

State-approved course § 28 GenTSV for Project Leaders and Biosafety Officers
Gene Technology, Biosafety and Biosecurity
Refresher Course
Beutenberg Campus, Jena, 07.11.2024

Program

- 9:00 **J. MERTSCHING**
Welcome and Introduction
- 9:05 – 9:45 **J. MERTSCHING**
Hazard potentials of organisms (Part I)
- Safety aspects in the handling of bacteria and parasites
 - Current safety assessments and statements of the ZKBS
- 9:45 – 10:30 **J. MERTSCHING**
Safety measures for genetic engineering facilities and deliberate releases (Part I)
- Facilities and equipment according to annexes 2-4 GenTSV
- 10:30 – 10:45 Coffee Break
- 10:45 – 12:15 **J. BOHNE**
Hazard potentials of organisms (Part II)
- Viral vectors and genome editing;
 - Gene therapy, clinical trials
- 12:15 – 13:15 Lunch
- 13:15 – 14:45 **J. KAHRMANN**
Legislation on safety measures (Part I)
- Application procedures (notification, registration, approval)
 - Responsibilities of project leader, biosafety officer and user
- 14:45 – 15:00 Coffee Break
- 15:00 – 15:45 **J. MERTSCHING**
Legislation on safety measures (Part II)
- Documentation (GenTAufzV)
 - Organizational measures (Access control, operating instructions)
- 15:45 – 16.30 **J. BOHNE**
Safety measures for genetic engineering facilities and deliberate releases (Part II)
- Sterilization, disinfection, and inactivation
 - Hygiene plan

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Under the German Genetic Engineering Act project leaders and biosafety officers must complete a supplementary training with emphasis on risk assessment, safety measures, principles of legislation and workers' protection. According to § 28 GenTSV, the knowledge acquired here must be updated at least every five years by renewed participation in a state-approved refresher course.

In this refresher training, new regulations on safety measures will be explained and classified. Current statements of the Central Commission for Biological Safety (ZKBS) and publications of the Committee for Biological Agents (ABAS) will be discussed. In addition, the rights and duties of project leaders and of biosafety officers in genetic engineering facilities will be explained on the background of the amended Genetic Engineering Safety Ordinance (GenTSV).

The content of this refresher course is based on the curriculum of the federal biotechnology authority (Bund/Länder-Arbeitsgemeinschaft Gentechnik - LAG) and includes:

Part I. Legislation on safety measures

Part II. Hazard potentials of organisms

Part III. Safety measures for genetic engineering facilities and deliberate releases.

The certificate of successful participation in this state-approved refresher course enables the participant to continue to perform the function of project leader or biological safety officer in accordance with the Genetic Engineering Act in the company or at the university.

Speakers:

PD Dr. rer. nat. Jens Bohne, Biosafety Officer Hannover Medical School

Ass. jur. Jens Kahrmann, Legal Officer, Berlin

Dr. rer. nat. Jürgen Mertsching, Consulting Mertsching Biosafety