



# **Global Harmonization Task Force**

**Working Towards Harmonization in Medical Device Regulation**

## **Training Seminar on Risk Management**

**Implementation of Risk Management –  
View of a Medical Devices Manufacturer**

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- **Dräger Medical – Company overview**
- **Risk management in a process organisation**
- **Organization involved in risk management**
- **Principles for risk analysis**
- **Risk analysis during whole product life cycle**
- **Risk Management is more...**



**Dräger Medical - Because you care**

**F.F.M.**



**Our mission is to provide innovative products, services and integrated CareArea™ Solutions that support patient-centered processes for efficiency and high quality care across all areas. From Emergency Care, Perioperative Care on to Critical Care, Perinatal Care and Home Care.**



# Core Business: Solutions for the Acute Point of Care and Home Care

# F.F.M.



**Pre Hospital**



**Hospital**



**Post Hospital**

## Emergency Care

- Ventilation
- Monitoring
- Neonatal Transport

## Perioperative Care

- Anesthesia
- Monitoring
- IT Systems
- OR Equipment (Tables, Lights)

## Critical Care

- Ventilation
- Monitoring
- IT Systems
- ICU Equipment

## Perinatal Care

- Ventilation
- Warming therapy
- IT Systems
- NICU Equipment
- Monitoring

## Home Care

- Oxygen Therapy
- Sleep Therapy
- Mechanical Ventilation
- Monitoring

- Innovative products with best-in-class applications performance
- Comprehensive solutions to optimize the clinical processes
- Complete offering including technical service, education and training

1902

2004

- Over 100 years of experience in medical technology.
- Around 7% R&D investment annually.
- Fully committed to remain the technological driving force for the acute point of care.



