

## Recording

The meeting is being recorded for record purposes, by participating you consent to the recording thereof.

## Competition law reminder and conflict of interest

The meeting is held with no intent to collude or engage in any matter that might contravene competition law. Conflicts of interest must be declared and if required, members recuse themselves, either before or during the meeting, as and when they become apparent.

## Disclaimer

The content i.e. presentations, views, opinions, advice expressed within the context of this event by invited speakers are theirs and not those of SAMED and as such does not imply an endorsement by SAMED of either the content or the speaker. The content is not a substitute for appropriate legal advice and is not binding on SAMED. SAMED, its board members, committees, employees and members, will not be responsible for any inaccuracies or omissions, or, liable for any damages or loss of whatsoever nature suffered by any person as a result of relying on or using the content provided.



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# SAMED Competition Law Guidelines: Do's and Don'ts

## Don't

**Don't** reach understandings or agreements or even hold discussions with a competitor (or even a potential competitor) on commercially sensitive topics such as selling or purchase prices, trading or credit terms (including delivery charges, minimum purchase quantities or interest rates) or billing practices, production, inventory, supply volumes, sales, costs, future business plans, budgets, upcoming tender or bids, or individual suppliers or customers.

**Don't** attend meetings with competitors or any industry body without written agenda or clear indication of the purpose.

**Don't** attend unscheduled gatherings with competitors or any industry body unless you know that they are for a bona fide purpose or that they are purely social gatherings.

**Don't** discuss business related topics at social functions.

**Don't** accept written non-public information or agree to the exchange of oral non-public information with Members who manufacture, market or sell (or could manufacture, market or sell) competing products.

**Don't** exchange any current or future information with your competitors (what your company intends to charge or do).

**Don't** participate in market surveys, or benchmarking exercises that allow access to any competitive information of any individual company. Any data published pursuant to a market survey must be aggregated and contain only aggregated/average data for at least 5 competitors.

**Don't** engage in joint negotiations, joint sales or joint buying without legal advice.

**Don't** agree to exclude competitors or engage in collective boycotts of suppliers or customers.

## Do

**Do** read the SAMED Competition Law Compliance Guidelines as contained in the [SAMED Committee SOPs](https://samed.org.za/about-samed/our-committees/) (<https://samed.org.za/about-samed/our-committees/>)

**Do** discuss public policy, education, scientific developments, regulatory matters of general interest, general industry trends, appropriately aggregated and non-individualized (statistical) market surveys or benchmarking projects, publicly available information and historical information, but be prepared to terminate the discussion and record your disagreement if anyone mentions any of the subjects listed in the "Don't" list above.

**Do** insist that your company's individual, commercial information is kept confidential by anyone conducting a survey.

**Do** inform SAMED if you disagree with any of its decisions and keep a copy for your files of any such correspondence.

**Do** return commercially sensitive information you receive from any competitor, without keeping copies, and explain in writing that you do not wish to obtain such information.

**Do** inform your company counsel of any approaches seeking to exchange non-public information or coordinate conduct on the market.

**Do** ask SAMED to have counsel attend SAMED meetings if you or your company has any doubts.

## Medical Device Code Forum: Supporting and Delivering Compliant Events and HCP interactions

25 October 2023, 09:00 - 10:00, Virtual

Engaging HCPs, supporting 3rd party educational events and providing compliant company events are integral to safe guarding against unethical business relationships - learn more in this forum.

**DON'T SUPPORT IT. REPORT IT.**

Report transgressions of the Medical Device Code

Freecall 24/7 hotline **0800 000 468**

Please make use of the chat function to send us your questions or raise your hand and the moderator will call on you to speak.



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# List of Abbreviations- changed to Glossary & Definitions Section 1

Definitions  
Added

- Charitable Donations
- Consulting Arrangement
- Customer Facing Personnel
- Day
- Delegate
- Educational Grant
- In Kind
- Employer Notification
- Fair Market Value (FMV)
- Financial Hardship
- Medical Technology
- Occasional
- Perception
- Scholarships and Fellowships
- Preceptorship
- Proctorship
- Virtual Event

# A few important definitions

## “Company Events”

means activities of any type that are planned, budgeted, managed, and executed in whole or in part by or on behalf of member companies to fulfil a legitimate, documented business need of the member company, including but not limited to a legitimate business need to interact with customers including HCPs and/or HCOs.

