CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

EU & UK MEDICAL DEVICE REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Recent studies have revealed that over **90% of medical devices now require Notified Body involvement under the current regulations**, compared to just 15% under previous directives, while conformity assessment timelines have extended **from 6-8 months to 12-18 months** or longer. Additionally, **technical documentation requirements have increased by 150-300%**, and **clinical evidence costs have escalated by 200-400%** across most device categories, creating substantial barriers for manufacturers seeking EU and UK market access.

This certified program is designed to provide you with an in-depth understanding of these intricate frameworks and equip you with the tools to effectively navigate the regulatory landscape. You will gain expertise in critical areas such as **EU MDR and IVDR compliance, UKCA and CE marking pathways, conformity assessment procedures, clinical evaluation and investigation requirements, and post-market surveillance obligations**. You will also gain insights into the technical documentation process, Unique Device Identification (UDI) and EUDAMED database registration while addressing regulatory challenges.

Furthermore, this program will provide you with practical skills to **integrate regulatory requirements into product development, quality management systems, and lifecycle management**. You will learn to address the challenges of **multi-jurisdiction compliance, manage interactions with notified bodies and regulatory authorities, and prepare for audits and inspections**. Additionally, the program will cover emerging challenges such as **digital health technologies, AI-driven devices, and cybersecurity obligations**,

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

PROGRAM OVERVIEW

ensuring that you are prepared for the future of medical device compliance. By the end of the program, you will be equipped with the strategies to mitigate risk, reduce delays, and maintain market access across the EU and UK.

Upon successful completion of the program, you will receive the **Certification in EU & UK Medical Device Regulations and Compliance**, enhancing your professional credentials and demonstrating your mastery in ensuring product safety, efficacy, and regulatory adherence. Internationally recognized and valued by leading medical device manufacturers, regulatory consultancies, and healthcare organizations worldwide, this certification maintains lifelong validity and will establish you as a **trusted authority in medical device regulatory affairs**, substantially enhancing your career prospects in this critical and rapidly evolving field.

