

IFCC Guidelines for Compliance with Applicable Codes of Ethical Business Practice

1. Introduction

National and international agencies have established codes of ethical business practice that are applicable to the *in vitro* diagnostics (IVD) industry and third party educational event organisers such as the IFCC and national societies.

The IFCC endorses these codes of ethical business practice and supports compliance for all educational events developed and/or supported by the IFCC.

A code with significant impact to the IFCC is the “MedTech Europe Code of Ethical Business Practice” since this code is applicable from an IFCC perspective to all third party educational events held in Europe or anywhere in the world if the delegates are from two or more “European” countries. Therefore this code is applicable to all WorldLab and EuroMedLab Congresses. Similarly this code or other comparable national or international codes may be applicable to educational events for which IFCC auspices may be requested.

The MedTech Europe Code of Ethical Business Practice is available for download (Medtech Europe Code of Conduct.pdf) from the MedTech Europe website. <http://www.medtecheurope.org/node/715>

To alleviate the complex administrative burden of determining compliance and to harmonize interpretation of the code, “EthicalMedTech” hosts a platform referred to as the “Conference Vetting System” that enables third party educational event organisers to ensure compliance with the MedTech Europe Code of Ethical Business Practice. <http://www.ethicalmedtech.eu/conference-vetting-system/objective>

The IFCC requires use of the EthicalMedTech - Conference Vetting System to ensure code compliance for all applicable third party educational events. For third party educational events for which the MedTech Europe Code of Ethical Business Practice is not applicable, the IFCC recommends a method of self assessment to ensure compliance with any other applicable code(s) of ethical business practice.

2. The MedTech Europe Code of Ethical Business Practice and The EthicalMedTech - Conference Vetting System

The information provided on the Ethical MedTech – Conference Vetting System (CVS) website enables third party educational events organisers such as the IFCC and national societies to focus on the applicable components of the MedTech Europe Code of Ethical Business Practice. Decisions of the CVS Compliance Officer are binding on the IVD members of MedTech Europe.

The information provided below summarizes the requirements, process and the assessment criteria for the CVS. For full details, consult the website.

2.1 CVS Eligibility

The submitted third party educational event must be attended by participants/delegates coming from two or more of the following countries:

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the UK.

Algeria, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Mauritania, Morocco, Oman, Palestinian Authority, Pakistan, Qatar, Saudi Arabia, Sudan, Syria, Tunisia, UAE , Yemen.

The educational event organiser must clearly indicate in its brochure, website or other easily accessible educational event materials that health care providers from more than one country will attend or have been invited to attend the conference.

2.2 CVS Registration

In order to submit a conference, you must first register or sign in using existing details.

<http://conferences.ethicalmedtech.eu/>

2.3 CVS Pre-Clearance

2.3.1 Objective

Pre-Clearance allows either Medical Societies or Conference Organisers the possibility to seek the advice of the Compliance Officer on whether or not certain aspects of a third party educational conference they are planning are compliant with the Codes before they sign any contracts or make any financial commitments regarding the conference.

2.3.2 Assessment Criteria

Minimum Information Required: Geographic location and details of the venue.

2.3.3 Timeline

A Pre-Clearance submission can be submitted at any time (which may be years in advance) but not later than 6 months prior to the start date of the educational event.

2.3.4 Submission

Pre-Clearance submissions must be made via the EthicalMedTech online Pre-Clearance submission form.

Go to <http://www.ethicalmedtech.eu/conference-vetting-system/pre-clearance> then click on the link “Pre-Clearance submission form” in the “Conditions for a Pre-Clearance Assessment” section.

2.3.5 Pre-Clearance Assessment Decision

The Compliance Officer will endeavour to provide a decision within 30 days of the submission.

Pre-Clearance decisions will only be published on the EthicalMedTech website calendar with the specific approval of the educational event organiser. The website contains a section to provide this authorization. As notice to the in vitro diagnostic members of MedTech Europe, it is highly recommended that positive Pre-Clearance assessments be posted as soon as the Conference Organiser is ready to make the conference public.

All educational events, whether or not they were Pre-Cleared, must go through the Regular Submission Process (see section 2.3). The fact that an educational event has received a positive Pre-Clearance assessment does not mean that the educational event is compliant with the MedTech Europe Code of Ethical Business Practice since other criteria must also be assessed before an educational event can be given an overall positive assessment.

2.4 CVS Regular Submission

2.4.1 Objective

The regular submission process when completed allows for an overall assessment of the compliance of an educational event.

2.4.2 Assessment Criteria

Minimum Information Required: Geographic location, details of the venue, hotel accommodation and communication support (website link, brochure).

Additional Information Required: Scientific programme and social programme and if applicable, entertainment details.

2.4.3 Timeline

The minimum timelines are provided below but it is strongly recommended that all submissions be made as early as possible.

A Regular Submission with at least the minimum information required must be submitted no later than 75 days prior to the start date of the educational event.

The additional information required must be submitted no later than 35 days prior to the start date of the educational event.

2.4.4 Submission

Regular submissions must be made via the EthicalMedTech online submission form.

