

Quality Management



The Way to Certification
according to ISO 9001 and ISO 13485

AKH Vienna

- 2200 beds
- 51 operation theatres and 21 intervention rooms
- 80 Nursing departments and 21 intensive care units
- 62 outpatient departments and 341 special polyclinics

CSSD :

- approx. 250 customers
- 40 employees
- approx. 80.000 STE per year
- ISO 9001:2000 and ISO 13485

Tasks of the CSSD

- Cleaning & Disinfection
- Control & Packing
- Sterilisation
- Batch- and product release
- Storage and Transport
- Documentation / Traceability

EDUCATION of the employees

- Training programme
- Checklists
- Operating instructions
- Process description
- Quality management system
- Basic education
- advanced training „Sterile Supply“

Technical Equipment

- 6 WDs
- 1 Ultrasonic device
- 2 work stations for manual cleaning
- 16 Hot sealing units
- 8 Steam sterilisers
- 2 FO- and 2 ETO-Sterilisers
- Conveying machinery (AT/KB)

ISO 9001: 2000

General requirements, adaptive to all organisations – independent from type and size and the types of products provided

Main focus:

- Process orientation
- Compliance with applicable requirements of the authorities
- Compliance with the customer's requirements
- **Increase of the customer's satisfaction**
- **Permanent advancement of the system**

ISO 13485:2003

Specific for organisations – which provide medical device –
independent from type and size of the organisation

Main focus: Basis - ISO 9001

- Process orientation
- Compliance with applicable requirements of the authorities
- Compliance with the customer's requirements
- **Maintenance of the system's effectivity**
- **Validation of Production processes**
- **Consideration of the risk management during the whole realisation of products**

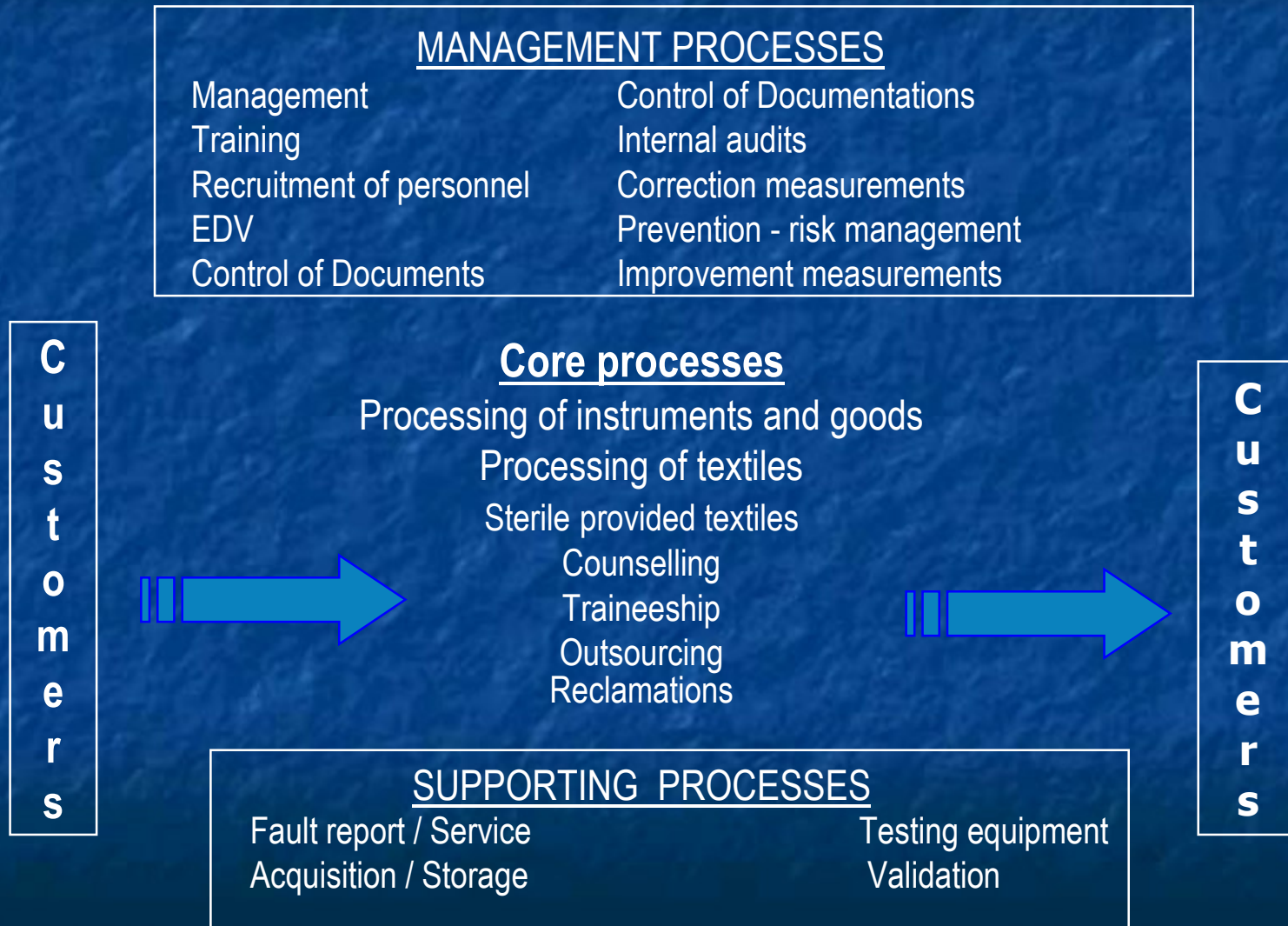
The way to certification acc. ISO 9001:2000

