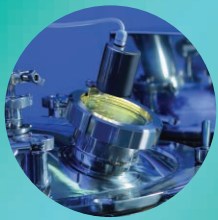


Irish Medtech
Association
SKILLNET

MASTERS IN MEDICAL TECHNOLOGY REGULATORY AFFAIRS



The Irish Medtech Skillnet is funded by member companies and the Training Networks Programme, an initiative of Skillnets funded from the National Training Fund through the Department of Education and Skills.

MASTERS IN MEDICAL TECHNOLOGY REGULATORY AFFAIRS

ABOUT THE COURSE

The Irish Medtech Skillnet and contracting organisation, the Irish Medtech Association, the Ibec group that represents the Medical Technology sector and IT Sligo in collaboration with NUI Galway are delighted to present the new Masters in Medical Technology Regulatory Affairs for its second student intake.

This programme has been designed to meet the growing requirements of companies in filling regulatory and quality assurance roles. The impetus for the development of this specialist programme emerged from industry needs and the content has been developed in conjunction with a taskforce comprised of regulatory experts from Irish Medtech Association's Regulatory and Quality Working Group.

The course will enable Regulatory Affairs personnel in the Medical Technology industry to understand all current device and diagnostic regulations and to develop the skills necessary to address and prepare for the ever-changing global environment of regulatory affairs. This is an international programme available to students from all regions and provides a unique opportunity to study global regulatory affairs.

It provides access to online lectures produced exclusively for the programme by international experts.

Upon successful completion of the programme, participants receive an MSc award at NFQ Level 9.

ABOUT IRISH MEDTECH SKILLNET

Working in partnership with Skillnets Ltd and our contracting organisation, the Irish Medtech Association (Ibec sector), the Irish Medtech Skillnet has over the past number of years grown substantially in direct response to the training needs of Industry. Total expenditure (2008 - 2015) is over €4.2 million, with 40% contribution from member companies and the remaining 60% funded by the state. Targets of over 6,000 trainees and 30,000 training days have been achieved.

ABOUT IRISH MEDTECH ASSOCIATION

The Irish Medtech Association is a business sector within Ibec that represents the Medical Technology sector and is a proactive membership organisation with over 170 members located throughout Ireland. It works directly with government and policy makers nationally and internationally, to shape business conditions and drive economic growth. Led by a board of 15 industry leaders, and facilitated by a dedicated professional executive staff, our working groups, forums and task forces are the primary enablers of our strategy.

ENTRY REQUIREMENTS

Open to students who have obtained a Level 8 primary degree in a science/engineering subject related to the life sciences. Previous or current experience in regulatory affairs (minimum two years) may be taken into account in assessing entry qualifications for candidates with relevant Level 7 qualification with appropriate experience.

Candidates who have completed modules in cognate programme areas may also enter the programme and gain exemptions as determined by the Programme Committee in accordance with the partner Institutions' guidelines. Cases will be assessed on an individual basis by the Programme Committee. Students applying on the basis of formal qualifications and supplementary accredited prior learning (APL) for core pre-requisites will be required to submit full details and references to the Programme Board for consideration of educational equivalencies. Prior experiential learning will be assessed using guidelines recommended by the Academic Council of IT Sligo and NUI Galway.



CERTIFICATION

NFQ Level 9 – 90 credits

PROGRAMME COSTS

Irish Medtech Skillnet members residing and working in Ireland	€8,100
Non Members residing and working in Ireland	€10,800
Eligible EU-nationals residing and working in Europe (outside of Ireland) within the last 3 years	€12,000
Parent company staff of Irish Medtech Association member companies, outside of Ireland, NON-EU nationals	€18,000
NON Irish Medtech Association member companies, outside of Ireland, NON-EU nationals	€20,000

DELIVERY

The programme will employ a blended learning approach involving synchronous and asynchronous online lectures. Lectures are delivered “Live” on a weekly basis to students using the software package Adobe Connect. Students who cannot attend the live lectures may view the recorded lectures anytime, with links to the recordings placed on the Moodle page for the respective subject. Lecture recordings can also be downloaded by students using Panopto software.

Moodle acts as the virtual learning environment (VLE) whereby students enrol on a VLE page for a respective subject and lecturers provide learning materials, notes and handouts to them via the VLE.

The VLE can also be used to assess students through open-book exams using multiple choices, matching questions as well as short and long answer questions. The blended delivery format proposed for this programme includes online (synchronous and asynchronous learning), and E-moderated discussion boards, as well as workshops, group project work, case studies and variety of other teaching and learning tools.

