

KNOWLEDGE.

**SIMPLY
EXPLAINED.**

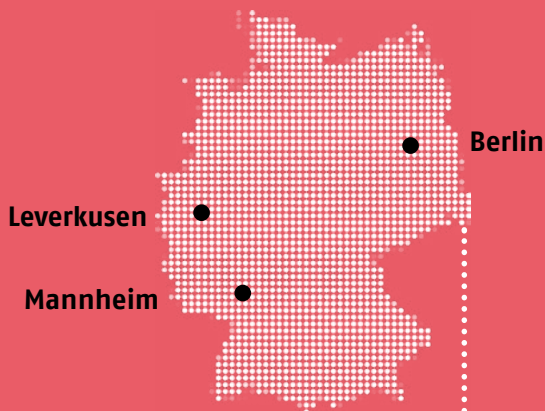




KNOELL ACADEMY.

knoell academy is a business area of knoell, a leading expert in the worldwide registration and authorization of chemical products and substances. We specialize in providing training courses for these highly complex and ever-changing areas. With our modular training and development program that can be tailored to your needs, knoell academy offers solutions for everyone.

WE KNOW WHAT YOU ARE TALKING ABOUT.



Working with over 50 experienced speakers, **knoell academy** offers training courses in **Mannheim, Leverkusen and Berlin**. Regardless of whether you are looking for training options for your employees, as a company, or want to build on your own qualifications, simply choose one of the courses from our modular training program to achieve your goals.

Not exactly what you had in mind? No problem, we can tailor our training modules and training options to precisely meet your needs.

CROP PROTECTION

Learn more about regulatory principles and the latest developments in the area of crop protection & biocontrol agents or take a training in specific, approval-related specialties.

BIOCIDES

The placement of biocidal active substances and biocidal products on a market is a broad and complex field due to the large spectrum of target organisms and extensive areas of application.

REACH AND ITS GLOBAL RELATIVES

Our team of experts will keep you informed about solutions to cope with the coming challenges of REACH and global chemical regulations.

COSMETICS

Navigate your way safely through the world of global regulations for cosmetic products and cosmetic ingredients with our expert consultants at your side.

FOOD CONTACT MATERIALS

Learn more about all regulatory or technical aspects of global food contact material regulations.

MEDICAL DEVICES

Our trainers will keep you posted about the latest local and regional legal developments of regulations for medical devices.

PRODUCT SAFETY

Safety Data Sheets, Globally Harmonized System of Classification and Labelling, Dangerous Goods, Safety regulations – our experts can help to ensure that your products will be used safely.

INHOUSE TRAINING COURSES

Our training program is flexible and can be tailored to meet your needs and company objectives. We can run courses either at your premises or alternatively as modular webinars.

GENERAL TECHNICAL TOPICS

Looking for a more generic technical topic or a topic relevant to more than one market area? This is the section of interest for you.



CROP PROTECTION.

Extend your regulatory knowledge in Crop Protection at knoell academy. Are you a regulatory manager wishing to better understand the implications of new assessment guidance documents? Are you a risk assessor and want to know the differences between substance approval and product authorization and who the stakeholders are? Are you a study director wishing to understand data requirements, how they apply and their underlying legislation? Do you need a basic introduction to crop protection regulations for an audience

without this particular background? Or are you looking for modeling approaches and higher-tier assessments in different technical areas? knoell academy provides clear and easy to follow crop protection training courses in a variety of highly complex areas: EU active substance and product registration, agricultural practice, endocrine disruptors, environmental fate and exposure modeling, dietary risk assessment or GLP trainings to cite only a few.

STAY INFORMED!

#CROPPROTECTION
www.knoellacademy.de

**INTRODUCTION
TO REGULATORY ECOTOXICOLOGY
FOR AGROCHEMICALS**

 1 Day

**ANALYSIS
OF ECOTOXICOLOGICAL
EXPERIMENTS WITH R**

 2 Days

**STATISTICS
IN ECOTOXICOLOGY**

 1 Day

**ENVIRONMENTAL FATE:
DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FATE
STUDIES IN THE REGISTRATION PROCESS**

 1 Day

**ENVIRONMENTAL EXPOSURE MODELING
IN THE REGISTRATION PROCESS
OF AGROCHEMICALS**

 1 Day

**DIETARY SAFETY
AND RISK ASSESSMENT**

 1 Day

**REGULATORY PROCESSES AND
DOSSIER STRUCTURE FOR THE
AUTHORIZATION OF PLANT PROTECTION
PRODUCTS IN THE EU**

 1 Day

**UNDERSTANDING THE GUIDANCE FOR IDENTIFYING
ENDOCRINE DISRUPTING CHEMICALS
IN THE BIOCIDES AND CROP PROTECTION AREA**

 1 Day



Union authorization. National authorization. Transitional provisions (Article 89). Mutual recognition. Biocidal Product family. metaSPC. Treated article. Parallel trade permit. Same biocidal product. Private label. Asset owner. Efficacy.