**1902:**  
The Roth-Dräger  
anesthesia  
apparatus



**1964:**  
Cardiac recording  
systems - the start  
of patient bedside  
monitoring



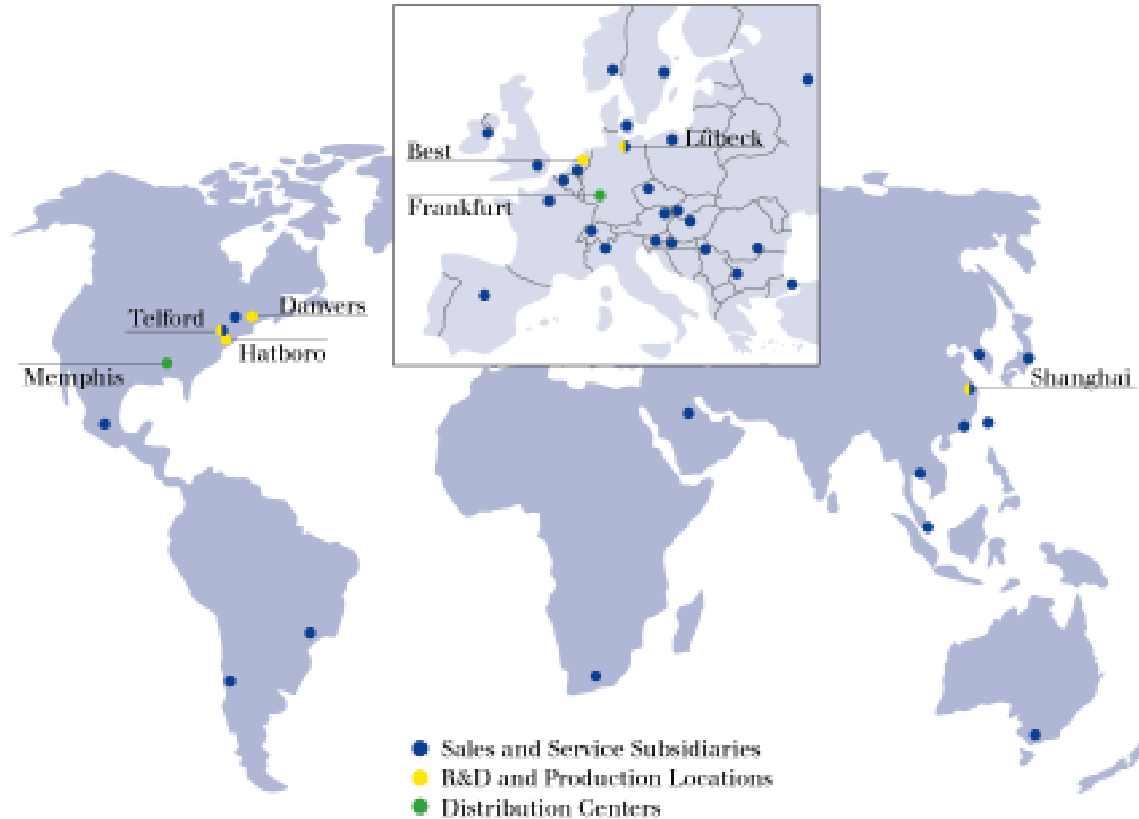
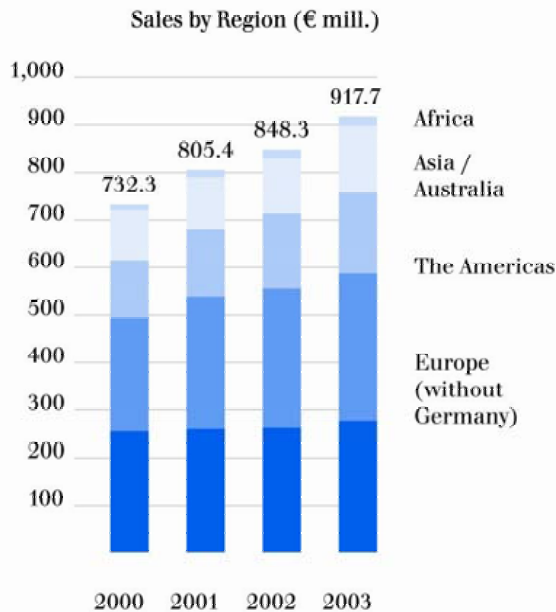
**2004:**  
Innovian™  
Anesthesia - New  
anesthesia IT  
solution improves  
clinical processes  
in the OR



# Global Reach, Global Strength

# F.F.M.

- > 6,000 Employees
- Represented in > 190 countries



Business process:

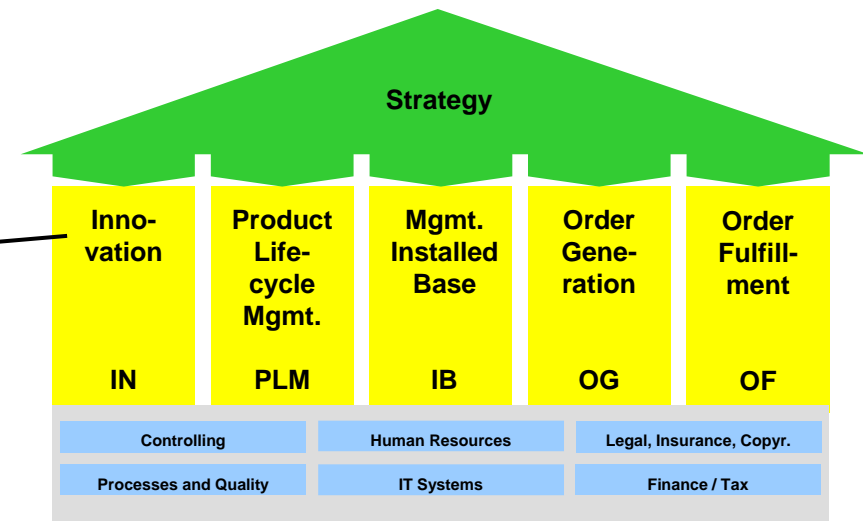
**Innovation**

Work processes:

**Define Roadmap & platform**

**Develop product**

**Research technology**



Subprocesses

- System Design
- Software Design
- Mechanics Design
- ....