PROPOSED STUDENT ENGAGEMENT

Students will study 3 modules per semester. The students will typically have a 1 hour live lecture per week on each of the three modules. These lecture slots and associated assessment

dates/times will be communicated to students at the start of each new semester. These lectures will be supplemented with additional reading material. Students will engage up to 5 hours independent learning per module per week.

This includes assessment times and assignments. The workload may vary slightly from week to week.

Assessment of students will be based on 100% continuous assessment with assignments throughout the course in conjunction with submission of the final dissertation at the end of year 2.

ASSESSMENT GRADING SYSTEMS

All assessments are assigned a percentage of the total module marks and this is indicated to the students at the commencement of each module or module part. These percentages are also indicated in the assessment matrices. This is to ensure that the students can assign the appropriate level of commitment and energy to any given assessment.

SAMPLE DELIVERY SCHEDULE

Year 1 - Semester 1
(September - December)

Week 2 September
1 day on campus student induction

Mid-Late November
1.5 days on campus workshop covering all 3 modules per semester

Year 1- Semester 2
Semester 2
(January - May)

Mid - Late March
1.5 days on campus workshop covering all 3 modules per semester

PROGRAMME TEAM

The educational elements will be provided by academic staff from the Institute of Technology Sligo and NUI Galway.

Additional lecturing and workshop contributions, as required, will be provided by industry experts from the Medical Technology sector.

The programme will be delivered over 2 years.

YEAR 1 SEMESTER 1

EU Medical Technology Regulatory Affairs - Introduction
US Medical Technology Regulatory Affairs- Introduction
Technical Report Writing

YEAR 1 SEMESTER 2

Global Medical Technology Regulatory Affairs - Introduction
Clinical Evaluation
Quality Management System

YEAR 2 SEMESTER 1

EU Medical Technology Regulatory Affairs - Advanced
US Medical Technology Regulatory Affairs - Advanced
Risk Management, Labelling & Promotion

YEAR 2 SEMESTER 2

Global Medical Technology Regulatory Affairs - Advanced
Design Assurance, Sterilisation and Biocompatibility
Post Market Surveillance

SYLLABUS **YEAR 1 SEMESTER 1****MODULE CONTENT****Introduction to EU Medical Technology Regulatory Affairs****MODULE DESCRIPTION**

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the EU. It explains the legislation applicable and guidelines available to medical device manufacturers.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the main EU directives and their context within the EU legislative framework including Directive 98/79/EC
2. **Source and interpret** medical device directives currently regulating medical device classification within the EU and demonstrate ability to classify devices, including complex combination or novel devices appropriately
3. **Demonstrate** they have detailed knowledge and understanding of the role and expectations of the manufacturer, authorized representative, Notified Body and Competent Authority
4. **Demonstrate** they have detailed knowledge and understanding of current conformity assessment procedures
5. **Source and interpret** ISO13485 and various other relevant standards and guidance documents e.g. MEDDEVs, NB MEDS, GHTF guidance
6. **Demonstrate** they have detailed knowledge and understanding of the essential requirements of each device and how a manufacturer will address and meet each essential requirement
7. **Identify** the submission types involved in the EU regulatory system

MODULE CONTENT**Introduction to US Medical Technology Regulatory Affairs****MODULE DESCRIPTION**

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the US. It explains the legislation applicable and guidelines available to medical device manufacturers.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the US FDA administrative and legislative structure (FD&C Act) and requirements
2. **Source and interpret** regulations and guidance documents currently applicable to medical device classification within the US and demonstrate ability to classify devices appropriately
3. **Critique FDA guidance documents**, consensus standards, FDA forms etc.
4. **Illustrate an understanding of the steps** required to achieve market clearance/approval for a US destined medical device including all aspects and types of 510(k), PMA, IDE and De Novo applications.
5. **Analyze requirements** for device registration, device listing and establishment registration and post market surveillance requirements once a product is placed on the market.



SYLLABUS **YEAR 1 SEMESTER 2****MODULE CONTENT****Technical Report Writing****MODULE DESCRIPTION**

Technical Report Writing teaches the participant not only the critical techniques a scientist needs to know when conducting research but also how to write about his or her work. Not only is this relevant for a dissertation and assignments but also for generating formal reports such as clinical evaluation reports.

