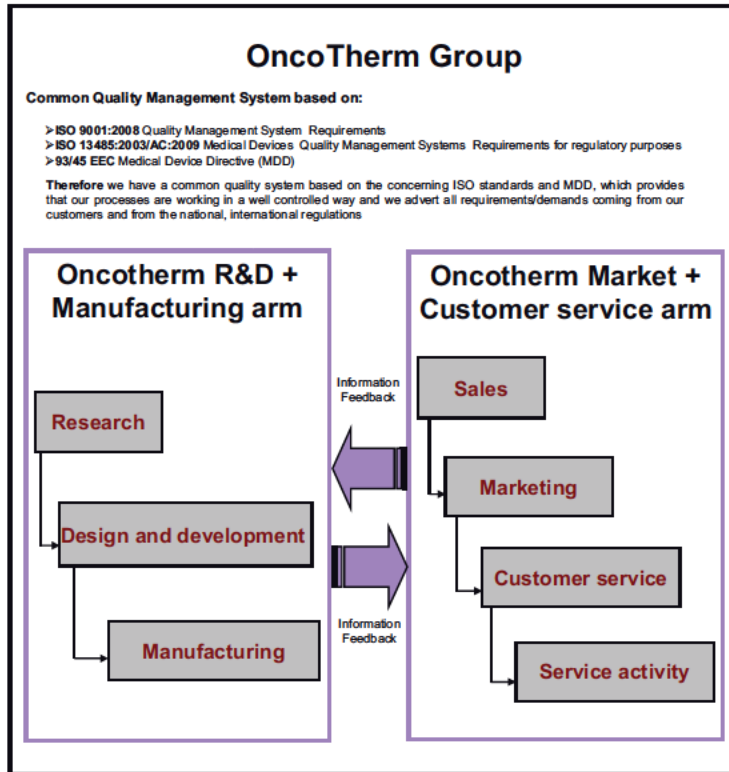


P-18 – Ms. Anett Gallne-Vályi - Introduction of the international quality management system: OncoTherm Group



Introduction of the international quality management system: OncoTherm Group

Anett Gállné-Vályi
Quality Manager of Oncotherm Group



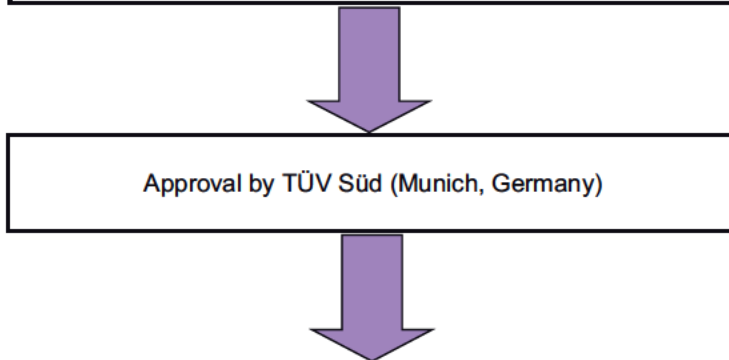
Objectives of the presentation:

- > Show the basis of the permanent improvement of the efficacy of oncothermia combined with high quality and complete safety for the users and patients
- > Keeping up the trust of our users and potential customers

Basic points:

- ✓ Oncotherm devices are prepared by team working of highly qualified experts
- ✓ This unification of the German medical and constructive knowledge with the general European manufacturing culture based on the concerning requirements
- ✓ Oncotherm solves the globalization requests inside of the EU, strengthening its reputation and good will
- ✓ Oncotherm established a perfect cooperation between the research, medical knowledge, marketing, manufacturing and services
- ✓ Oncotherm operates in the frame of strict common German quality management systems based on the below mentioned aspects
 - > Our devices are distributed for over fifteen countries worldwide, using the German medical knowledge and practical expertise
 - > Most medical feedbacks are coming from the smart German physicians from more than hundred oncothermia installations in the country. This is a good input for the research, design and development as well as an important help of the manufacturing and controlling channels
 - > Feedback from the service activity and the customer service is an integrative part of the company's progress. These pieces of information directly and permanently improve oncothermia method and its devices
 - > Oncotherm manufacturing facilities are organized reacting flexible and quickly on the market demands and challenges
 - > The oncothermia methods are in the focus of our marketing policy. The devices are serving this state of art methodology, giving effective weaponry in the hand of the medical staff for fighting in the war against cancer. This marketing strategy requests integrative and tight cooperation with research, design and development amalgamated by interdisciplinary approaches of modern technical and medical knowledge

Oncothermia marketing and manufacturing arms are working like an integrative unit that makes us strong and effective on the market.



Oncotherm System (OS) =
Oncotherm Device (OD) + Oncotherm Method (OM)

„Product of Germany, Made in EU by German approval“

Conclusion:

The OncoTherm Group is a marketing method which is in synergy with the devices and jointly presented on the market as a system. There is a 21 years hard work, experience and knowledge behind the OncoTherm System which certifies that this system has stood the test of the time.

OncoTherm Group doesn't follow the practice of the large globalized European companies who are transferring the manufacturing outside Europe. We do everything in Europe and proud on that high level production culture which is represented by our 21 years old company.

Our quality management systems are satisfying the highest European medical standards. The production process of the devices has ISO13485 medical standard and it is approved by TÜV Süd Product Service GmbH (Munich, Germany), who also certifies our products according to the European Medical Device Directive (medical CE mark).

The business processes have also the highest standard (ISO9001) granted by the TÜV Süd Management Service GmbH (Munich, Germany), vouching for the standardized available processes to satisfy oncothermia users and potential customers.

TÜV Süd as the largest Notified Body for medical devices in EU justifies the operation of our quality management systems and keeps it well controlled to fulfill every necessary European requirements.



Integrity:

We don't sell only a device but an **OncoTherm System** which consists of **OncoTherm Device** and **OncoTherm Method**.

Full process is controlled by unified overall leadership and unified overall quality system!

