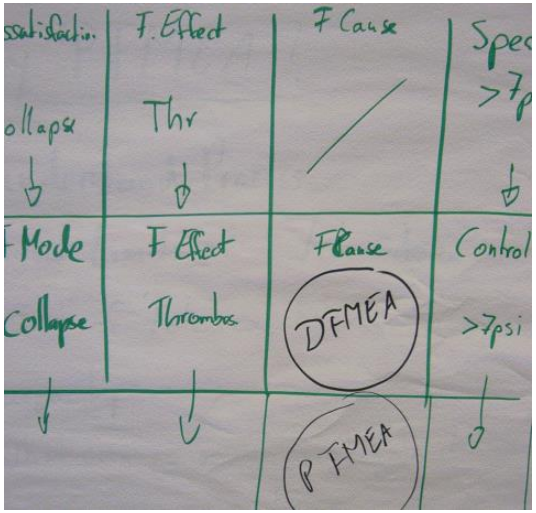
Apply the right tools at the right time

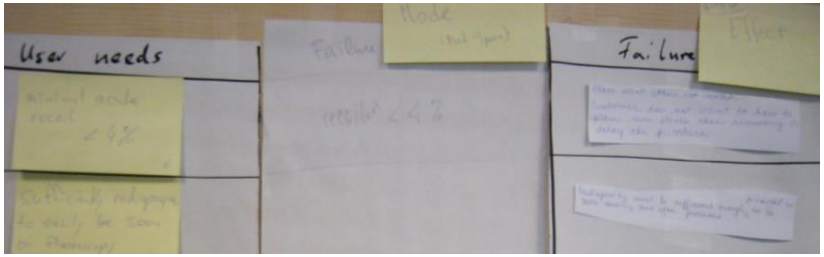
FTA‘s are often used to evaluate the „reasonable sequence of events“





Brainstorming is the start of each analysis

„Cut & paste“‘ can still be done with paper and scissors



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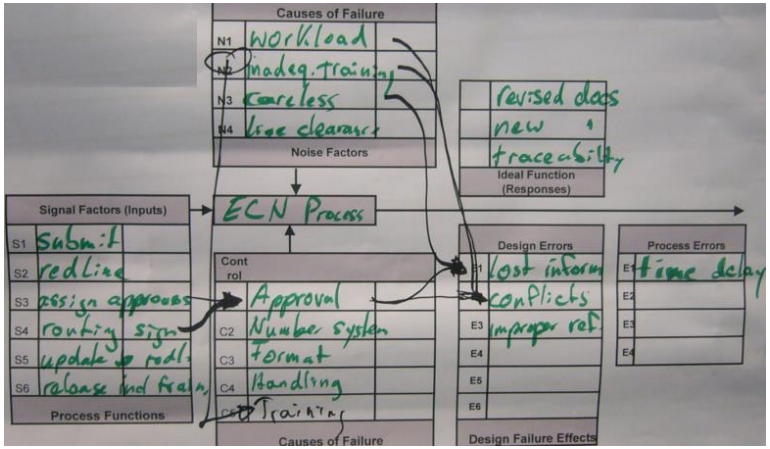
Apply the right tools at the right time

P-Diagrams are ideal to prepare Risk Analysis meetings



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Apply the right tools at the right time

Software will be helpful and reduce your workload and problems ....

...but don't use it before you determined <u>your</u> process and the way <u>you</u>'d like to live Safety Risk Management.

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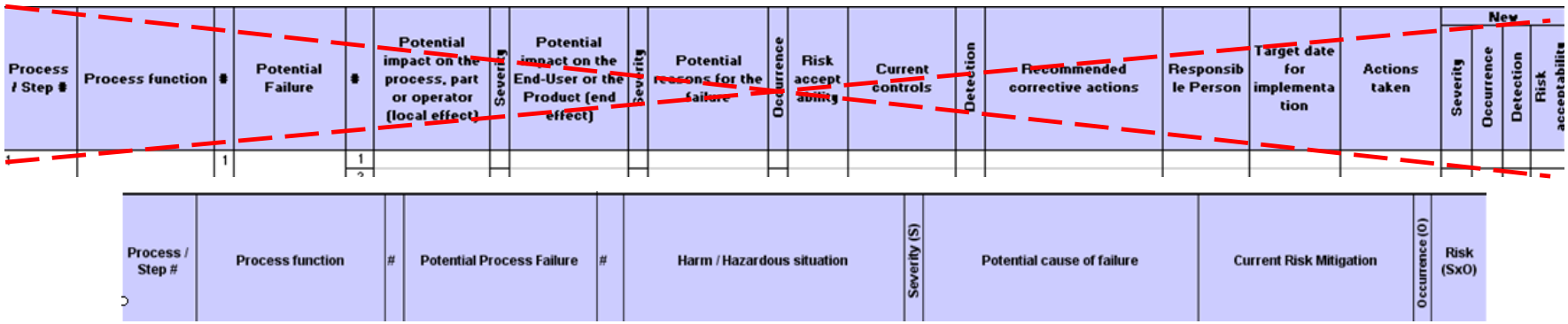
Keep your templates simple and remove the non-essentials

- Do you really need pre- and post-control within one document?
- Is Detectability needed or isn't it easier to go by SxO only?
- Skip local effects like reduced yield or increased costs?



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Change the way we facilitate risk analyses

- Never start a meeting without having the products in your hands
- Process Risk Analysis can be facilitated at the machine
- Use flip-charts, white-boards and clean up afterwards
- Never do it by phone!

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