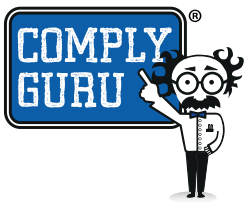


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COMPLYGURU.COM

TRAINING GUIDE

TRAINING TRANSFORMED.

Innovation Leaders for ISO Standards, Auditing & Medtech QA/RA Training



Message From Founder & CEO

I founded Comply Guru as I saw a major gap for training that is more accessible, flexible, and scalable. From the outset, we have been committed to offering innovative learning solutions that are highly effective. Whether it is an online, face to face, or blended format, we have it covered.

Our team of industry experts, experienced Instructors, graphic and instructional designers combined are helping transform training and deliver learning solutions that are trusted & recognized globally.

Eoin Philip Kelly



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Profile ABOUT US

Comply Guru has the distinction of being the first learning provider in the world to achieve multi-accreditations for our learning methodologies in the industries we serve. Our mission is to transform compliance training to simplify the complex landscape of international standards and ever-evolving regulations.

-  3,800+ Learners Successfully Trained
-  98% Recommend Us
-  Trusted by Industry & Notified Bodies
-  Training Delivered Globally

Visit Our Website!



OUR ACCREDITATIONS



Comply Guru are a CQI and IRCA Approved Training Partner (6081148) since March 2019.



Since April 2020, Comply Guru has been an approved training provider of Exemplar Global.

Management TEAM



Eoin Philip Kelly
Founder & CEO

Eoin founded Comply Guru & manages the day-to-day running of the company. Prior to forming Comply Guru, he was Director & Chief Operations Officer in a management consulting & training company and oversaw projects in over 40 countries globally. During that time, he setup the U.S. entity and as its President spent over 6 years based in Chicago, IL.

His experiences led him to conclude that there was a growing need in the market for innovation & more flexible learning solutions in the fast-changing world of Compliance Training. For that reason, he founded Comply Guru.



John Collins

Blended Learning Director

John has 25+ years' experience as a Quality Professional, including 15 years as a Lead Auditor & Instructor on CQI & IRCA Accredited Auditor Training Programs.



Leon Donnellan

eLearning Director

Leon has over 20 years experience in eLearning. During his career, he has spent 10+ years designing programs within highly regulated industries & brings vast experience to Comply Guru in both graphical & instructional design.



Jim Fitzgerald

Learning Success

Jim has a Masters in Marketing & Management Strategy from Limerick Institute of Technology (LIT). He supports Learners on their journey to success from initial enquiry to completion and beyond.

What Differentiates COMPLY GURU



Innovation Leaders

Comply Guru are the first of our kind. We have set a precedent for innovation by becoming the first organization to specialize in both online and blended learning solutions. Our pioneering approach has enabled us to develop exceptionally effective methodologies that provide more accessible and flexible avenues for obtaining premium certifications.



Scalable Learning

We have the capacity to serve individuals up to large organizations with global teams with ease. Our online solutions are available as and when you need them. More than just online learning, we utilize industry-leading methodologies that can be deployed on a global scale.



Accreditation Advocates

Since our launch, Comply Guru has been a strong advocate for accredited training that provides worldwide recognition for our learners. We take great pride in being the first organization to attain several groundbreaking accreditations in online and blended learning for Medical Device QA/RA, ISO Standards and Internal & Lead Auditor Courses.



Bespoke Solutions

We can customize any of our training courses around your specific needs. We can deliver training globally that is either online, at a venue of your choice, blended, or available within your own Learning Management System. Our experienced team has an average of 20 years experience supporting training needs for customers all over the world.



Proven Expertise

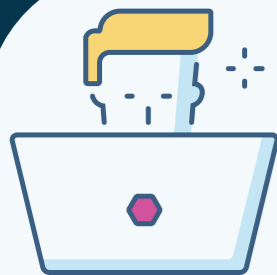
At the heart of our organization lies our exceptional team of experts. We strive to recruit the most accomplished and proficient individuals in their respective fields. Our experts possess a wealth of industry experience acquired over years of practical application, and in addition, they demonstrate a combination of unwavering passion and a proven aptitude for training.