Are you exhausted with biocidal terminology? Are you finding it hard to keep yourself on track and up to date with the continual flow of information, competent authority (CA) developments or position papers? Did you ever wish that someone else could digest this complex information for you and deliver the key messages of what is actually required for biocidal active substance approval or biocidal product authorizations? knoell academy can help. Our experts will share their expertise to enable you to easily navigate through the biocidal regulatory requirements, whilst paying particular attention to the rights

and obligations of the applicant. We can train you and your team to identify the regulatory hurdles and learn how to develop strategies to meet the increasingly stringent efficacy and data requirements. We can show you the key features of how you can keep your biocidal actives and products on the market. In addition, we address borderline cases, the regulation of treated articles, endocrine disrupting property assessment, risk assessment concepts (human, dietary and environmental). Our training topics are always adapted to current events in the field of biocide regulation such as biocides produced in situ, private labels, the consequences of Brexit for the approval of biocides and emerging regulatory requirements worldwide, such as that in China or Korea („K-BPR“). Our training courses are ideal for companies seeking biocidal approval in Europe or worldwide.

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#BIOCIDES
www.knoellacademy.de

AUTHORIZATION OF BIOCIDAL PRODUCTS IN THE EU

 1 Day

CLASSIFICATION AND LABELLING OF MIXTURES: APPLYING THE CLP-REGULATION (PHYSICAL, HEALTH AND ENVIRONMENTAL HAZARDS)

 1 Day

EFFICACY WORKSHOP: HOW TO BUILD A SOLID CASE

 1 Day

UNDERSTANDING THE GUIDANCE FOR IDENTIFYING ENDOCRINE DISRUPTING CHEMICALS IN THE BIOCIDES AND CROP PROTECTION AREA

 1 Day

IUCLID 6 FOR BIOCIDES – BACKGROUND AND PRACTICE

 1 Day

RISK ASSESSMENT UNDER THE BIOCIDAL PRODUCTS REGULATION (HUMAN HEALTH AND ENVIRONMENT)

 1 Day

**THIS SECTION
IS GROWING FAST!
CHECK THE WEBSITE FOR
LATEST UPDATES:**

www.knoellacademy.de



REACH AND ITS GLOBAL RELATIVES.

For Industrial Chemicals, EU REACH is without doubt the leading regulation, but the responsibility for your products does not end at the European border. If you are selling your products globally, global regulatory compliance should not be a "terra incognita". An incomplete world map of the numerous regulations relating to the marketing and safe use of chemical products may get you into stormy seas. knoell academy therefore not only offers training courses on any regulatory as well as technical aspect of the European REACH regulation, but also covers these aspects for a variety of non-

European countries. Topics include but are not limited to regulatory overviews, (eco-)toxicological hazard, exposure and risk assessments, as well as IUCLID6 and CHESAR training. Our training sessions also address special topics like assessment of endocrine disrupting properties and nanomaterials in a regulatory and technical context. Whether you are a beginner or a long-time expert, product manager or responsible for safety and compliance – we have the suitable training for everyone. Do you have a special need not mentioned here? Contact us! We will be pleased to make an individual offer.

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#REACH
www.knoellacademy.de

**CHEMICALS LEGISLATION IN CHINA,
SOUTH KOREA, TAIWAN, JAPAN, THAILAND
AND MALAYSIA**

 1 Day

**ECOTOXICOLOGICAL ASSESSMENT
OF INDUSTRIAL CHEMICALS**

 1 Day

**EXPOSURE ASSESSMENT REACH –
CHESAR 3**

 1 Day

**IUCLID 6 BASIC TRAINING –
BACKGROUND & PRACTICE**

 1 Day

REACH: IUCLID 6 MEMBER DOSSIER

 1 Day

**REACH FOR DOWNSTREAM USERS ,
DISTRIBUTORS AND IMPORTERS OF ARTICLES**

 1 Day

**REACH: READING AND UNDERSTANDING
EXPOSURE SCENARIOS**

 1 Day

**THE PRINCIPLES OF REACH:
BASIC KNOWLEDGE, LEGAL FRAMEWORK
AND PRACTICAL CONSIDERATIONS**

 1 Day

**TSCA SECTION 5 NEW CHEMICAL
NOTIFICATION WORKSHOP**

 0,5 Days



COSMETICS.