- Nov 01: Start of the project
Orientation to the overall statements for Nursing and the AKH
- Nov – Dec 01: Definition phase – Planning phase
Organisation – Coordination – basic team – Basic training
- Jän - Oct 02: Implementation and Configuration phase
Analysis-target concept–working process–ongoing education
- Oct - Nov 02: Internal Audit and Management Review
- - Jan 2003: Optimising phase – Realisation phase
System optimising in the course of the first use
- Jan 03: Certification Audit
- March 03: Certificate acc. ISO 9001:2000 – End of project

The way to the certification acc. ISO 13485:2003

- March 03 - April 06: Internal audits and Inspection audits – annually, Planning for the additional certification acc. ISO 13485 – in coordination and assistance with the directorates, the organisation and the nursing service
- April 06: Short audit for relevant demands acc. ISO 13485
- April - June 06: Adaption and completement of available means for the compliance of the additional requirements of the standard
- June 06: Extension audit acc. ISO 9001:2000 and additional Certification audit acc. ISO 13485:2003
- since June 06: Certificate acc. to both standards – beeing the first CSSD of an Austrian hospital

The „living“ Quality management system



The „living“ Quality management system (1)

- Job instructions and additional checklists for the whole processing cycle
- Complete documentation and recordings for all steps of processing
- Standards for
 - Processing of instruments
 - Basic training for new employees
 - Trainees and students
- Cataloguing of all medical device
- Classification of medical devices in risk groups acc. to the risk during use
 - non critical - Contac with intact skin
 - semi critical - Contact with mucosa and pathological modified skin
 - critical - Contact with wounds, penetration of skin or mucosa

The „living“ Quality management system (2)

- Organigram and job description
- Training, further training and ongoing training of the employees
- Survey of the satisfaction of the staff members in regular personal orientation interview
- Point of intersection with the customer:
Customer contact on a regular basis including:
consulting, survey of the satisfaction of the customers,
customer list

The „living“ Quality management system (3)

- Collection of reclamations – setting of measurements
- Measurement and control of the most important processes by characteristics, statistical techniques and control charts
- Ongoing preventive and correction measures including transformation measurement
- Platform for improvement – once a month for all members of the staff
- Supplier assessments – once a year and when necessary
- Risk analysis on a regular basis

The „living“ Quality management system (4)

- Annualy - internal audit and surveillance audit or recertification audit
- Fixing of aims and checking of the achivement of aims in a management review
- Refurbishment of important topics in internal working groups
- Monthly QM- Jour Fixes of the executive team
- Advancement and ongoing improvement of the QM - System under consideration of all employees of the central sterilisation

We achieve quality through:

- Motivated employees
- Training and further training
- Equipment acc. to the state of the art
- Quality management system acc.
EN ISO 9001:2000 and EN ISO 13485:2003
- Customer orientation
- Cooperation with hospital hygiene and building service

The „living“ (and certificated)
Qualitymanagement - System
leads to optimised processes
and
assures safety
for user and patient!



**Wir freuen uns
über unseren
Erfolg!**

Thank you!

Monika Semler