Professionals in industry require the skills to share their work with others, to communicate their learning, their discoveries and their failures, thus improving research and thus benefiting the industry as a whole and more importantly, the patient.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Appreciate** the nature and importance of technical report writing and review in industry
2. **Evaluate** the suitability of research methodologies for the purpose of undertaking research
3. **Conduct and synthesise** an academic literature search relevant to a proposed dissertation or topic
4. **Present the research findings** in a critically reflective manner which acknowledges the limitations of the research methods
5. **Critically review the ethical issues** involved in the undertaking of clinical research
6. **Formulate and compare methods** for data analysis and the presentation of results and compare different methods when presenting different results
7. **Present** a comprehensive dissertation proposal

MODULE CONTENT**Introduction to Global Medical Technology Regulatory Affairs****MODULE DESCRIPTION**

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market outside of the US and EU, specifically Russia/CiS; Brazil/Latin America; Canada/Australia. It explains the legislation applicable and guidelines available to medical device manufacturers. It also addresses emerging technologies.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the administrative and legislative structure and requirements for medical devices in key global markets to include Russia/CIS; Brazil/Latin America; Canada/Australia
2. **Identify key differences** between these regulatory systems and that of the EU and US and outline methodology to ensure a device can utilize key documentation from EU and US applications in achieving market approval in the above defined jurisdictions
3. **Critique guidance**, directives and legislation currently regulating medical device classification within these global markets and demonstrate ability to classify devices appropriately
4. **Articulate an understanding** of how to define the regulatory pathway for medical devices in these global markets including complex combination or novel devices
5. **Demonstrate** they have detailed knowledge and understanding of how to manage change control from a global point of view.
6. **Source** and interpret reimbursement requirements





SYLLABUS YEAR 1 SEMESTER 2

MODULE CONTENT

Clinical Evaluation

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the EU. It explains the legislation applicable and guidelines available to medical device manufacturers.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the key clinical terms, types of studies, key clinical requirements and associated standards
2. **Source and interpret**, regulations, standards and guidances on how clinical requirements in chosen markets are achieved
3. **Critique the role** of human factors studies and the impact of risk assessment
4. **Demonstrate** an ability to prepare documentation associated with clinical evaluations
5. **Demonstrate they have detailed knowledge** and understanding of clinical investigations application process and reimbursement
6. **Illustrate** an ability to prepare regulatory submissions and clinical trial applications
7. **Formulate and communicate** a competency in how to complete a full clinical evaluation plan, which will include objectives, methodology and literature searching processes and resulting clinical evaluation report including format, contents and layout
8. **Demonstrate** an ability to prepare a clinical evaluation report
9. **Identify** the interaction between risk analysis and clinical evaluation
10. **Evaluate and assess** a medical device to determine what, if any, clinical studies are required based upon a critical review of existing data for comparable medical devices (consider strategy development, investigation design and clinical evaluation context)

MODULE CONTENT

Quality Management System

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the US. It explains the legislation applicable and guidelines available to medical device manufacturers.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of how a medical device is designed, developed and manufactured in line with 20 CFR 820 and ISO13485
2. **Source and interpret** ISO13485, CFR 820 and various other relevant standards
3. **Understand and evaluate** the key elements of 21 CFR 820 including but not exclusive to Quality Management System, Management responsibility, Resource Management, Product Realization, Measurement Analysis and Improvement
4. **Demonstrate** they have detailed knowledge and understanding of a QMS as specified by CFR820
5. **Illustrate a thorough understanding** of the underlying principles involved in regulatory compliance, the importance of auditing, best practice on dealing with auditors, Supplier and vendor approach, audit programme, preparation, audit management, dealing with regulatory agencies, audit response process, internal quality standards communication, effective line clearance, training, process flow charts, Part II compliance etc.
6. **Conduct a systematic and independent examination** of the effectiveness of a quality system or of its parts and demonstrate an awareness of the importance of auditor training and the internal auditing programme and how to deal with unannounced audits
7. **Formulate and communicate** an ability to implement quality and technical agreements
8. **Demonstrate** they have a detailed knowledge and understanding of the required actions to release product post regulatory approval
9. **Demonstrate** they have detailed knowledge and understanding of the regulatory role and requirements throughout the product development process