ACCREDITATIONS

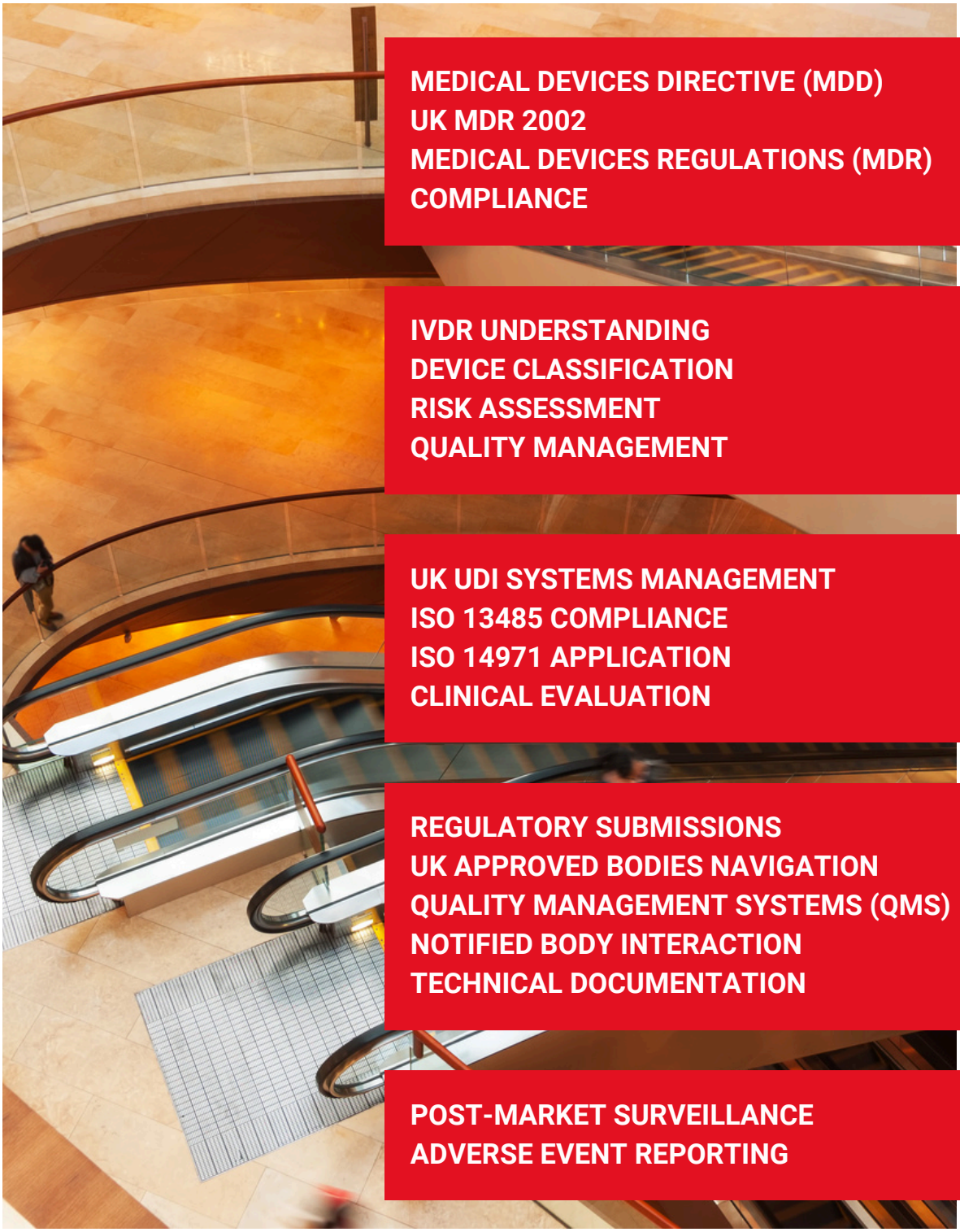
CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

