



MEDICAL LAW, BIOETHICS, AND REGULATORY LIABILITY TRAINING COURSE

23 - 27 Nov 2026

MILAN

5900 € (PER PERSON)

REF: #HSM1228_106295



COURSE INTRODUCTION / OVERVIEW:

The intersection of medicine, law, and ethics presents one of the most complex and rapidly evolving professional landscapes today. This training course provides a comprehensive exploration of the critical legal principles, ethical frameworks, and regulatory requirements that govern the healthcare industry. Participants will navigate the intricate web of patient rights, professional duties, and organizational liabilities that define modern medical practice. Drawing upon foundational concepts articulated by scholars like Tom L. Beauchamp and James F. Childress in their seminal work, "Principles of Biomedical Ethics," this program moves beyond theoretical knowledge to focus on practical application. We will dissect real-world case studies involving medical malpractice, informed consent, and end-of-life decisions. BIG BEN Training Center has designed this course to empower healthcare professionals and administrators with the foresight to identify potential legal risks, the wisdom to make ethically sound decisions, and the competence to ensure regulatory compliance. This is an essential program for anyone committed to upholding the highest standards of care while mitigating the significant legal and financial risks inherent in the healthcare sector.

TARGET AUDIENCE / THIS TRAINING COURSE IS SUITABLE FOR:

- Physicians, Surgeons, and Medical Consultants.
- Nurses and Nurse Practitioners.
- Hospital Administrators and Healthcare Managers.
- Clinical Department Heads.
- Medical-Legal Consultants and Paralegals.
- In-House Legal Counsel for Healthcare Organizations.
- Compliance Officers and Risk Managers.
- Pharmaceutical and Medical Device Professionals.
- Public Health Officials and Policymakers.
- Members of Institutional Review Boards (IRBs) and Ethics Committees.



TARGET SECTORS AND INDUSTRIES:

- Hospitals and Clinical Care Facilities.
- Private Medical Practices and Specialty Clinics.
- Pharmaceutical and Biotechnology Companies.
- Medical Device Manufacturing and Sales.
- Health Insurance and Managed Care Organizations.
- Medical Research and Academic Institutions.
- Long-Term Care and Rehabilitation Centers.
- Governmental Health Agencies and Regulatory Bodies.
- Legal Firms Specializing in Healthcare Law.
- Non-Profit Health Advocacy Organizations.

TARGET ORGANIZATIONS DEPARTMENTS:

- Legal and Corporate Counsel Departments.
- Compliance and Regulatory Affairs.
- Risk Management and Quality Assurance.
- Clinical Operations and Patient Services.
- Medical Affairs and Physician Relations.
- Human Resources and Professional Credentialing.
- Research and Development.
- Executive Leadership and Administration.
- Ethics Committees.
- Patient Advocacy and Relations.



COURSE OFFERINGS:

By the end of this course, the participants will have able to:

- Analyze the core principles of medical law and bioethics.
- Navigate the legal requirements for informed consent and patient confidentiality.
- Identify and mitigate the risks associated with medical malpractice and negligence.
- Evaluate complex bioethical dilemmas related to patient care and medical research.
- Ensure organizational compliance with key healthcare regulations like HIPAA.
- Develop effective risk management strategies to minimize regulatory liability.
- Understand the legal framework governing the physician-patient relationship.
- Manage legal issues related to end-of-life care and advance directives.
- Address the ethical and legal implications of new medical technologies.
- Respond effectively to regulatory investigations and legal challenges.

COURSE METHODOLOGY:

The training methodology at BIG BEN Training Center is designed to be immersive, interactive, and directly applicable to the professional challenges faced by participants. This course moves beyond traditional lectures to foster a dynamic learning environment where theory is consistently linked to practice. A cornerstone of our approach is the extensive use of case studies drawn from landmark legal precedents and contemporary ethical controversies, allowing participants to analyze complex scenarios and debate potential outcomes in a structured setting. Interactive group discussions and role-playing exercises will be used to explore sensitive topics such as breaking bad news, obtaining informed consent under pressure, and navigating conflicts of interest. Expert-led sessions will break down complex legal statutes and regulatory frameworks into understandable components. Participants will engage in practical workshops focused on drafting compliance policies and developing risk mitigation protocols. Continuous feedback and Q&A sessions are integrated throughout the course to ensure concepts are fully grasped and can be confidently applied in the workplace.



