



Biorisk Management International

IN ASSOCIATION WITH



PRESENTS

ISO 35001:2019 - LEAD AUDITOR

**IMPLEMENTATION AND AUDITING OF A
BIORISK MANAGEMENT SYSTEM**

5-DAY COURSE (SOUTH AFRICA)

COURSE OVERVIEW

The ISO 35001:2019 Lead Auditor 5-Day Course is designed for biosafety and biosecurity professionals in South Africa, and beyond, who will be responsible for, or involved in, the implementation, auditing, or oversight of a Biorisk Management Systems (BRMS) in laboratories and related organizations. In addition, this course is designed for those biorisk management professional, laboratory managers, scientists, and executives, who would like to be instrumental in moving biosafety and biosecurity to the next level and improve their professional knowledge and credentials. This workshop has been successfully deployed in Europe, Australasia and Asia. It is the only premier course offering in-person training and certification from a world-leading expert.

The course provides in-depth knowledge of ISO 35001:2019 requirements and integrates the auditing principles of ISO 19011:2018, enabling participants to competently audit biorisk management systems in line with international best practice while remaining aligned with local regulatory and operational contexts.

The course is Exemplar Global certified and delivered by one of the most recognized international leaders in biorisk management.



COURSE OBJECTIVES

On successful completion of the course, participants will be able to:

- Implement a biorisk management system and its principles within an organization

Apply ISO 19011:2018 auditing principles, procedures, and techniques

- Plan, manage, and conduct ISO 35001:2019 audits
- Evaluate organisational conformity of a Biorisk Management System
- Establish and manage audit teams effectively
- Support full or partial implementation of a BRMS within South African and international institutions
- Develop leadership, performance evaluation, and continuous improvement programmes for BRMS
- Demonstrate the professional attributes expected of ISO Lead Auditors

COURSE STRUCTURE AND CONTENT

The five-day programme combines theory with practical application and includes:

- Detailed review of ISO 35001:2019 clauses and requirements
- Practical implementation strategies for a Biorisk Management System based on ISO 35001:2019
- Auditing principles and practices aligned with ISO 19011:2018
- Risk-based thinking applicable to laboratory and research environments
- Real-world case studies, group exercises, and role-play scenarios
- Ongoing assessments to measure learning outcomes and competence

This course is not an introductory programme in biosafety or biosecurity and is intended for senior professionals with relevant experience.





Biorisk Management International

WHO SHOULD ATTEND

This course is ideally suited to:

- Biosafety and biorisk management professionals
- Laboratory managers and quality managers
- Health, safety, and compliance professionals
- Internal and external auditors
- Senior and executive management within laboratories, research institutions, health care, and life science environments

COURSE APPROACH

The course places strong emphasis on practical, real-world application through:

- Interactive group discussions
- Individual and team-based exercises
- Role-playing of audit scenarios
- Facilitated learning guided by experienced ISO auditors

Participant numbers are limited to ensure a high-quality learning experience.



INTERNATIONAL CERTIFICATION

Biorisk Management International (BRMI), the course developer, is recognized by Exemplar Global as a Recognized Training Provider (RTP). Participants who successfully complete the course will receive:

- A BRMI Certificate of Training
- An Exemplar Global Certificate of Training

COURSE FACULTY

Dr. Stefan Wagener

Dr. Stefan Wagener is the internationally recognised expert in biosafety, biosecurity, and biorisk management with more than 30 years of experience. He has managed high and maximum containment laboratories, held executive roles within government, and played a key role in the development of the ISO 35001 standard. As the founder of Biorisk Management International, he provides global training, consulting, and auditing services.

COURSE DELIVERY AND CONTEXT

The ISO 35001:2019 Lead Auditor Course is delivered internationally and is highly relevant to South African and international laboratories and institutions operating within healthcare, research, pharmaceutical, and life science sectors. The principles and methodologies taught support alignment with both international standards and local legislative and regulatory frameworks.

WHY ATTEND

By completing this course, South African and international professionals will gain the skills and competence required to:

- Strengthen institutional biosafety and biorisk management
- Improve audit readiness and regulatory compliance
- Enhance organisational credibility and international recognition
- Support safer laboratory environments and sustainable operations
- Move biorisk management to the next level

MONDAY 6 JULY - FRIDAY 10 JULY, 2026

VENUE:

Midrand

Labotec Park, 21 Bavaria Ave,
Randjespark, Midrand, 1685
PO Box 6553, Halfway House 1685,
South Africa

PRICE:

R 37 500 pp
(excl accommodation)

\$ 2500 pp
(excl accommodation)

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