Dedicated Customer Care

98% of our customers would recommend us. We recognize the importance of being customer focused beyond just providing the learning solution. It is about the total experience from the start to the end of the engagement. We care and do our best to continually improve the level of support we offer our wonderful customers.

Why choose our E-LEARNING

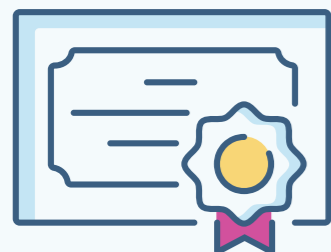


Anytime, Anywhere Learning

- ✓ More flexible compared to Instructor-led training
- ✓ Easy to schedule your training around a busy home or work life
- ✓ More scalable and practical for training teams at site, national or global locations

Highly Effective Learning Experience

- ✓ Professionally designed interactive & engaging content
- ✓ Frequent knowledge checks to ensure learning is achieved as you progress through each module
- ✓ Robust final assessments required to achieve certification



Internationally Accredited Certifications

- ✓ Accreditation offers global recognition for your training and sets Comply Guru apart from the rest
- ✓ Benchmarked and independently assessed courses offer assurance in both the quality & effectiveness of the training

Why choose our BLENDED LEARNING

Blended Learning is a highly effective approach for acquiring knowledge and skills, combining the flexibility of eLearning and the benefits of Instructor-led Learning, where by the end of the training, learners are better equipped and more confident in their ability to apply what they have learned in their workplace.

A crucial feature of blended learning is its phased approach, which extends over a longer period (versus classroom formats alone) as Learners first master the underlying theory before attending skills-based workshops with a Live Instructor which results in superior, longer lasting learning outcomes.

Knowledge



- ✓ Complete at own pace & schedule offering maximum flexibility
- ✓ Ensures familiarity with underlying principles & theory
- ✓ Better prepared for the Instructor-led Workshops

Skills



- ✓ Accelerated Learning Methodology instead of 'Death By PowerPoint'
- ✓ Focus on practical application in a real world environment
- ✓ Expert Instructors with a proven track record



Why choose our **INSTRUCTOR-LED LEARNING**

Accelerated Learning Methodology

Rather than learners engaging in short exercises following instructor presentations, Accelerated Learning has learners discovering and creating their own knowledge through meaningful activities and authentic experiences that lead to greater learning. The instructor becomes a facilitator of a learning process and delivers content only to supplement the learners' process of discovery and creation.

01 Learning is a Creative Journey.

Knowledge is not something a learner absorbs, but something a learner creates. Our courses will help Learners integrate new knowledge and skills into his or her existing structure of self.

02 Learning By Doing.

People learn best in context. Our courses are designed with practical exercises that have Learners working with scenarios, case studies and material that is focused on a 'learn by doing' approach.

03 Collaboration Aids Learning.

All good learning has a social base. Our courses focus on facilitating Learners collaborating together for better learning outcomes. Cooperation among learners speeds learning.

04 Experts with Proven Experience.

All our Instructors have vast industrial experience, but also have proven skills in training delivery. They are current Practitioners in their field ensuring the currency of their knowledge & skills.

05 Bespoke Delivery.

We can easily customize our courses to meet your organization's specific needs ensuring the training is highly relevant to your organizations system, values and culture, making it instantly applicable.

Meet **OUR INSTRUCTORS**

At the heart of our organization lies our exceptional team of experts. We strive to recruit the most accomplished and proficient individuals in their respective fields. Our experts possess a wealth of industry experience acquired over years of practical application, and in addition, they demonstrate a combination of unwavering passion and a proven aptitude for training.



John Collins

Lead Auditor & Instructor

Aside from being our Blended Learning Director, John has 25+ years' experience as a Quality Professional, including 15 years as a Lead Auditor & Instructor on CQI & IRCA Accredited Auditor Training Programs.

