Quality Management

The Way to Certification
according to ISO 9001 and ISO 13485

OEGSV-WFHSS
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Monika SEMLER
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 policlinics

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 – being the first CSSD of an Austrian hospital
The „living“ Quality management system

MANAGEMENT PROCESSES
- Management
- Control of Documentations
- Training
- Internal audits
- Recruitment of personnel
- Correction measurements
- EDV
- Prevention - risk management
- Control of Documents
- Improvement measurements

Core processes
- Processing of instruments and goods
- Processing of textiles
- Sterile provided textiles
- Counselling
- Traineeship
- Outsourcing
- Reclamations

SUPPORTING PROCESSES
- Fault report / Service
- Testing equipment
- Acquisition / Storage
- Validation
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: Contact 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)

- Annually - internal audit and surveillance audit or recertification audit
- Fixing of aims and checking of the achievement 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
- 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

ZENTRALSTERILISATION AKH WIEN