Do you manufacture innovative cosmetic products or cosmetic ingredients and you are not sure regarding your responsibilities? Are you planning to enter new markets and need regulatory or technical support in order to comply with local legislations? Do you import cosmetic products from foreign countries and are you concerned about the regulatory compliance in your own country?

Then, our training courses on cosmetics legislations will help to gain an overview of the regulatory framework applying to cosmetic products and cosmetic ingredients in different markets and explain in detail the duties of the key players in the supply chain. Relevant aspects of the cosmetics legislations are translated into a logical and easy-to-use guide. Participants

will be able to apply the gained knowledge to their daily work. Our training courses are suitable for individuals involved in the manufacture or distribution of cosmetic products or cosmetics ingredients and are directly or indirectly affected by the scopes of Regulatory Affairs, Research & Development or Safety Assessments.

Are you interested in training courses on cosmetics legislations in countries not addressed in our signature training? Or do you have specific concerns that you do not want to share with other participants during the training course? We will be happy to offer customized trainings either at knoell academy, your own premises or as tailored webinars. Please contact us in order to discuss the options available.

**STAY
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#COSMETICS
www.knoellacademy.de

COSMETICS REGULATION (EC) NO. 1223/2009 – WHAT IS ESSENTIAL TO KNOW?

 1 Day

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FOOD CONTACT MATERIALS.

Potential migration of food contact substances (FCS) into food needs to be carefully investigated when it comes to food contact materials and articles (FCM and FCA) i.e., food packaging, kitchenware or equipments used in the food processing industry and consumer households. As FCS may represent a high risk in case these have a negative impact on human health, the EU established certain key regulations that provide the current regulatory framework for FCM & FCA to be manufactured and assessed with respect to their compliance status and consumer safety. Under the same principles, the US FDA has established specific rules and measures, which

need to be considered for a compliance check or to obtain an authorization for the US market. Highly similar measures currently exist in other countries. Therefore, the biggest challenge for FCM & FCA industry is to ensure that its products are compliant with the latest FCM regulations, in a given country/region. In our training sessions you will learn about the key regulatory requirements in the different countries and regions, enabling you to check the compliance of your products or to achieve an approval for your new FCS or FCM. We also offer tailored FCM in-house training courses that will help you better understand the complex FCM regulatory requirements.

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#FOODCONTACTMATERIALS
www.knoellacademy.de

KEY REGULATORY REQUIREMENTS FOR YOUR PLASTIC FOOD CONTACT MATERIALS IN THE EU

 1 Day

HOW TO REACH REGULATORY COMPLIANCE FOR YOUR FOOD CONTACT SUBSTANCES IN THE USA

 1 Day

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www.knoellacademy.de



PRODUCT SAFETY.

Safety Data Sheets, extended Safety Data Sheets, Globally Harmonized System (GHS) of Classification and Labelling, Dangerous Goods regulations – complex chemical regulations worldwide are challenging all actors of the supply chain and require well-trained staff for product safety tasks. knoell academy offers numerous training courses for hazard assessment and management of chemicals to ensure chemical compliance of your products. Our various training courses at different levels are dedicated to professionals and managers in this field. The experienced knoell trainers will share practical knowledge from their daily work with you.

Do you need to classify or label your substances or mixtures according to CLP regulation in Europe or different country-specific GHS implementations in Asia? Do you need to author safety data sheets (SDS) or extended SDS for your products or check supplier raw material SDS for compliance? Do you want to get an overview or deeper understanding of the classification of dangerous goods or applicable packaging requirements? Are you a product safety senior or just getting started in this field? knoell academy offers you the right training course to match your specific needs, to enable you to network with other participants and to discuss current topics with the knoell experts.