During his career, he has worked with all sizes and forms of organizations across a broad range of industries, including extensive experience in the Life Sciences Industry.



Kristian Hill

Lead Auditor & Instructor

Kristian has over 20 years' experience and is formally registered as a CQI & IRCA Lead Auditor for both ISO 9001:2015 & ISO 45001:2018, as well as registered with IEMA as a Principal Environmental Auditor.

He has delivered hundreds of CQI & IRCA Auditing courses covering ISO 9001, ISO 14001, & ISO 45001 to customers all over the world.



Tess Egan

Lead Auditor & Instructor

In a career spanning over 20 years, Tess has audited across the globe for compliance with various standards and regulations for the medical device and pharmaceutical industries, including GMP, GLP, GCP, GcLP, GDP, ISO 13485, ISO 9001, and ISO/IEC 17025.

She brings her vast experience & passion for auditing to every training course she delivers.

Please visit our website to view more instructor profiles.

Our Courses



ISO 13485 LEAD AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 13485 Lead Auditor Training is for anyone that wants to gain the knowledge and skills required to perform full system first, second and third-party audits based on ISO 13485, in accordance with ISO 19011 and ISO IEC 17021-1.

ASSESSMENT METHODOLOGY

In order to successfully complete this course, each Learner will need to:

- Complete the eLearning modules (incl. assessments) prior to the Live Workshops
- Maintain 100% attendance during the Live Workshops
- Pass all continuous assessments during the Live Workshops
- Achieve 70% or higher in the CQI & IRCA Lead Auditor Examination

ENTRY REQUIREMENTS

It is recommended that before completing this course, each Learner has some work-based experience in Quality Management, and this should include sufficient familiarity with ISO 13485 requirements, commonly used terms and definitions, and Plan-Do-Check-Act (PDCA). Some auditing experience is also beneficial.

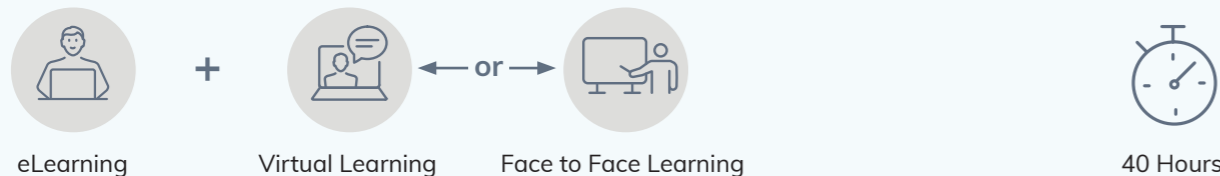
COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2244). Upon successful completion, each Learner shall receive a digital Certificate of Achievement that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

Our industry-leading blended methodology requires Learners to first complete highly interactive eLearning modules on the underlying knowledge & theory before attending skills-based Workshops with an Instructor that focus on practical application in a real life context.



ISO 13485 INTERNAL AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 13485 Internal Auditor Training is for anyone that wants to be part of the team that performs internal audits of part of their Quality Management System (QMS) based on ISO 13485.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2286). Upon successful completion, each Learner shall receive a digital Certificate of Achievement that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

Our industry-leading blended methodology requires Learners to first complete highly interactive eLearning modules on the underlying knowledge & theory before attending skills-based Workshops with an Instructor that focus on practical application in a real life context.



ISO 13485 FOUNDATION TRAINING

WHO IS THIS COURSE FOR?

ISO 13485 Foundation Training is for anyone looking to gain a comprehensive understanding of the underlying principles of Quality Management & core requirements of ISO 13485. This course is strongly recommended in advance of completing either Internal or Lead Auditor training.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2327). Upon successful completion, each Learner shall receive a digital Certificate of Completion that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

eLearning is a highly interactive way to learn at a time & a pace that works best for you, making it easier to get the training you need while balancing a busy home or work life.