KEY SKILLS YOU WILL GAIN

From This Program



MEDICAL DEVICES DIRECTIVE (MDD)
UK MDR 2002
MEDICAL DEVICES REGULATIONS (MDR)
COMPLIANCE

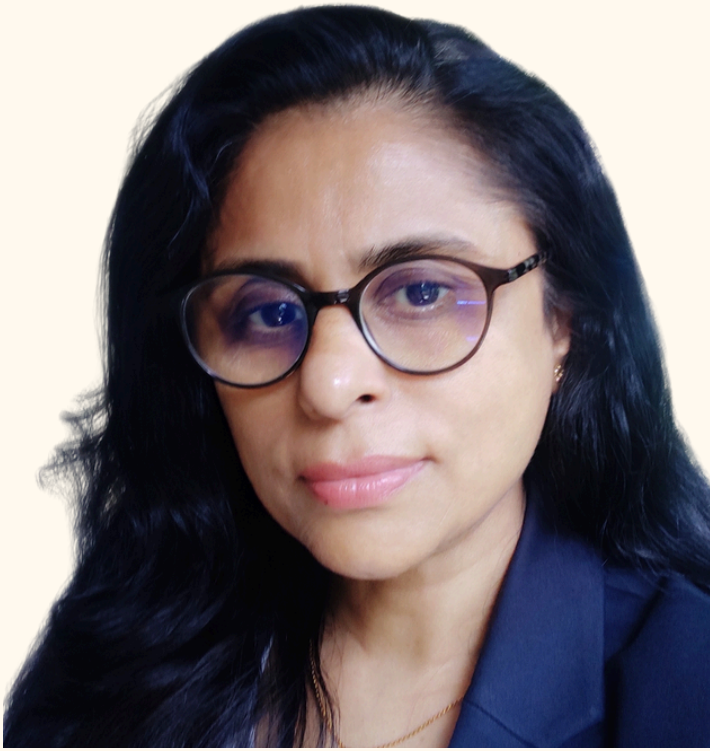
IVDR UNDERSTANDING
DEVICE CLASSIFICATION
RISK ASSESSMENT
QUALITY MANAGEMENT

UK UDI SYSTEMS MANAGEMENT
ISO 13485 COMPLIANCE
ISO 14971 APPLICATION
CLINICAL EVALUATION

REGULATORY SUBMISSIONS
UK APPROVED BODIES NAVIGATION
QUALITY MANAGEMENT SYSTEMS (QMS)
NOTIFIED BODY INTERACTION
TECHNICAL DOCUMENTATION

POST-MARKET SURVEILLANCE
ADVERSE EVENT REPORTING

YOUR FACULTY DIRECTOR



Asha Jacob

Distinguished Leader in Regulatory Affairs and Compliance

Asha Jacob is a distinguished leader in regulatory affairs and compliance within the MedTech industry, boasting an impressive 18-year career. Her expertise spans across **R&D, regulatory affairs, clinical affairs, medical writing, quality assurance, and quality management**. Currently, she serves as the Head of the Regulatory Affairs and Compliance team at Philips Medical Systems in the Netherlands. Asha also holds the crucial roles of **EU Authorized Representative Officer for EU MDR & EU IVDR and Person Responsible For Regulatory Compliance-2 at Philips**.

Asha's holistic, cross-functional understanding of EU MDR has enabled her to guide both business and market organizations through regulatory complexities. Her expertise is further validated by **BSI training in MDR Implementation for CE Marking and CQI & IRCA ISO 13485:2016 Auditor/Lead Auditor Certification**, underscoring her commitment to maintaining the highest standards in regulatory affairs and compliance.

OUR PARTICIPANTS

Over 70% of FORTUNE 500 Companies Have Attended Our Accredited Programs Before

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO EU MEDICAL DEVICE REGULATION

- Understand the Shift
  - Explore the transition from EU MDD to MDR and the post-Brexit divergence shaping UK regulations.
- Stay Ahead of Timelines
  - Get clarity on CE and UKCA marking deadlines and what they mean for market access in the EU, UK, and Northern Ireland.

MODULE 2 - CE & UKCA MARKING ESSENTIALS

- Device Qualification & Classification
  - Learn how EU MDR and UK MDR 2002 define medical devices and apply classification rules that shape conformity routes and documentation scope.
- Conformity Assessment Procedures
  - Understand how to select Notified Bodies and UK Approved Bodies, and navigate conformity assessment steps for CE and UKCA marking.

MODULE 3 - COMPLIANCE, AUDITS AND CERTIFICATIONS FOR MEDICAL DEVICES

- Regulatory Alignment
  - Understand QMS requirements under EU MDR and UK MDR 2002.
- Audit Readiness
  - Gain insights into certification pathways and audit expectations.

MODULE 4 - RISK & POST-MARKET SURVEILLANCE ESSENTIALS

- Lifecycle Risk Management
  - Apply ISO 14971 across product development and post-market phases.
- Vigilance Framework
  - Understand MDR and UK MDR 2002 driven PMS and incident reporting requirements.

MODULE 5 - CLINICAL STRATEGY AND LIFETIME CLINICAL EVIDENCE

- Master EU MDR Clinical Demands
  - Build strong clinical evidence through State-of-the-Art analysis, CEPs, CERs, and PMCF—demonstrating safety, performance, benefit-risk, and compliance.

PROGRAM AGENDA

- Strategize for Dual Markets
  - Align clinical development with EU and UK needs, including clinical investigations and Real-World Evidence to support both CE and UKCA pathways.

MODULE 6 - REGULATORY STRATEGIES FOR NAVIGATING COMPLIANCE & MARKET ACCESS

- Design Adaptive Regulatory Strategies
  - Create agile plans that embed regulatory intelligence, lifecycle thinking and market-specific needs—driving faster approvals and sustained compliance.
- Bridge Regulatory Execution and Commercial Models
  - Sync regulatory execution with sales strategy by aligning claims, labeling, and go-to-market plans—accelerating launches and strengthening market presence.