## “Product and Procedure Training and Education Event”

means a type of company event that is primarily intended to provide HCPs with genuine education, including information and/or training on:

- The safe and effective use of medical technologies, therapies and/or related services, and/or
- The safe and effective performance of clinical procedures, and/or
- Related disease areas.

In all cases the information and/or training directly concern a member company’s medical technologies, therapies and/or related services.

## “Third-party”

in the context of educational events and grants, means national, regional, or specialty medical associations or societies, hospitals, professional conference organizers, training institutions (such as medical schools and teaching hospitals), patient organizations or accredited continuing medical education providers. Legal entities established by HCPs in private practice are not considered compliant under the definition of a third-party as such entities serve the self-interest of the HCP’s, does not allow for unbiased selection criteria, and fails to safeguard the anonymity of potential beneficiaries due to the generally small size of the pool of potential beneficiaries.

## “Professional Conference Organizer (PCO)”

means a for-profit company or organisation which specialises in the management of congresses, conferences, seminars, and similar events.

## “Third-party Organised Educational Event”

means activities of any type that are planned, budgeted, managed, and executed in whole, or partly, by or on behalf of a person or entity other than a member company to fulfil HCPs medical educational needs.

## “Third-party Organised Educational Conferences”

means a type of third-party organised educational event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, professional conference organisers (PCOs), patient organisations or accredited continuing medical education providers.

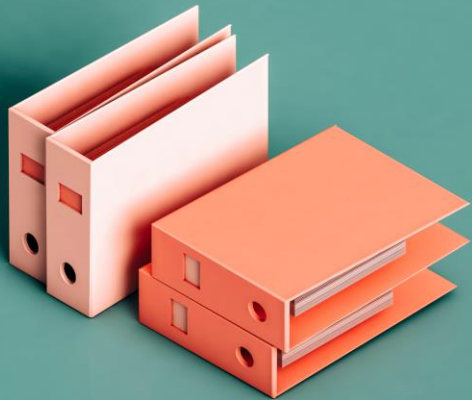
## “Third-party Organised Procedure Training”

means a type of third-party organised educational event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies).
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
- For the avoidance of doubt, proctorship and preceptorship are not considered to constitute third-party organised procedure training.

## “Virtual Event”

means a Third-Party Organised or Company Organised Event that is characterised by the participation of HCP delegates who attend exclusively remotely in a virtual environment that is generally enabled by digital technology rather than meeting in a physical location. As a result, a Virtual Event is not connected in any way with a physical Third-Party Organised Educational Event. For example, the filming of presentations, discussions, etc. taking place during a Third-Party Organised Educational Event (“hybrid” events), and their broadcasting to audiences, not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event, and therefore need to comply with all requirements of (in person) Third-Party Organised Events.



Some of the major changes  
Chapter One: General criteria  
for events

# Chapter One: General criteria for events

- “Member company events, third-party organised educational events, conferences, and procedure training, allow member companies to support Healthcare Professional- and patient-related training and education; to participate in clinical research and scientific exchanges related to their medical technologies; and to advertise and promote their products and services.



# Event Programme, Entertainment, Venues & Guest

## Event Programme

- Adherence to Programme Standards
- Accreditation Standards
- Advertisement and promotion at events

## Prohibition on Entertainment and Recreation

- Stance remains firm
- Template letter for members to respond to entertainment / recreation support

## Venues

- Perceptions
- No luxury / holiday / entertainment venues
- Includes: SAMED Directive regarding conference venues

## Guests

- Strengthened the wording to include a wider definition of guests
- Only bona fide professional interest in the information being shared

# Reasonable Hospitality: Meals

**Purpose.** The meal or refreshments should be subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational, or business information. Companies should provide meals and refreshments in a manner conducive to the presentation or discussion of such information. The meal or refreshments should not be part of an entertainment or recreational event.

**Setting and Location.** Meals and refreshments should be provided in a setting that is conducive to bona fide scientific, educational, or business discussions. This may include, for example, the Healthcare professional's place of business or an off-site space that is conducive to the discussion, such as a restaurant.

**Participants.** A Company may provide a meal or refreshments only to Healthcare Professionals who actually attend and have a bona fide purpose for attending the meeting.



