

**Advanced Training Course
according to the German Federal
Law
"Gentechnik-
Sicherheitsverordnung"
(GenTSV § 28)**

Venue:
Magnus-Haus of the
German Physical Society
Am Kupfergraben 7
D-10117 Berlin

Course Director: Reinhard Geßner, MD, PhD
Deputy Director of Institut for Laboratory Medicine,
Pathobiochemistry and Molecular Diagnostics
Universitätsklinikum Giessen-Marburg

Program

Monday (morning session)

starting 08.15	Arrival and registration of participants; distribution of course materials	
08:45 – 09.30	Welcome and Course Introduction <ul style="list-style-type: none"> - Presentation of the course concept - Risks linked to genetic engineering - Introduction of regulations in the USA and in Germany - Hierarchy of European and German regulations - Position statements by the ZKBS 	R. Geßner, MD, PhD Deputy Director Institut for Laboratory Medicine, Pathobiochemistry and Molecular Diagnostics Universitätsklinikum Giessen-Marburg
09:30 – 10.15	Introduction to the German Genetic Engineering Act (GenTG) <ul style="list-style-type: none"> - Definitions used in German genetic engineering regulations - Central Committee on Biological Safety (ZKBS) - Biohazard risk reduction principle - System of biosafety levels 1 to 4 	R. Geßner, MD, PhD Deputy Director Institut for Laboratory Medicine, Pathobiochemistry and Molecular Diagnostics Universitätsklinikum Giessen-Marburg
10.15 – 10.30	<i>Coffee Break</i>	
10.30 – 11.15	German Federal Regulations on Genetic Engineering <ul style="list-style-type: none"> - Structure, legal definitions and interpretation of German laws - European regulations of genetic engineering - Application of the regulations in a genetic engineering facilities - Regulations that are directly related to the Genetic Engineering Act 	W. Pellnitz, Med.Dir. a.D. Former Head of Dept. I C, Berlin State Office of Health and Social Affairs (LAGeSo) Berlin
11.15 – 12.00	Genetic Engineering Act (GenTG) <ul style="list-style-type: none"> - Announcement, registration and licensing of genetic engineering facilities and projects - Controlled release of GMO and placing on the market - Confidentiality of information provided to the authorities - Decision process of the permit authority - Public participation process - Liabilities, fines and penalties 	W. Pellnitz, Med.Dir. a.D. Former Head of Dept. I C, Berlin State Office of Health and Social Affairs (LAGeSo)
12.00 – 13.00	Microbial Infections <ul style="list-style-type: none"> - Routes of infection with viruses, bacteria and parasites - Pathogenesis and epidemiology - Immunological aspects including vaccination - Preventive measures and therapy 	Prof. H. Zeichhardt, PhD Institute for Quality Validation in Viral Disease Diagnostics - (IQVD), Berlin or: H.-P. Grunert, PhD Biotechnological Diagnostics Corporation (GBD), Berlin
13.00 – 14.15	<i>Lunch Break</i>	

Monday (afternoon session)

14.15 – 15.45	Construction, Equipment and Maintenance of Genetic Engineering Facilities <ul style="list-style-type: none">- Requirements according to the German Genetic Engineering Safety Regulations- Practical approach to fulfill the requirements when building and operating a genetic engineering facility	R. Geßner, MD, PhD Deputy Director Institut for Laboratory Medicine, Pathobiochemistry and MolecularDiagnostics Universitätsklinikum Giessen-Marburg
15.45 – 16.00	<i>Coffee Break</i>	
16.00 17.00	Sterilization, Disinfection, Inactivation <ul style="list-style-type: none">- Sterilization by physical procedures- Surface disinfection- Hand disinfection	R. Geßner, MD, PhD Institute of Clinical Chemistry, Hannover Medical University (MHH)
17.00 – 18.00	Genetically Modified Plants <ul style="list-style-type: none">- Risk assessment- Biosafety classification- Environmental considerations upon conducting deliberate controlled release experiments- Placing on the market of genetically modified plants	Th. Pickardt, PhD Institute of Applied Genetics Free University of Berlin
18.00 – 20.00	<i>Networking and Refreshments</i>	

Tuesday (morning session)

08.30 – 09.15	Occupational Safety Aspects in Genetic Engineering <ul style="list-style-type: none">- Occupational Safety Regulations- Federal Immission Control Act	W. Pellnitz, Med.Dir. a.D. Former Head of Dept. I C, Berlin State Office of Health and Social Affairs (LAGeSo)
09.15 – 10:00	Genetic Engineering Safety Regulation (GenTSV) <ul style="list-style-type: none">- Biosafety classification in laboratories, green houses and animal facilities- Waste and waste water of genetic engineering facilities- Responsibilities of the operator, the project leader and the biological safety officer- Penalties	W. Pellnitz, Med.Dir. a.D. Former Head of Dept. I C, Berlin State Office of Health and Social Affairs (LAGeSo)
10.00 – 10.15	<i>Coffee Break</i>	
10.15 – 11.00	Other Federal Regulation Applying to Genetic Engineering <ul style="list-style-type: none">- Bioweapon Convention- Infection Prevention Act- Animal Epidemia Protection Act and Animal Infectious Agents Regulation- Animal Protection Act	W. Pellnitz, Med.Dir. a.D. Former Head of Dept. I C, Berlin State Office of Health and Social Affairs (LAGeSo)
11.00 – 11.45	Additional Regulations Applying to the Genetic Engineering Facility <ul style="list-style-type: none">- Chemical hazards in the genetic engineering facility (GefStoffV)- Radiation protection upon using radionuclide-labeled GMO (StrlSchV)	R. Geßner, MD, PhD Deputy Director Institut for Laboratory Medicine, Pathobiochemistry and MolecularDiagnostics Universitätsklinikum Giessen-Marburg
11.45 – 13.00	<i>Lunch Break</i>	

Tuesday (afternoon session)

13.00 – 14.30	Organizational Safety Measures, Processing of Applications and Case Presentations <ul style="list-style-type: none">- Biological risk assessment and biosafety classification- Announcement, registration and licensing of genetic engineering facilities and projects- Access to and designation of genetic engineering facilities- Disinfection directory, emergency plan and operating instruction- Recording of experiments with GMO- Surveillance of genetic engineering facilities	P. Witkowski, PhD Head of Genetic Engineering Unit, Berlin State Office of Health and Social Affairs (LAGeSo)
14.30 – 14.45	<i>Coffee Break</i>	
14.45 – 16.15	Risk assessment and biosafety classification <ul style="list-style-type: none">- Safety aspects when working with GMO- Risk potential of common donor and acceptor organisms- Risk potential of common cloning and expression systems- Biosafety classification of genetic engineering projects involving different organisms and vectors- Biological safety measures	M. Kaspari, PhD Federal Office of Consumer Protection and Food Safety (BVL), Berlin
16.15 – 17.00	Final discussion: case studies and trouble shooting <ul style="list-style-type: none">- Risk assessment of genetic engineering projects- Practical applications using case studies that are either provided or may be proposed by the participants	R. Geßner, MD, PhD P. Witkowski, PhD M. Kaspari, PhD