MODULE 7 - TECHNICAL DOCUMENTATION AND CLINICAL EVALUATION

- Engineer for Compliance Excellence
  - Master the EU MDR and UK MDR technical file structure, including Clinical and Post Market Surveillance documentation, to ensure your device meets performance, safety, and lifecycle traceability standards.
- Empower Your EU Authorised Representative and UK Responsible Person
  - Understand the critical role of the EU Authorised Representative & UK Responsible Person in maintaining UK-specific documentation and enabling fast, compliant responses to MHRA inspections.

MODULE 8 - EU UDI & UK UDI AND DATABASES

- Understand EU UDI & EUDAMED
  - Learn how the EU UDI system supports traceability and surveillance through structured EUDAMED modules.
- Explore the UK Approach
  - Get familiar with MHRA's registration database and the planned UK UDI system.

PROGRAM AGENDA

MODULE 9 - ECONOMIC OPERATORS AND SUPPLY CHAIN COMPLIANCE

- Know the Key Players
  - Understand the roles and responsibilities of key actors under EU MDR and UK MDR 2002—and how they shape supply chain accountability.
- Strengthen Compliance
  - Explore how to structure mandates, agreements/ contracts that clarify liability, documentation obligations, and regulatory duties across EU and UK supply chains.

MODULE 10 - LEADERSHIP INSIGHTS AND STAKEHOLDER COMMUNICATION

- Elevate Strategic Influence
  - Discover how to foster resilient RA teams and Position Regulatory Affairs as a business enabler by linking regulatory priorities to portfolio strategy, innovation planning, and competitive advantage—driving early, high-impact involvement.
- Communicate with Impact
  - Explore best practices for engaging effectively with Authorities to support seamless regulatory interactions.

YOUR CHARTER DESIGNATION

Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon successfully attending this program, you will be awarded with the **Certification in EU & UK Medical Device Regulations and Compliance** that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity. Globally demanded and recognized, this certification underscores your expertise in managing complex regulatory environments, elevating your professional standing and effectiveness in ensuring medical device compliance across international markets. This program is developed by **Chartered Institute of Professional Certifications** and the content of this program has been certified by **CPD Certification Service** as conforming to continuing professional principles.