EU MDR TRAINING FOR PRACTITIONERS

COURSE OVERVIEW

EU MDR Training for Practitioners takes you through the new European Medical Device Regulation (2017/745), not just from an industry perspective, but also from a Notified Body perspective. This course has been specifically designed for Quality & Regulatory Professionals who are new to the Regulation.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2378). Upon successful completion, each Learner shall receive a digital Certificate of Achievement within 1 business day.



COURSE FORMAT

eLearning is a highly interactive way to learn at a time & a pace that works best for you, making it easier to get the training you need while balancing a busy home or work life.



eLearning



20 Hours

EU IVDR TRAINING FOR PRACTITIONERS

COURSE OVERVIEW

EU IVDR Training takes you through the new European In Vitro Diagnostic Regulation (2017/746), not just from an industry perspective, but also from a Notified Body perspective. It has been specifically designed for Quality & Regulatory Professionals who are new to the Regulation.

COURSE ACCREDITATION

Exemplar Global certifies our Comprehensive EU IVDR Training for Practitioners Course. Successful completion will entitle each Learner to receive a digital Certificate of Achievement that is recognized globally.



COURSE FORMAT

eLearning is a highly interactive way to learn at a time & a pace that works best for you, making it easier to get the training you need while balancing a busy home or work life.



eLearning



18 Hours

ISO 14971 FOUNDATION TRAINING

COURSE OVERVIEW

ISO 14971 Foundation Training provides a comprehensive overview of the international standard for risk management for medical devices. This course has been specifically designed for Quality & Regulatory Professionals in the Medical Device Industry for are new to the Standard.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2415). Upon successful completion, each Learner shall receive a digital Certificate of Completion that is recognized globally. Exemplar Global accreditation is also available.



eLearning



8 Hours

U.S. FDA QMSR & ISO 13485 FOUNDATION TRAINING

WHO IS THIS COURSE FOR?

U.S. FDA Quality Management System Regulation (QMSR) Training is for anyone who wants to understand the requirements, including similarities, differences and key aspects of both the ISO 13485 standard and the FDA QMSR.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2589). Upon successful completion, each Learner shall receive a digital Certificate of Completion that is recognized globally. Exemplar Global accreditation is also available.



eLearning



12 Hours

MDSAP AUDITOR FOUNDATION TRAINING

COURSE OVERVIEW

Medical Device Single Audit Program (MDSAP) Auditor Foundation Training provides learners with the knowledge required to understand the IMDRF's MDSAP and Audit Approach. This course has been specifically designed for those who are new to MDSAP.

COURSE ACCREDITATION

Exemplar Global certifies our MDSAP Requirements & Auditor Foundation Training. Successful completion will entitle each Learner to receive a digital Certificate of Completion that is recognized globally.



eLearning



8 Hours

Course Spotlight



ISO 9001 LEAD AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 9001 Lead Auditor Training is for anyone that wants to gain the knowledge and skills required to conduct full system first, second and third-party audits of quality management systems against ISO 9001, in accordance with ISO 19011 and ISO IEC 17021.

ASSESSMENT METHODOLOGY

In order to successfully complete this course, each Learner will need to:

- Complete the eLearning modules (incl. assessments) prior to the Live Workshops
- Maintain 100% attendance during the Live Workshops
- Pass all continuous assessments during the Live Workshops
- Achieve 50% or higher in the CQI & IRCA Lead Auditor Examination

ENTRY REQUIREMENTS

It is recommended that before completing this course, each Learner has some work-based experience in Quality Management, and this should include sufficient familiarity with ISO 9001 requirements, commonly used terms and definitions, and Plan-Do-Check-Act (PDCA). Some auditing experience is also beneficial.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2192). Upon successful completion, each Learner shall receive a digital Certificate of Achievement that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

Our industry-leading blended methodology requires Learners to first complete highly interactive eLearning modules on the underlying knowledge & theory before attending skills-based Workshops with an Instructor that focus on practical application in a real life context.



ISO 9001 INTERNAL AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 9001 Internal Auditor Training is for anyone that wants to be part of the team conducting internal QMS audits of part of their Quality Management System based on ISO 9001.

COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2149). Upon successful completion, each Learner shall receive a digital Certificate of Completion that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

Our industry-leading blended methodology requires Learners to first complete highly interactive eLearning modules on the underlying knowledge & theory before attending skills-based Workshops with an Instructor that focus on practical application in a real life context.



ISO 9001 FOUNDATION TRAINING

WHO IS THIS COURSE FOR?

ISO 9001 Foundation Training is for anyone looking to gain a comprehensive understanding of the underlying principles of Quality Management & core requirements of ISO 9001. This course is strongly recommended in advance of completing either Internal or Lead Auditor training.

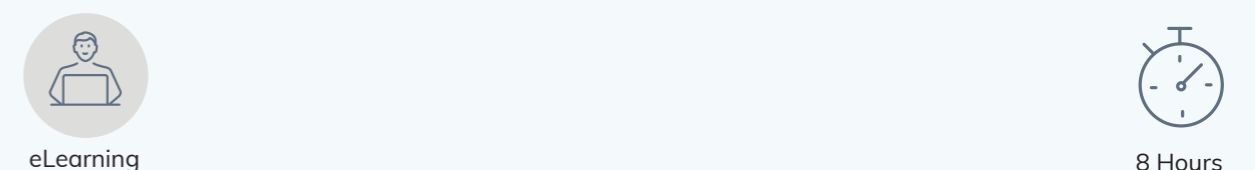
COURSE ACCREDITATION

CQI & IRCA certify this course (No. 2148). Upon successful completion, each Learner shall receive a digital Certificate of Completion that is recognized globally. Exemplar Global accreditation is also available.



COURSE FORMAT

eLearning is a highly interactive way to learn at a time & a pace that works best for you, making it easier to get the training you need while balancing a busy home or work life.



Course Spotlight



ISO 14001 & ISO 45001 LEAD AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 14001 and ISO 45001 Lead Auditor Training Course is for anyone who wants the knowledge and skills required to perform first, second and third-party audits of EH&S management systems against ISO 14001 and ISO 45001, in accordance with ISO 19011 and ISO IEC 17021-1, as applicable.

ASSESSMENT METHODOLOGY

In order to successfully complete this course, each Learner will need to:

- Complete the eLearning modules (incl. assessments) prior to the Live Workshops
- Maintain 100% attendance during the Live Workshops
- Pass all continuous assessments during the Live Workshops
- Achieve 50% or higher in the CQI & IRCA Lead Auditor Examination

ENTRY REQUIREMENTS

It is recommended that before completing this course, each Learner has some work-based experience in Environmental and/or Health & Safety Management, and this should include sufficient familiarity with ISO 14001 & ISO 45001 requirements, commonly used terms and definitions, and Plan-Do-Check-Act (PDCA). Some auditing experience is also beneficial.

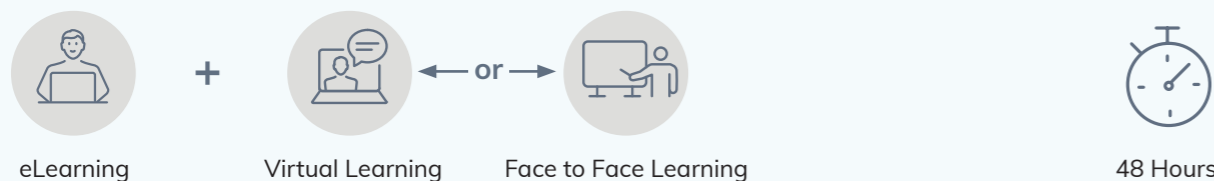
COURSE ACCREDITATION

Exemplar Global certifies our ISO 14001 & ISO 45001 Lead Auditor Training. Successful completion will entitle each Learner to receive a digital Certificate of Achievement that is recognized globally.



COURSE FORMAT

Our industry-leading blended methodology requires Learners to first complete highly interactive eLearning modules on the underlying knowledge & theory before attending skills-based Workshops with an Instructor that focus on practical application in a real life context.