Go to <http://www.ethicalmedtech.eu/conference-vetting-system/full-regular-submission> then click on the link “submission form” in the “Conditions for the assessment of Regular Submissions” section.

2.4.5 Regular Assessment Decision

The Compliance Officer will endeavour to provide a decision within 30 days of the submission.

If only the **minimum information required** is initially submitted, the Compliance Officer will render a partial assessment decision limited to the criteria which have been assessed at that point. The provisional decision will be posted on the EthicalMedTech website calendar with a notice that the educational event will remain under a provisional status until 35 days prior to the start date of the educational event.

If the **additional information required** is not received within 35 days prior to the start date of the educational event, the educational event will not be assessed and a non-assessment notice will be published on the EthicalMedTech website calendar.

Once the **additional information required** is submitted, the Compliance Officer will render a decision.

If this decision is negative, the Compliance Officer will notify the identified relevant stakeholders via a correction notice regarding the identified deficiencies which render the educational event non-compliant and advise those stakeholders that they have 10 calendar days prior to publication of the final assessment decision to correct those deficiencies.

All decisions will be published on the EthicalMedTech website calendar.

2.5 Assessment Criteria

The information provided below is not all-inclusive and the reader is encouraged to consult the following websites for complete comprehensive information.

MedTech Europe <http://www.medtecheurope.org/node/715>

Ethical MedTech - Conference Vetting System <http://www.ethicalmedtech.eu/conference-vetting-system/objective>

2.5.1 General Considerations

Decisions are based on the MedTech Europe Code of Ethical Business Practice. However consideration is also given to the image that will be projected to the public.

Decisions are based on the documents and information provided via the online submission form. The Compliance Officer does not independently verify the information or documents are up-to-date.

Decisions do not take into account nor supplant national or local laws, regulations or professional or company codes that may impose more stringent requirements.

The scientific programme is reviewed but not the value of the scientific content.

2.5.2 Educational Event Programme

The schedule of the scientific conference programme – The detailed programme should present a clear schedule with no gaps during the conference scientific sessions (i.e., a minimum of 6 hours for full conference day / 3 hours for a half day), the faculty for each session must be identified, the session topics must be serious medical subjects.

The availability of the programme in advance – The programme should be available at least 90 days prior to the conference and contain sufficient information to enable an evaluation of the scientific value of the sessions.

The relevance of the programme – The programme content should directly relate to specialty and/or medical practice of the healthcare provider who will attend the conference or have a sufficiently reasonable relationship to justify the attendance of the health care providers. Minor components of the agenda content relating to non-scientific topics, such as leadership skills, practice management, and speaking and presentation skills are acceptable.

2.5.3 Geographic Location

The geographic location – The geographic location should be in or near a city or town which is a scientific or business centre conducive to exchange of ideas and the transmission of knowledge. The geographic location should not be the main attraction of the conference.

The time of the year – The selected time of the year will be taken into account in determining if a geographic location is appropriate. For European and international events, ski resorts in the ski season (ski season is considered as running from December 20 to March 31), island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. The appropriateness of a geographic location may be assessed differently for strictly local events attended by local healthcare professionals.

The central location – Taking into account the place of origin of health care provider delegates, the geographic location must be centrally located. If the health care provider delegates are primarily from one country, the geographic location of the conference should be in that country. If the participants are from multiple countries, then a country affording ease of access for participants should be chosen. The country selected should be the residence of at least some of the health care provider participants of the meeting.

The ease of access – The geographic location should have ease of access for the attendees (for example, close proximity to airports, train stations, highways) and have good ground transportation infrastructure.

2.5.4 Conference Venue Facility

The Conference Venue – The conference venue should be a business or commercial center with providing conference facilities conducive to the exchange of scientific and medical information and the transmission of knowledge. It should not be the main attraction of the conference. The image of the location among the public, media and authorities cannot be perceived as purely luxury, touristic/holiday and/or entertainment venue.

2.5.5 Hospitality

The reasonableness of hospitality – Hospitality should be reasonable, e.g., coffee breaks, an opening reception, a conference dinner or cocktail reception which all health care provider delegates are expected to attend.

The hospitality offered to spouses, partners, family and/or guests subject to a separate charge – This category of person may not benefit from hospitality provided to the health care provider delegates. Any hospitality offered to spouses, partners, family and/or guests must be the subject of a separate charge and paid for by the participant.

2.5.6 Spouses, partners, family & guests

Spouses, partners, family and/or guests' packages must be separate from that of the health care provider delegates and must be paid for by the participant. This category of person may not register for the conference or participate in the scientific programme unless he or she is also a qualified healthcare provider with a legitimate interest in the programme.

2.5.7 Entertainment

The social programme - Any social, sporting and/or leisure activities or other forms of entertainment must be outside of the programme schedule and paid for separately by the health care provider delegates. They should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with scientific session. They should not be the main attraction of the conference.

2.5.8 Communication Support

The program advertising - Advertising support (brochures, website and other materials) should highlight the scientific nature of the programme content. They should not overly emphasize the geographic location and should not make excessive or inappropriate references to or contain images of entertainment, sporting events or other non-scientific activities.

The registration fee - The registration fee should cover only the scientific programme and authorized activities and hospitality.