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# Symposium

Market Access for Advanced  
Therapy Medicinal Products

# Workshop

Concepts for Cell Quality Markers

10–11 June 2010, 10 a.m.–5 p.m.

**BMW Welt, Munich**

**Germany**



TÜV SÜD Product Service GmbH

TÜV®



Advanced Therapy Medicinal Products (ATMP) are manufactured by applying the basic principles of engineering and life sciences. Know-how from the fields of cell biology, cell culture technology, biochemistry, molecular biology and biophysics is used for this task. Representing a prospering branch of biotechnology, first ATMPs are entering the European market following a harmonized authorization procedure.

A symposium organized by the Medical and Health Services unit of TÜV SÜD Product Service GmbH focuses on the regulatory requirements for this novel type of medicinal products. Contributions concentrate on the authorization process in Europe, an introduction to the Committee for Advanced Therapies (CAT), and the relevance of guidelines. Requirements for the United States market will also be addressed.

## Target group

The symposium addresses responsible parties and decision-makers from politics and industry, manufacturers of medical devices, pharmaceuticals and biologics utilizing material of Animal Origin, and competent authorities.

### **Moderation:**

Dr. Christian Schübel, TÜV SÜD Product Service GmbH

# Symposium, 10 June 2010

**Prof. Dr. Paula Salmikangas**

**Senior Researcher, Finnish Medicines Agency, and  
Co-Chairperson of CAT**

- The approval process
- The relevance of opinion papers

**Dr. Patrick Celis (requested)**

**EMA and Secretary of CAT**

- An introduction to the Committee for Advanced Therapies (CAT)

**Dr. Jana Straßburger**

**German Federal Ministry of Health, Division 121 –  
Blood and Blood Products, Sera, Vaccines, and Tissue**

- Article 28 of the ATMP regulation: The “hospital exemption”

**Dr. Gabriele Tröscher**

**Project Manager, DIN Deutsches Institut für Normung e. V.,  
Optics and Precision Mechanics Standards Committee NAFu0**

- Update on international and European standardization projects for ATMPs

**Prof. Dr. Sabine Kloth**

**Senior Product Specialist, TÜV SÜD Product Service GmbH**

- The new type of combination products





## Workshop, 11 June 2010

For almost one century, cells, tissues, and organs have been used to replace non-functional parts of the human organism. Thus, long-standing experience with the safe use of these unique biological materials has been established. In this context, the need for cell quality markers is evident.

The focus of the workshop will be an exchange of information on the basic requirements for cell quality markers, with the aim of stimulating the development of a common consensus on these requirements. The workshop will consist of a series of short presentations and round-table discussions.

## Key note

**Prof. Dr. Paula Salmikangas**  
**Senior Researcher, Finnish Medicines Agency, and**  
**Co-Chairperson of CAT**



**Attendance fee:**

€250.00 excl. or €297.50 incl. VAT for one day

€400.00 excl. or €476.00 incl. VAT for two days

The attendance fee includes refreshments and lunch.

Members of Forum MedTech Pharma e.V. receive a discount of 10%.

**Venue:**

BMW Welt, Munich

Am Olympiapark 1

80809 Munich

Germany

**Registration:**

The registration form is available at:

[www.tuev-sued.de/ATMP-Symposium](http://www.tuev-sued.de/ATMP-Symposium)

Please complete this form by 19 April 2010 at the latest.

**Number of participants:**

The number of participants in the symposium is limited to 150.

**Further information can be obtained from:**

Ms. Ulrike Müller-Wachtveitl

Phone: +49 89 5008-4315

E-mail: [ps-marketing@tuev-sued.de](mailto:ps-marketing@tuev-sued.de)



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