ISO 14001 & ISO 45001 INTERNAL AUDITOR TRAINING

WHO IS THIS COURSE FOR?

ISO 14001 and ISO 45001 Internal Auditor Training is for anyone that wants to be part of the team conducting internal EH&S audits of part of their Environmental and/or Occupational Health & Safety Management System based on ISO 14001 and/or ISO 45001.

COURSE ACCREDITATION

Exemplar Global certifies our ISO 14001 & ISO 45001 Internal Auditor Training. Successful completion will entitle each Learner to receive a digital Certificate of Completion that is recognized globally.



ISO 14001 FOUNDATION TRAINING

WHO IS THIS COURSE FOR?

ISO 14001 Foundation Training is for anyone that wants to gain a comprehensive understanding of the requirements of ISO 14001.

COURSE ACCREDITATION

Exemplar Global certifies our ISO 14001 Foundation Training. Successful completion will entitle each Learner to receive a digital Certificate of Completion that is recognized globally.



ISO 45001 FOUNDATION TRAINING

COURSE OVERVIEW

ISO 45001 Foundation Training is for anyone that wants to gain a comprehensive understanding of the requirements of ISO 45001.

COURSE ACCREDITATION

Exemplar Global certifies our ISO 45001 Foundation Training. Successful completion will entitle each Learner to receive a digital Certificate of Completion that is recognized globally.



ISO 13485 Essentials

COURSE OVERVIEW

Comply Guru offers an ISO 13485 Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours

ISO 9001 Essentials

COURSE OVERVIEW

Comply Guru offers an ISO 9001 Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours

ISO 14001 Essentials

COURSE OVERVIEW

Comply Guru offers an ISO 14001 Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours

ISO 45001 Essentials

COURSE OVERVIEW

Comply Guru offers an ISO 45001 Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours

EU MDR Essentials

COURSE OVERVIEW

Comply Guru offers a European Medical Device Regulation (EU MDR 2017/745) Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours

EU IVDR Essentials

COURSE OVERVIEW

Comply Guru offers a European In Vitro Diagnostic Regulation (EU IVDR 2017/746) Essentials Course for organizations looking for a concise, high-level introduction for their staff.



eLearning



2 Hours



ESSENTIALS COURSES

Comply Guru offer a number of Essentials Courses covering:

- ✓ ISO 9001
- ✓ ISO 13485
- ✓ ISO 14001
- ✓ ISO 45001
- ✓ EU MDR 2017/745
- ✓ EU IVDR 2017/746

Offered exclusively to in-company groups of 10 or more, these courses are for organizations looking for a concise, high-level introduction for their staff.

A member of our team is ready to help so get in touch today to discuss your training needs by contacting us at training@complyguru.com!

Custom eLearning DEVELOPMENT

Comply Guru can develop eLearning specifically tailored to **your** needs

- We take your training materials and create content rich, highly engaging and interactive eLearning courses
- We create customer focused solutions, tailored to requirements of your business and the specific needs of your learners
- We will work with your budget, and deliver value for money results



01 Concept

Exploring customers content & requirements

We will begin by reviewing and refining your content, ensuring the finished course is tailored exactly to your requirements.

02 Development

Agreeing approach & project outline

We explore learning methodologies, keeping in mind the nature of your content and the profile of end users.

03 Draft

Ensuring the customer is involved in development

We create initial draft content including scripts, layouts and storyboards, confirming that the overall approach suits your vision for the material.

04 Structure

All content is included and structured correctly

We build a course skeleton for the customer, ensuring all of the required content is included within the course.

05 Development

Continual buy-in from customer throughout production

We build out the course, module by module, ensuring you have enough opportunity to review and approve the content as it is developed.

06 Final Checks

Ensuring the project is completed to customer's satisfaction

When all content is developed and approved the final course is tested and checked to ensure it meets professional quality standards.

07 Deployment

Confirming the course works perfectly in customer's LMS

Once complete, we deploy the finished course to your learning management system and test it to ensure it is working correctly.



GET IN TOUCH

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