ABOUT US

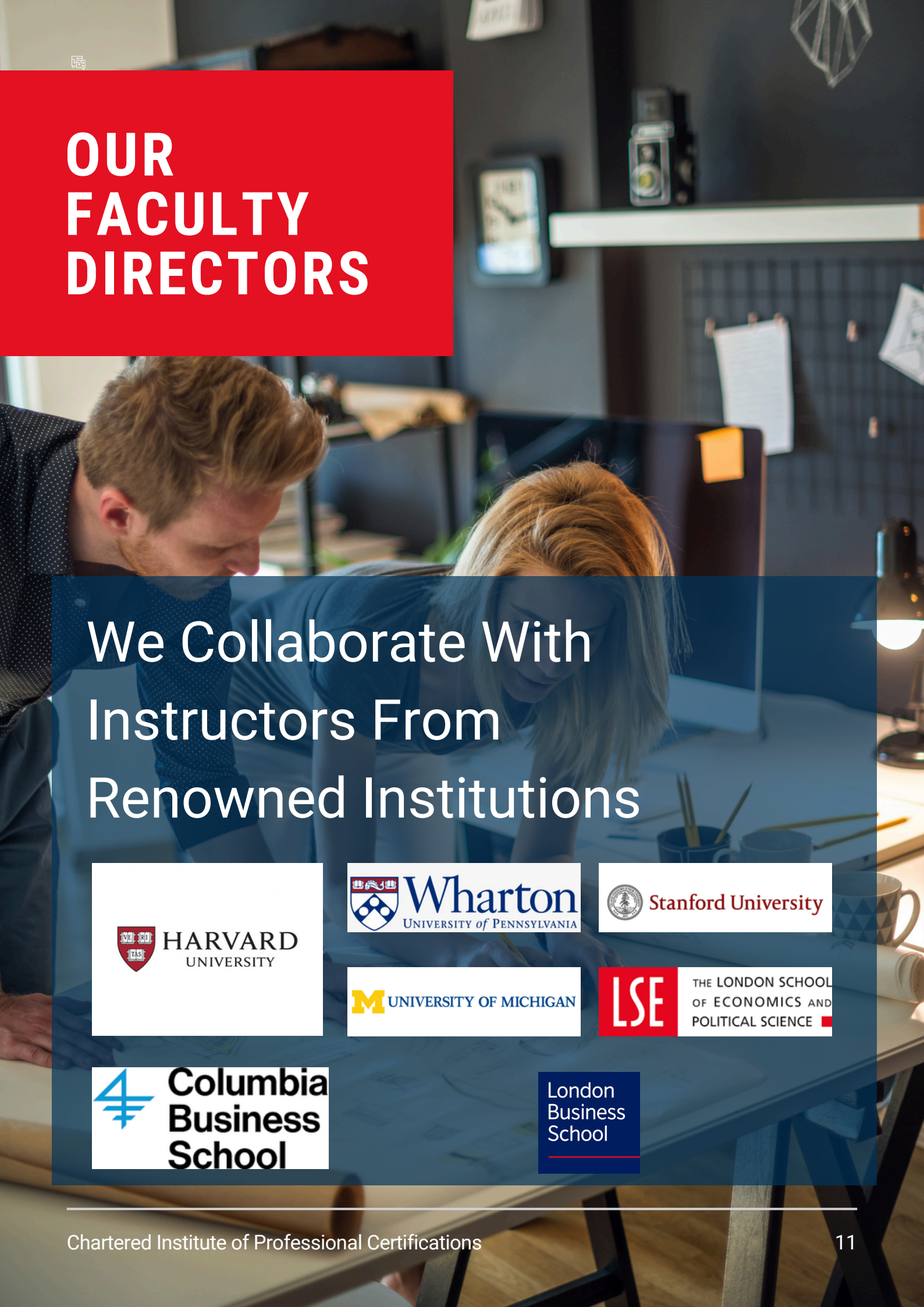
49,525 Business Leaders Have Attained Their Chartered Certifications Since 2009

390 Certified and Fully Accredited Programs

87% Chartered Leaders Have Reported Career Promotions and Enhancements

Chartered Institute of Professional Certifications

All of Chartered Institute of Professional Certifications programs are fully accredited programs. The professional charters and designations are trademarked credentials that can only be used by professionals who have completed and passed our accredited program. It is also independently accredited by CPD as adhering to the highest standards of continuing professional principles.



OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

HARVARD UNIVERSITY

Wharton University of Pennsylvania

Stanford University

University of Michigan

LSE The London School of Economics and Political Science

Columbia Business School

London Business School

CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

Singapore and Asia Pacific Enquiries

Email: advisor@charteredcertifications.com
Phone: +65 6716 9980
Address: Chartered Institute of Professional Certifications
1 Gateway Drive
#20-04 Westgate Tower
Singapore 608531

Australia and New Zealand Enquiries

Email: advisor@charteredcertifications.com
Phone: +61 3 9909 7310
Address: Chartered Institute of Professional Certifications
530 Little Collins Street, Level 1
Melbourne VIC 3000, Australia

UK, Europe and Middle East Enquiries

Email: advisor@charteredcertifications.com
Phone: +44 (020) 335 57898
Address: Chartered Institute of Professional Certifications
86-90 Paul Street
London, EC2A 4NE

USA Enquiries

Email: advisor@charteredcertifications.com
Phone: +1 888 745 8875
Address: Chartered Institute of Professional Certifications
99 Wall Street #3936
New York, NY 10005