Ethical MedTech Webinar
Training for event organisers and sponsors

10 November 2021 from 11.00 to 12.00 (CET)

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## Agenda and training objectives

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Housekeeping

This training session will be recorded for educational purposes and posted on EthicalMedTech website.

For questions, please send us an email and we will address them in writing.

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Current situation
Post Covid landscape: when it is not always about the science

Surge in non-compliant criteria

- Late submissions
- Incomplete submissions
- Reorganisations
- More events
Rationale behind CVS and e4ethics
Safeguard industry reputation and harmonise assessments

- Public perception
- Regulators perception
- Reduce risk for companies
- Harmonise assessments
- Appropriate sponsoring
- Preserve reputation
A unique compliance approach in the Healthcare industry

Ethical MedTech

CVS e4ethics
Independent EMT Team & Compliance Panel
Main features of the common submission platform

- Online submission, proactive and mandatory
- Strict deadlines to ensure viability of the system
- No submission possible by Compliance Officers EthicalMedTech
- Pre-clearance allowing early submissions
- Special procedure for late submissions
- Appeal only possible after final status decision
Event submission: Mandatory requirements
What type of events should be submitted?

MANDATORY & BINDING

Regular + Hybrid events

No financial support if final non-compliant status
What type of events should be submitted?

Voluntary submission for virtual events

Virtual events = 100% fully online (participants)

Simple publication in calendar / sponsors’ rules
# Rules and guidelines for events submissions

## Late Submissions
- 75 days deadline
- New automatic system rejection
- Request for expedited assessment
- Waiver not always granted
- No right to appeal

## Incomplete Submissions
- 35 days deadline
- Causes huge delay
- Submission may end up with incomplete submission/ not assessed status

## Correction Notice
- 10 days to solve the problem
- Not a final status
- Event could become compliant if corrective measures

## Appeal
- Within 10 days of final status decision
- Addressed to Compliance Panel Chair
- Last resort decision
All parties may check directly if event was submitted
To sponsors: Event not submitted? YOU can do it 😊

NO SUBMISSION WITHOUT PRIOR CALENDAR CHECK

SUBMIT

Register first to be able to submit an Event
Submission form
When submitting an event - select the right option

All fields in submission form must be completed, especially correct contact details for Event Organiser to ensure automatic status notifications and emails sent by the platform can be delivered.
Systematic upload of documents via the platform

- **Name(s) of organiser(s)**
- **Organiser email**
- **Proposed accommodation (Include http:// for URL)**
  - e.g. http://www.ethicalmedtech.eu
- **Scientific programme (Include http:// for URL)**
  - e.g. http://www.ethicalmedtech.eu
- **Event registration package (Fee & benefits for all category of participants, include http:// for URL)**
  - e.g. http://www.ethicalmedtech.eu

**Information on delegates**
Will the event be attended by Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area?
- **Yes**

**Appendices/links**
- **Supporting documents/Multifile upload**
  - Select files / Aucun fichier choisi

- **I have read and understood: The MedTech Europe Code of Ethical Business Practice**
User account - where to find EMT reference
EMT reference is key
Alignment between Sponsors / Organisers

Align and agree in writing on WHO MAKES THE EVENT SUBMISSION – to avoid duplicates and delays

Any potential change of date, of geographic location, or venue must be communicated urgently to the Ethical MedTech team, as it may have an impact on assessment decision
COMING SOON – FLAG & FOLLOW EVENT STATUS

You will be able to select event by event if you wish to be informed of status changes (opt-in)
Criteria: focus on hospitality & registration fees
6 criteria assessed with same weight

- Scientific Programme
- Geographic location
- Communication
- Registration fees
- Conference venue
- Hospitality

26 000 submissions
13 octobre 2021
What is covered by hospitality criteria?

- Scientific Programme
- Geographic location
- Conference venue
- Registration fees
- Communication
- Hospitality
Hospitality - reminder

Hospitality covers accommodation, meals/breaks and receptions (opening reception, gala dinner, networking event, get-together, etc).

HOSPITALITY ≠ ENTERTAINMENT

Our team only looks at the hospitality that is covered by registration fees.
Hospitality – one clear example

Dear Ladies and Gentlemen, here you will find our main program booklet with all information about the program of the xxxxxxxx Congress (from p. 10) and also the contents of the registration packages (p. 7).

Hospitality will be provided on a self-pay basis (managed by in-house caterers at the venue) at the bistro station xxxxxxx located xxxxxx. An entertainment program is not planned.
What is meant by registration fees?
How to clarify what registration fees precisely cover?

The registration fee in person includes:
- Entrance to Scientific Sessions and Exhibition
- Congress materials
- Refreshment
- Welcome Cocktail
- CME credit certificate
- Access to Online Conference during the event and 3 months on demand
- Admission to the Online Exhibition area and Poster session

The registration fee remote participation includes:
- Access to Online Conference during the event and 3 months on demand
- Admission to the Online Exhibition area and Poster session
- Access to the satellite symposium and virtual library after the event
- CME credit certificate

How to register
Back-up slides on events status
What are the possible status of an Event?

Final Status

• Compliant (in green): the Event presents no liability for EFPIA/MedTech Europe members and is eligible to receive appropriate support from members

• Not Compliant (in red): a flag is raised. Different forms, as per the respective Codes, of support to an Event should be suspended, withdrawn, or cancelled as per the agreement with the Event organiser

• Not assessed (in grey): the Event submitted is not eligible to be assessed under CVS/e4ethics. For example, strictly National Events are not eligible

• Virtual Events (in yellow): the Event was submitted voluntarily and there will be no formal assessment conducted. But the Compliance Officers will check and confirm by publishing this status on the Calendar that the Event is a 100% online/virtual with no in-person HCP attendance
What are the possible status of an Event?

Intermediary status

• To be reviewed (in purple): the Event submitted is in the review process and no decision has yet been rendered by the Compliance Officers.

• Provisionally Compliant (in blue): means the most challenging criteria of an Event, namely the geographic location and conference venue, have been assessed compliant. The Compliance Officers are waiting for additional information from the submitting party to finalise the assessment.

• Correction Notice (in orange): means that a non-compliant aspect of an Event has been identified by the Compliance Officers. A communication has been sent to the organisers with a proposed correction. The organiser have 10 days to implement that correction and provide proof of the change to the Compliance Officers to avoid having their Event assessed as not compliant.
Virtual Events

Virtual Third Party Organised Educational Event (“Virtual Event”) are not subject to the e4ethics.

But we recommend to submit them anyway in the platform to keep track and visibility (yellow category in the Calendar). No CVS decision

Companies are free to sponsor or not these virtual events according to their internal guidelines.

Sponsors may not require from PCO a CVS / e4ethics assessment or decision on virtual events.
Thank you for your attention!

https://www.ethicalmedtech.eu/

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