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#PRODUCTSAFETY
www.knoellacademy.de

**GERMAN WATER HAZARD CLASSES (WHC) –
KNOW YOUR OBLIGATIONS WITHIN
THE LEGAL FRAMEWORK**

 1 Day

**GAINING EXPERTISE IN PREPARATION
OF SAFETY DATA SHEETS**

 2 Days

**THE EXTENDED SAFETY DATA SHEET (eSDS) –
COMMUNICATION IN THE SUPPLY CHAIN
WITH EXPOSURE SCENARIOS**

 1 Day

**THE REACH SAFETY DATA SHEET (SDS) –
AN ADVANCED TRAINING FOR SDS AUTHORS**

 1 Day

**PROPER PACKAGING AND SHIPPING
OF DANGEROUS GOODS**

 1 Day

**BASICS OF TRANSPORT CLASSIFICATION
WITH FOCUS ON ADR**

 1 Day

**TRANSPORT CLASSIFICATION ADVANCED WITH FOCUS ON
ADR, RID, ADN, IMDG AND IATA FOR THE INTERNATIONAL
MULTIMODAL TRANSPORT OF DANGEROUS GOODS**

 1 Day

**GLOBALY HARMONIZED SYSTEM (GHS) –
CLASSIFICATION AND LABELLING
WITH FOCUS ON ASIA**

 2 Days

**UNDERSTANDING AND APPLYING THE
GHS-/CLP-CRITERIA FOR CLASSIFICATION
AND LABELLING**

 1 Day

**CLASSIFICATION AND LABELLING OF MIXTURES:
APPLYING THE CLP-REGULATION
(PHYSICAL, HEALTH AND ENVIRONMENTAL HAZARDS)**

 1 Day



MEDICAL DEVICES.

The knoell medical device expert team offers client-specific strategic and regulatory consulting for global registration of medical devices. We support you from the initial product idea to the launch of the medical device and thereafter.

We accompany you in designing your quality management systems and with the preparation and maintenance of submission documentations. Additionally, we conduct training sessions and audits, and provide support with the implementation of development and production processes.

knoell academy provides regulatory and quality medical device training courses and professional qualifications. Our training courses are highly interactive and based on real scenarios,

helping you to meet international requirements throughout the product life cycle. Design and develop medical devices to international quality standards, ensure smooth submission, meet ISO standards, satisfy customers and stay ahead of regulatory developments with our medical device training courses. Our trainers are experts in their technical area and use practical examples from their own experiences. Regardless of the size or location of your organization, our technical support and expertise can get you ahead of the game. We can also tailor a course to meet your specific training needs, helping you to overcome challenges and making sure your medical devices are more than ready for their purpose.

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#MEDICALDEVICES
www.knoellacademy.de

**MEDICAL DEVICES WITH MATERIALS OF ANIMAL ORIGIN –
HOW TO PERFORM A RISK ANALYSIS ACCORDING TO
ISO 22442-1, MDR AND RESPECTIVE FDA GUIDANCE**

 1 Day

**BIOLOGICAL EVALUATION OF MEDICAL DEVICES –
REVISIONS OF ISO 10993-1, -18, -17**

 1 Day

**WORKSHOP: TAKE ADVANTAGE OF
ISO 13485 TO EXPLORE THE MDSAP WORLD**

 1 Day

**MEDICAL DEVICE SOFTWARE TRAINING
FOR LEGAL MANUFACTURERS
OF MEDICAL DEVICE SOFTWARE**

 1 Day

TAKE ADVANTAGE OF YOUR CE MARK TO ENTER BRAZIL

 1 Day

**MERGING RISK MANAGEMENT AND USABILITY –
MAKE YOUR PRODUCTS SAFE AGAIN**

 1 Day

**DESIGN PROCESS VERSUS DESIGN CONTROL –
EUROPE MEETS USA**

 1 Day

**PREPARING FOR THE US MARKET:
MEDICAL DEVICES – WHAT TO EXPECT FROM THE US FDA**

 1 Day

**POST FDA CLEARANCE/APPROVAL/GRANTING –
THE KEY TO MANAGING AND MAINTAINING
FDA COMPLIANCE FOR MEDICAL DEVICES**

 1 Day

**HOW TO BRING YOUR MEDICAL DEVICES
ON THE US MARKET – GAINING BASIC KNOWLEDGE,
IDENTIFYING REGULATORY PATHWAYS AND
DEVELOPING SOUND REGISTRATION STRATEGIES**

 1 Day

WORKSHOP: HOW TO DEVELOP REGULATORY STRATEGIES FOR MEDICAL DEVICES AND HOW TO IMPLEMENT HOT TOPICS OF KEY MARKETS

 1 Day

WORKSHOP: MEDICAL DEVICE REGISTRATION – HOW TO INTERACT WITH REGULATORY BODIES SUCH AS FDA, CFDA, ANVISA, COMPETENT AUTHORITIES AND NOTIFIED BODIES?