Supporting processes

- Risk Management**
- Verification
- Configuration Management
- ....



## General Rules

- Requirements to the organization involved in risk management: responsibility, qualification independency.
- Assignment of the Risk Manager and permanent Risk Management Team is documented in the project plans (e.g. Design and Development Plan).
- Names and domains of expertise of people actually involved in the risk management process is named in every Product Risk Management Report.
- Principles of risk management are approved by top management.

## Risk Manager

- The Risk Manager takes over the most important task in product risk management. He/she is responsible for performing the product risk management.
- A Risk Manager is assigned to each device/module which is under development, in production and in the field for the defined life time of the device/module.
- Risk analysis is performed by using comparisons with existing devices, scientific knowledge and estimations.
- He/she must experience in the field of application of the device and experience in product risk management itself.
- The Risk Manager needs not to be independent, this has to be considered in the project organization.



## Risk Management Team

- Provides expertise and performs related tasks, e.g. regarding application of device, service, electronics and mechanics and software design.
- For larger projects there is a permanent Risk Management Team, sometimes with user experts.

## Risk Chart

- All risk analysis follow a “risk chart”, developed by the experienced Risk Managers of all manufacturing facilities of Dräger Medical. This risk chart is part of DMS IN1640 Product Risk management.

## DMS IN1640 A6, risk chart (example):

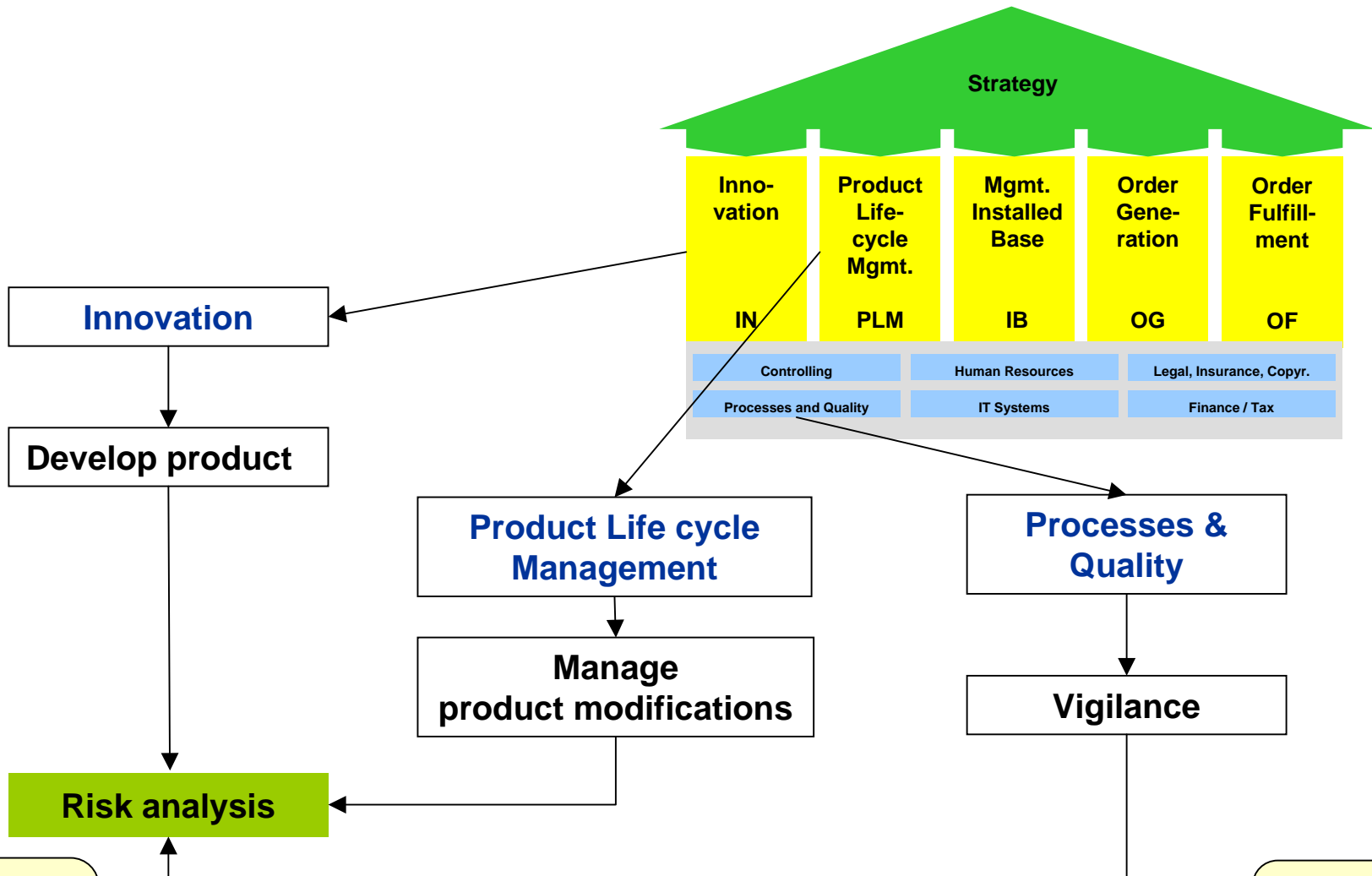
	Severity					
Probability (per device per annum)	<i>no harm at all</i>	<i>reduced comfort</i>	<i>less- serious injury</i>	<i>serious injury</i>	<i>death of one person</i>	<i>death of several persons</i>
>3	Green	Yellow	Red	Red	Red	Red
<3	Green	Yellow	Red	Red	Red	Red
$<3 \cdot 10^{-1}$	Green	Green	Yellow	Red	Red	Red
$3 \cdot 10^{-2}$	Green	Green	Green	Red	Red	Red
$< 3 \cdot 10^{-3}$	Green	Green	Green	Green	Red	Red
$< 3 \cdot 10^{-4}$	Green	Green	Green	Green	Green	Red