SYLLABUS YEAR 2 SEMESTER 1

MODULE CONTENT

EU Medical Technology Regulatory Affairs Advanced

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the EU, the essential requirements of devices and submission types & emerging technologies.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of how to manage change control from a EU regulatory perspective throughout the entire medical device lifecycle
2. **Demonstrate** they have detailed knowledge and understanding of how to define the regulatory pathway for medical devices including complex combination or novel devices and devise appropriate regulatory strategies for a number of theoretical devices
3. **Demonstrate** they have detailed knowledge and understanding of the submission types involved by completion of mock technical documentation from classification through to commercialisation
4. **Demonstrate** they have detailed knowledge and understanding of CE Mark renewal process and Directive 98/79/EC
5. **Demonstrate** they have detailed knowledge and understanding of additional country specific requirements prior and post placement on market
6. **Source and interpret** reimbursement requirements in each member state

MODULE CONTENT

US Medical Technology Regulatory Affairs Advanced

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market in the US, the essential requirements of devices, submission types and change control and emerging technologies.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the submission types involved by completion of mock submission documentation from classification through to commercialization
2. **Formulate and communicate** judgements with regard to regulatory decision making process for devices and demonstrate ability to interact effectively with FDA agents
3. **Analyse and evaluate data** from US FDA MAUDE (Manufacturer and user facility device experience) database
4. **Demonstrate** they have detailed knowledge and understanding of how to manage change control for a product destined for US market
5. **Source and interpret** relevant reimbursement requirements



SYLLABUS **YEAR 2 SEMESTER 1****MODULE CONTENT****Risk Management, Labelling & Promotion****MODULE DESCRIPTION**

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the labelling, sale and supply regulatory requirements for medical devices. The module also covers the application of risk management to medical devices.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the content and application of ISO 14971: Medical devices - application of risk management to medical devices & risk management planning and the key components of a risk management file.
2. **Implement** a risk management plan including risk analysis, risk evaluation, implementation of appropriate risk controls and conduct a risk/benefit analysis.
3. **Communicate** they have a detailed knowledge and understanding of the EU/US/Global legislation and regulations associated with medical device labelling and global perspectives on UDI, harmonised symbols, structure of IFU, intended use, contraindications, label / IFU review best practice, labelling.
4. **Demonstrate** they have a detailed knowledge and understanding of the legislation and regulations associated with medical device advertising and promotion from EU/US and Global perspective and also country specific requirements.
5. **Communicate** a detailed knowledge of context of off label use/on label use and particular requirements for website content.
6. **Evaluate** the relevance of social media (twitter, blogs..) and future directions for advertising and promotion. Evaluate the place of physician /customer contact and direct to consumer advertising in promotion strategy.
7. **Formulate and communicate** judgements from a regulatory standpoint in each step of the risk management process and demonstrate ability to interact effectively with regulatory agents.

SYLLABUS **YEAR 2 SEMESTER 2****MODULE CONTENT****Global Medical Technology Regulatory Affairs Advanced****MODULE DESCRIPTION**

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the regulatory pathway for placing medical devices on the market outside of the US and EU, specifically China, Japan, SE Asia (Taiwan/Korea etc). It explains the legislation applicable and guidelines available to medical device manufacturers. It also addresses emerging technologies.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of the administrative and legislative structure and requirements for medical devices in key global markets to include but not limited to China, Japan, SE Asia (Taiwan/Korea etc)
2. **Identify key differences** between these regulatory systems and that of the EU and US and outline methodology to ensure a device can utilize key documentation from EU and US applications in achieving market approval in the above defined jurisdictions
3. **Source and interpret** guidance, directives and legislation currently regulating medical device classification within these global markets and demonstrate ability to classify devices appropriately
4. **Source and interpret** local global market standards
5. **Demonstrate** they have detailed knowledge and understanding of how to define the regulatory pathway for medical devices in these global markets including complex combination or novel devices
6. **Demonstrate** they have detailed knowledge and understanding of how to achieve market clearance/ approval for a medical device destined for a global marketplace and how to address post market surveillance requirements once a product is placed on the market
7. **Demonstrate** they have detailed knowledge and understanding of the submission types involved by completion of mock technical documentation from classification through to commercialization
8. **Formulate and communicate** judgements with regard to regulatory issues for devices such as country specific nuances connected with entry/exit from each country and demonstrate ability to interact effectively with appropriate authorities
9. **Demonstrate** they have detailed knowledge and understanding of how to manage change control from a global point of view
10. **Source and interpret** reimbursement requirements