 1 Day

IVDR - WHAT MANUFACTURERS NEED TO CONSIDER TO GET FROM TRANSITION TO IMPLEMENTATION

 1 Day

HOW TO REGISTER YOUR MEDICAL DEVICES IN BRAZIL

 1 Day

OVERVIEW OF REGULATORY REQUIREMENTS FOR MEDICAL DEVICES IN CHINA AND JAPAN

 1 Day

REQUIREMENTS AND IMPLEMENTATION OF THE MEDICAL DEVICE REGULATION (EU) 2017/745 (MDR) FOR CE MARKING

 1 Day

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www.knoellacademy.de



GENERAL TECHNICAL TOPICS.

If you would like to learn how to make best use of your scientific data, our courses on programming with R might be what you are looking for. However, knowing how to work with your data is only half of the equation. Understanding the circumstances of how they were generated is essential as well:

Our well-received course on Good Laboratory Practice (GLP) works not only as stand-alone information platform for those working under GLP, but also ideally complements the more regulatory focussed workshops we offer.

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R PROGRAMMERS COURSE ADVANCED

 2 Days

R BASIC COURSE

 2 Days

GOOD LABORATORY PRACTICE – GLP

 1 Day

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www.knoellacademy.de

HOW TO SIGN IN.



Search for the desired training course on www.knoellacademy.de



Access the page of the chosen training course and select a date.



Click on the date-specific login button.



Fill in the form and send it. You will automatically receive a copy of the completed form.



Confirmation of registration and an invoice will be sent shortly after your registration. An invitation will follow about two weeks before the training course is due to take place.



Attend the course – please ensure that payment has been done.

INHOUSE TRAINING COURSES.

All our training courses can also be held at your own premises or as modular webinars – tailored to your company goals. You specify the topic and the location; we create an individual concept for your company based on your specifications. Training courses held at your location of choice or as tailored

webinars are not only convenient and can reduce costs, but also enable you to integrate internal processes as effectively as possible. Working individually with your company means that we can also examine sensitive issues and company specific examples.



Search for the desired training course on www.knoellacademy.de



Access the page of the chosen training course.



Click „request“ in the „In-house training“ box on the right side of the page.



Fill in the form and send it.



We will contact you and prepare a quotation.



In case you do not find your desired topic in our program, please send an email to service@knoellacademy.de or use our form for individual inquiries at the bottom of the start page. We will contact you to discuss the different tailored possibilities.

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#INHOUSE
www.knoellacademy.de

REFERENCES.



B | BRAUN
SHARING EXPERTISE

B. Braun Melsungen AG




**BRITISH AMERICAN
TOBACCO**
GERMANY

British American Tobacco
(Germany) GmbH



 **CHEMISCHE FABRIK
KARL BUCHER**

Chemische Fabrik
Karl Bucher GmbH



**SHOWA
DENKO**
EUROPE

SHOWA DENKO EUROPE GmbH



 **BERNER Group**

Berner Group



 **EVONIK**
KRAFT FÜR NEUES

Evonik Industries AG



Jungbunzlauer

Jungbunzlauer Ladenburg GmbH




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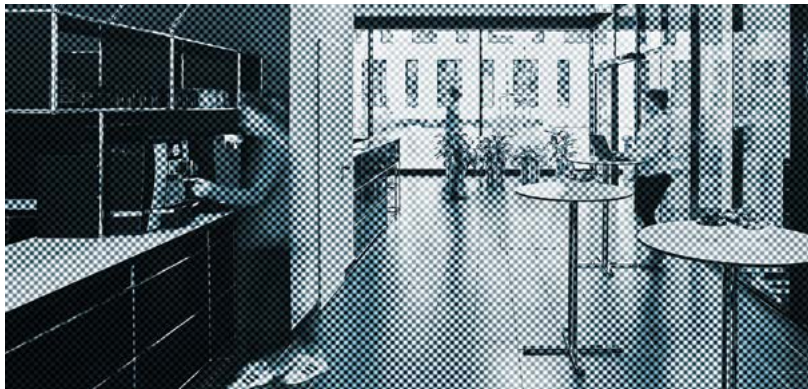




J. Sigel & Sohn GmbH



TRAINING FACILITIES.



Since customer proximity is important to us, our training courses open to the public are available at several locations in Germany. Enjoy a friendly and hospitable atmosphere at our training facilities in Mannheim, Leverkusen and Berlin!

CONTACT.



Terese Diehm

Tel +49 621 718858-134

Eva Schweitzer

Tel +49 621 718858-124

knoell Germany GmbH

knoell academy

Konrad-Zuse-Ring 25

68163 Mannheim

Germany

Fax +49 621 718858-100
service@knoellacademy.de

www.knoellacademy.de

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APPLY.