comprei®

CERTIFICATION PROGRAM CLEANROOM EXPERT

CONTINUING EDUCATION DIPLOMA*

ISO 9001 comprei

ISO 21001 comprei

ISO 29993 comprei

CERTIFICATION PROGRAM CLEANROOM EXPERT

More manufacturing companies in the pharmaceutical and life sciences sectors are sharpening their competitive edge by implementing an effective Contamination Control Strategy (CCS). Highly trained staff is a critical factor in realising that goal.
The Cleanroom Expert Certification Program is designed with that in mind: High quality work is the product of high quality training!

Clear Focus on Cleanroom

YOUR BUSINESS ADVANTAGE – YOUR PERSONAL BENEFIT

The Cleanroom Expert Certification Program gives you the most comprehensive and state-of-the-art qualifications according to the latest science and technology applied to cleanroom hygiene, technology and quality assurance.

The acquired theoretical learning is immediately connected to real-world scenarios using realistic workshops and collaborative learning applied in the comprei training cleanroom.

You become solidly equipped to implement your new skills at your company: a highly trained employee – producing the highest quality.

MODULE QUALITY ASSURANCE

The introductory module addresses the relevant legal and regulatory framework, and how it affects a sound contamination control strategy (CCS), including cleanroom hygiene and technology.

During these three days, a sound understanding is gained of the latest risk-based pharmaceutical quality management.

Get to know characteristics of quality management tools such as *Change Control*, *CAPA* and *Deviation Management*, and become familiar with practical application in the cleanroom environment as it relates to your unique needs. A practice-oriented programme section on planning and conducting successful inspections/audits provides learners with essential tools.

MODULE CLEANROOM HYGIENE

The intersection of personnel/cleanroom/product is contamination critical. This fact, coupled with the rigorous oversight of regulating agencies is good reason to develop effective personnel and industrial hygiene strategies. In this module, you will learn how to lay the foundation for deliberate, competent employee behaviour by means of a comprehensive contamination control strategy.

Relevant factors for establishing such a strategy are defined in well-founded lectures and applied in realistic workshops. This includes safe and efficient cleaning/disinfection strategies, practical clothing/lock policies and continuous monitoring through risk-based procedures.

Clear visualisations and practical experiments in the training cleanroom will leave a lasting impression and provide you with the motivation to follow through.

MODULE CLEANROOM TECHNOLOGY

This module provides a deeper look into the classification of cleanrooms (ISO 14.644-1, EU-GMP), and provides a clear understanding of the normative requirements for planning, construction and qualification of cleanroom facilities and its relationship to implementation (eg. V-model).

Reinforced by tips from experienced speakers, you will get to know the potential pitfalls of ongoing cleanroom monitoring and particle measurements. Different segregation-concepts are compared – analysing how hygiene requirements from the subsequent operations can be anticipated in project phases.
In addition to the characteristics of the established sterilization and decontamination procedures, you will gain insight into their rationale.

TARGET GROUPS:

INDUSTRIES

» Biotechnology
» Blood Banks
» Pharmacies
» Cosmetics
» Food Industry
» Medical Device Manufacturing
» Nutritional Supplement Industry
» Pharmaceutical
» Pharmaceutical Industry Suppliers

PROFESSIONS

» Auditors And Public Officials
» Document Managers
» Quality Control Personnel
» Hygiene And Cleaning Administrators
» Production Managers
» Quality Safety Administrators
» Cleanroom Operators
» Training Administrators
» Technical Departments: Service & Maintenance
» Validation Specialists

TRAINERS

DR. MICHAEL BERANEK, MSC

After graduating from the Rosensteingasse Technical School with a focus on microbiology, Michael Beranek completed his studies in Quality Management at the University for Continuing Education Krems with a Master's degree. He then worked in Quality Management at *BMW*, *Octapharma*, and *Baxter Bioscience*. Since 2002, he has been an authorized signatory of *RIZ-Nord* with a leading function at the Krems start-up centre with a focus on bioscience, and took over its management in 2020. At the same time, Michael Beranek has been self-employed since 1999 doing GMP consulting and audits. In 2019, he obtained his PhD in Business Administration with a focus on Healthcare Management.

SIMON FIALA

In 2005, he first encountered pharmaceutical cleanrooms and required hygiene standards as part of his work as a product specialist for orthomolecular medicine. Three years later, his work at *comprei* got him more deeply involved on special application areas of cleanroom technology. He draws his expertise from internationally recognized seminars and intensive cooperation with specialists from various disciplines of cleanroom technology. In his function as Head of Training and Education, he plays a leading role in developing and decisively shaping the portfolio at comprei, and tailoring it to individual customer processes. In addition to the continuous development and implementation of innovative learning methods in the training program, he is responsible for the qualification and ongoing coaching of the internal trainers. Simon Fiala gives lectures at an Austrian university of applied sciences as part of their Medical and Pharmaceutical Biotechnology program.