SYLLABUS YEAR 2 SEMESTER 2

MODULE CONTENT

Design Assurance, Sterilisation and Biocompatibility

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. It aims to provide students with a detailed knowledge and understanding of the design assurance process, common sterilization techniques for medical devices, associated standards and validation. It aims to provide a basic understanding of common biocompatibility testing methods and interpretation of results.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** an ability to develop verifiable design inputs and understand the links to risk management activities
2. **Demonstrate** an ability to design a test protocol including risk based acceptance criteria, sample sizes and use of appropriate statistical methods
3. **Develop a test report strategy** and demonstrate ability to generate reports
4. **Critically assess** the use of standard and non standard test reports
5. **Demonstrate** they have a detailed knowledge and understanding of the common sterilization techniques for medical devices
6. **Source and interpret** procedures and standards currently regulating medical device sterilization and validation requirements
7. **Source and interpret** ISO10993 1 for evaluation of the biocompatibility of medical devices. Apply classification of the device as outlined in the standard
8. **Demonstrate** an understanding of the common biocompatibility testing methods and interpretation of the test results
9. **Formulate and communicate** an understanding of the rationale and benefit of product characterization
10. **Evaluate sterilization methods** under various headings to include packaging, products effects, costs etc
11. **Formulate and communicate** an ability to generate biocompatibility reports to meet regulatory requirements

MODULE CONTENT

Post Market Surveillance

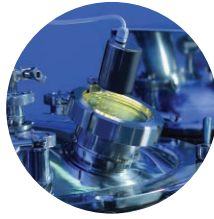
MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs and it aims to provide students with a detailed knowledge and understanding of post market requirements for medical devices. Specifically this module aims to develop the student's ability to create and implement a comprehensive post market surveillance plan to collect, evaluate and respond to data on device safety and performance after market approval.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Demonstrate** they have detailed knowledge and understanding of global statutory reporting requirements including local interpretation and current expectations with particular emphasis on EU and US requirements
2. **Demonstrate** they have detailed knowledge and understanding of post market surveillance requirements and development of a post market surveillance plan that is consistent with the risk associated with the device based on its intended use
3. **Demonstrate** they have detailed knowledge and understanding of complaint management including assessment, evaluation and response to post market data
4. **Demonstrate** they have detailed knowledge and understanding of risk management principles and requirements including the role of detailed risk assessment in the evaluation and response to post market data
5. **Demonstrate** they have detailed knowledge and understanding of requirements for all types of potential field actions including field safety corrective actions, advisory notices and recalls. This shall include an understanding of the critical components of effective field action management
6. **Understand** the links between CER and risk management and other documentation to proactively incorporate these into routine post market surveillance activities
7. **Analyse and evaluate** post market surveillance data within a risk management process to achieve a lower risk/better product, e.g. data from US FDA MAUDE (Manufacturer and user facility device experience) database
8. **Formulate and communicate** a post marketing surveillance strategy which meets appropriate regulatory requirements



YEAR 2

MODULE CONTENT

Medical Technology Regulatory Affairs Dissertation

MODULE DESCRIPTION

This module is taken by Level 9 students in Medical Technology Regulatory Affairs. This module aims to equip participants with the requisite advanced knowledge, understanding and skills to perform medical device related research using traditional and emerging research designs informed by a critical awareness of developments at the forefront of legislation and practice in the medical device industry.

LEARNING OUTCOMES

On completion of this module the learner will/should be able to:

1. **Articulate and elaborate** an understanding of current thinking on the nature of medical device industry challenges and the value of related research in that context
2. **Articulate and elaborate** an awareness of the ethical dimensions and philosophical consideration relating to the device industry in a range of context
3. **Manage a research project** combining independent study, support sessions and supervision effectively
4. **Write a coherent research proposal** with an acceptable research question or hypothesis
5. **Conduct** a critically focused literature review
6. **Analyse data** according to accepted models of analysis, showing awareness of alternative models of analysis and theoretical frameworks
7. **Sustain from the evidence obtained**, a reasoned argument and draw consistent and coherent conclusions from the research evidence
8. **Express the relevance** and significance of the outcomes/ conclusions of the research project
9. **Reflect self critically** on the outcomes/conclusions of the enquiry and on the research process itself
10. **Write a dissertation** which meets postgraduate standards of technical expertise investigating the subject area or testing the hypothesis outlined in the research proposal
11. **Develop the skills** to present and defend aspects of their research at seminars, conferences and viva's



“Participating in this course has already opened up a new career path and new opportunities for me, at both site and global level.”

Deborah Scanlon

Regulatory Affairs Manager, ProTek Medical, a Molex Company

“The Masters is well worth pursuing, broadens knowledge with regard to regulatory compliance in European and Global markets.”

Dymphna Power

Quality and Regulatory Manager, Fleming Medical



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Irish Medtech Association is a business sector within Ibec