	Risk is acceptable
	Risk is not acceptable
	ALARP Region*

\*ALARP Region: As Low as Reasonably Practicable:  
 For respirators, anesthesia devices and incubators medical benefits outweigh the risk.  
 - applied risk mitigation measures are at least state of the art,  
 - applicable International Standards are obeyed.

Class	Definition
negligible	no harm or reduced comfort to patient, operator or bystander
marginal	reduced comfort, but no injury to patient, operator or bystander
less-serious	non-serious injury to patient operator or bystander
serious	serious injury to patient, operator or bystander
critical	death of one patient, operator or bystander
very critical	death of several persons

Class	Definition (Occurrences per device per annum)
very high	$\geq 3$
high	$< 3$
medium	$< 3 \cdot 10^{-1}$
low	$< 3 \cdot 10^{-2}$
very low	$< 3 \cdot 10^{-3}$
extremely low	$< 3 \cdot 10^{-4}$





## Lessons learned after 2 years experience

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- **Using a very deep level of detail does request tool support and does constrict the possibility to handle the risk analysis by paper (e.g. for product approvals)**
- **Completeness of risk analysis in regard to other development results is important (e.g. warnings in user manuals have to be addressed)**
- **Using a library does support comparable levels of detail for the risk analysis and their re-use**
- **Updating the risk analysis after design changes and complaints is an issue for “old” devices without risk analysis or with risk analysis following former methods or using other critical values**
- **The trend goes from one risk chart for all devices to different risk charts for groups of devices, in order that probabilities can be assigned adequately**
- **Evaluation of overall residual risk cannot follow best practices yet, no common industrial guidance available**



## Risk Management is more....

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- **Risk Management manages and controls**
  - **Products**
  - **Finance**
  - **IT-Systems and Infrastructure**
  - **Workers Safety**
  - **...**
  
- **Risk Management is for**
  - **Legal....**
  - **Regulatory...**
  - **Analysts...**
  - **Environment...**
  - **Public...**
  - **...**

**reasons and for high quality care.**

# Drägermedical

A Dräger and Siemens Company