COURSE AGENDA (COURSE UNITS):

UNIT ONE: FOUNDATIONS OF MEDICAL LAW AND BIOETHICS

- Introduction to Medical Law and the Legal System.
- The Four Pillars of Medical Ethics: Autonomy, Beneficence, Non-Maleficence, and Justice.
- Sources of Medical Law: Statutes, Case Law, and Regulations.
- The Structure of the Healthcare Regulatory Environment.
- The Physician-Patient Relationship as a Legal Construct.
- Professionalism and Fiduciary Duties in Healthcare.
- Understanding Legal and Ethical Codes of Conduct.

UNIT TWO: PATIENT RIGHTS, CONSENT, AND CONFIDENTIALITY

- The Doctrine of Informed Consent and Its Elements.
- Assessing Patient Capacity and Competence.
- Legal Issues in Treating Minors and Incapacitated Adults.
- Patient Confidentiality and the Health Insurance Portability and Accountability Act (HIPAA).
- Exceptions to Confidentiality: Public Health and Safety.
- Advance Directives, Living Wills, and Durable Power of Attorney for Health Care.
- Managing and Protecting Patient Medical Records.

UNIT THREE: MEDICAL MALPRACTICE AND PROFESSIONAL LIABILITY

- Defining the Standard of Care in Medicine.
- Elements of a Medical Negligence Claim: Duty, Breach, Causation, and Damages.
- Common Causes of Medical Malpractice Litigation.
- Defenses Against Malpractice Claims.
- Vicarious Liability and Corporate Negligence for Healthcare Organizations.
- The Role of Expert Witnesses in Medical Litigation.
- Understanding Malpractice Insurance and Settlement Processes.



UNIT FOUR: CONTEMPORARY BIOETHICAL CHALLENGES

- Ethical and Legal Issues in End-of-Life Care.
- The Law of Reproductive Technologies and Genetic Testing.
- Human Subject Research and the Role of Institutional Review Boards (IRBs).
- Organ Donation and Transplantation Ethics.
- Allocation of Scarce Medical Resources.
- Conflicts of Interest in Clinical Practice and Research.
- Ethical Considerations in the Use of Artificial Intelligence in Medicine.

UNIT FIVE: REGULATORY COMPLIANCE AND RISK MANAGEMENT

- Overview of Key Healthcare Regulations (Stark Law, Anti-Kickback Statute).
- Healthcare Fraud and Abuse Prevention.
- Corporate Compliance Programs for Healthcare Organizations.
- Strategies for Effective Healthcare Risk Management.
- Responding to Government Investigations and Audits.
- Legal Aspects of Telemedicine and Digital Health.
- Future Trends in Medical Law and Regulatory Liability.

FAQ:

QUALIFICATIONS REQUIRED FOR REGISTERING TO THIS COURSE?

There are no requirements.

HOW LONG IS EACH DAILY SESSION, AND WHAT IS THE TOTAL NUMBER OF TRAINING HOURS FOR THE COURSE?

This training course spans five days, with daily sessions ranging between 4 to 5 hours, including breaks and interactive activities, bringing the total duration to 20 - 25 training hours.

SOMETHING TO THINK ABOUT:

As artificial intelligence becomes more integrated into diagnostics and treatment, how should legal frameworks adapt to address issues of liability and ethical oversight when an AI system makes a critical error?



WHAT UNIQUE QUALITIES DOES THIS COURSE OFFER COMPARED TO OTHER COURSES?

This course distinguishes itself by moving beyond a purely academic recitation of laws and theories to a practical, decision-focused masterclass in navigating the medical-legal landscape. While other programs may focus separately on law, ethics, or compliance, our curriculum holistically integrates these three pillars, reflecting the reality that clinical and administrative decisions are never made in a vacuum. The core of the learning experience is built around a robust case-study methodology, dissecting real-world scenarios where legal precedent, ethical principles, and regulatory pressures collide. This approach equips participants not just with knowledge of the rules, but with the critical thinking and analytical skills to apply them under pressure. Furthermore, the course places a unique emphasis on proactive risk management and strategic compliance, teaching participants how to build resilient systems that prevent legal and ethical breaches before they occur. It is designed for professionals who seek not only to understand the law but to lead with integrity and foresight in an increasingly complex healthcare environment.