DI MICHAEL HABENICHT

Has over 30 years of experience in the field of ventilation, already being exposed to cleanroom technology during his training as a HVAC draughtsman. As he continued his studies as a graduate engineer (FH) in the areas of energy and heat technology, he continued to supervise projects in cleanroom technology.
As his professional life developed, he occupied positions as project and sales managers at various leading providers of cleanroom technology. The focus has been on consulting, planning and execution of hygiene systems, both in the semiconductor and pharmaceutical industries. In particular, the development of qualification services and measurement technology were among his tasks. He is a member of the VDI Technical Committee Cleanroom Technology, and works on various standards of the VDI 2083 series, including VDI2083-3 “Cleanroom Technology – Metrology”, and VDI 2083-4.2 "Cleanroom technology energy efficiency". Since 2023, he has been Head of Cleanroom Business Development at *SIGMA Process & Automation GmbH*, a provider of process automation, and since 2022 part of the *ZETA Group*. With this background, projects can be mapped comprehensively, so that cross-contamination across an entire operation can be minimized through the integrated engineering of processes, building systems, and cleanroom technology.

DI MICHAEL RICHTER

Michael Richter is Global Director, Strategic Customer Partnerships & Innovations of *Ecolabs Division Life Sciences*. He also organizes and speaks at seminars about cleaning and disinfection in GMP environments. He has developed a global business strategy for *Ecolab's* Contamination Control business and built a successful global key account management. In 2006, *Ecolab* acquired the second European and market leader in contamination control: *Shield Medicare Ltd.* In this context, Michael Richter became a member of the new management team and Regional SBU Manager. He studied technical chemistry at the Vienna University of Technology, and subsequently completed the postgraduate course as an export sales manager at the Vienna University of Economics and Business. In addition, he has also obtained the following certificates/licenses: pharmaceutical representative, quality manager, license to trade medical devices and pharmaceuticals.

DI ROBERT SCHWARZ

Offers twenty years of hands-on experience in aseptic processing, contamination control and cleanroom technology, as well as over 15 years of experience in qualification and validation. He holds a degree in Bioprocess Engineering and Biotechnological Quality Management. In 2001, he joined *Baxter Wien* where he led the environmental monitoring team for 4 years. From 2005 to 2018, he worked as a validation specialist, where he was responsible for equipment qualification, sterilization validation, and cleaning validation at *Baxter* and *Shire* (since 2016 in an SME function). In this position, he acquired in-depth knowledge of GxP compliance, including in-depth knowledge of quality assurance. Since 2010, he has also been passing on his experience as a lecturer at a university of applied sciences. In addition, he is often seen as a speaker at conventions and conferences and is a known author of various scientific publications. In 2019, he began working as an independent consultant.

DATES AND VENUES

Training Duration: 9 days (3 x 3 days)
excluding module project work and examination.

Locations in Villach and Frankfurt area.

Current dates can be found at:
https://www.comprei.eu/en/certification-program/

In-house company training also available on request.

comprei Reinraum-Handel und Schulungs GesmbH.
Technologiepark Villach, Europastraße 10
9524 Villach, Austria

INVESTMENT

Participation Fee:
€ 10,500,– excl. VAT,
for 9 days incl. exam fee.

Each module can also be booked individually, with the option of taking the final examination after completing all 3 modules.

Individual Module Participation Fee:
€ 3.900,– excl. VAT
(3 days per module).

DATES AND REGISTRATION

Phone: +43 4242 – 44075-60
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Online: https://www.comprei.eu/en/certification-program/

Cover (*): According to the WIFI training criteria, the course is completed with a diploma.

COURSE REQUIREMENTS & EXAMINATION

Training sessions take place daily from 8.30 a.m. to 5 p.m. (Fridays until 4 p.m.). Successful completion of the course requires attendance on at least 6 days of the entire program and participation in all 3 modules. Project work assignments are distributed during each of the 3 modules.

Project work must be submitted at the latest by the beginning of the next module (for modules 1 and 2), or one week prior to final examination (for module 3).

The final examination consists of a presentation of the project work and fielding questions from an examination board.

CONDITIONS

Participation fees are due within 10 days of receipt of invoice. In case of cancellation, the following fees apply:

- up to 28 calendar days before the start of the event no participation fee
- up to one week before the start of training 50% of the participation fee
- within one week before the start of training 100% of the participation fee

At no additional cost, it is possible to name a substitute participant from the same company until the day the course begins.

In the event of a course cancellation on the part of the organizer, participation fees will be refunded in full. Speakers are subject to change.

In cooperation with WIFI Kärnten
www.wifikaernten.at

www.comprei.eu

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