A member company may not provide a meal or refreshments:

- For an entire office staff where everyone does not attend the meeting.
- For guests of Healthcare Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

## **Establishing meal policies:**

Companies are strongly encouraged to develop policies on providing modest and occasional meals to Healthcare Professionals

# Travel

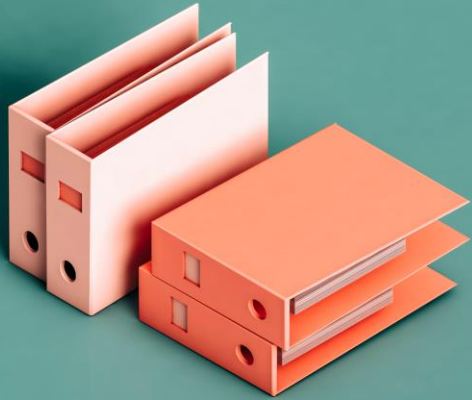


- In all instances, there must be objective, legitimate reasons that support the need for travel for Healthcare Professionals.
- **First class is never appropriate.**
- Support in relation to travel pertaining to member company arranged events
  - The general principles under Part 1: Interactions with HCPs, “Chapter 1: General criteria for events, 6.1.9 Travel” pertaining to travel are applicable. Travel may be arranged and paid for by the member company (or their designated travel agent).
- Support in relation to travel pertaining to indirect educational grants provided by member companies
  - Member company indirect educational grants may be used to defray the cost of travel, however, travel must be arranged and paid for by the third-party / entity that the educational grant was provided to and the general principles under Part 1: Interactions with HCPs, Chapter 1: General criteria for events, 6.1.9 Travel pertaining to travel are applicable.

# Employer notification

SAMED sent a communication to members on notifying the employers of HCPs when opportunities become available

- Member company arranged events be they training or other, should not, interfere with or disrupt HCP obligations to their patients, their academic training and/or their employment duties.
- Such events should also promote equity (impartial, fair, and just treatment without favouritism or discrimination), diversity (including or involving people from a range of different social and ethnic backgrounds and of different genders, ages, etc.), and inclusion (providing equal access to opportunities and resources for people who might otherwise be excluded or marginalized).
- This is especially true for HCPs in training, such as registrars.



# Some of the major changes

## Chapter 2: Third-Party Organised Educational Events

# Third-Party Organised Educational Events support

- Member Companies support for Third-party Organised Educational Conferences may take the form of:



## Educational Grants

To be covered at a future forum in detail



## Promotional Activity

- advertisement space
- booth space

**Note:** It should never bring discredit upon or reduce confidence in the medical technology industry.



## Satellite Symposia

See next slides

# Satellite Symposia

A Satellite Symposium is a Company-organized and funded program that is appended to a Third-Party Program agenda but that the Third-Party Organizer does not control. Member Companies may purchase satellite symposia packages at Third-party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third-party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection.

## Provisions

- Member Satellite Symposium within Third-Party Organized Educational Conferences criteria:
  - It is consistent with the overall content of the Event.
  - It should not be part of the scientific agenda of the Third- Party Organized Educational Conference.
  - Are only held in a room that is separate from the main auditorium of the event.
  - Company controls content and agenda
  - Open to all delegates attending the Third-Party Conference
  - Excludes business meeting, advisory board, consultant meeting or product launch

# Satellite Symposia

It is permissible for member Companies to:

- Select speakers for their Satellite Symposia
- Add company-sponsored Satellite Symposia speaker names to the website/brochure of the event
- Directly engage with Speakers (i.e., pay honorarium / hospitality expenses) to their satellite symposium through a contractual agreement
- Pay the speaker's registration fee related to the Satellite Symposium time, where payment of such fee is required for speaker access to that Satellite Symposium.
- Invite HCPs already attending the Third-Party Educational Event to a Company Organized Satellite Symposium provided that member companies do not directly cover any cost related to registration, travel and accommodation of the participants at Third-Party Educational Event.
- Provide participants at Satellite Symposia with reasonable and modest hospitality.

**Note:** It is not permissible to cover additional hospitality expenses for the Speaker of the Member Company's Satellite Symposium to attend the Third-Party Educational Event (e.g., accommodation for all the event days).



# Third-party Organised Procedure Training (TPPT)

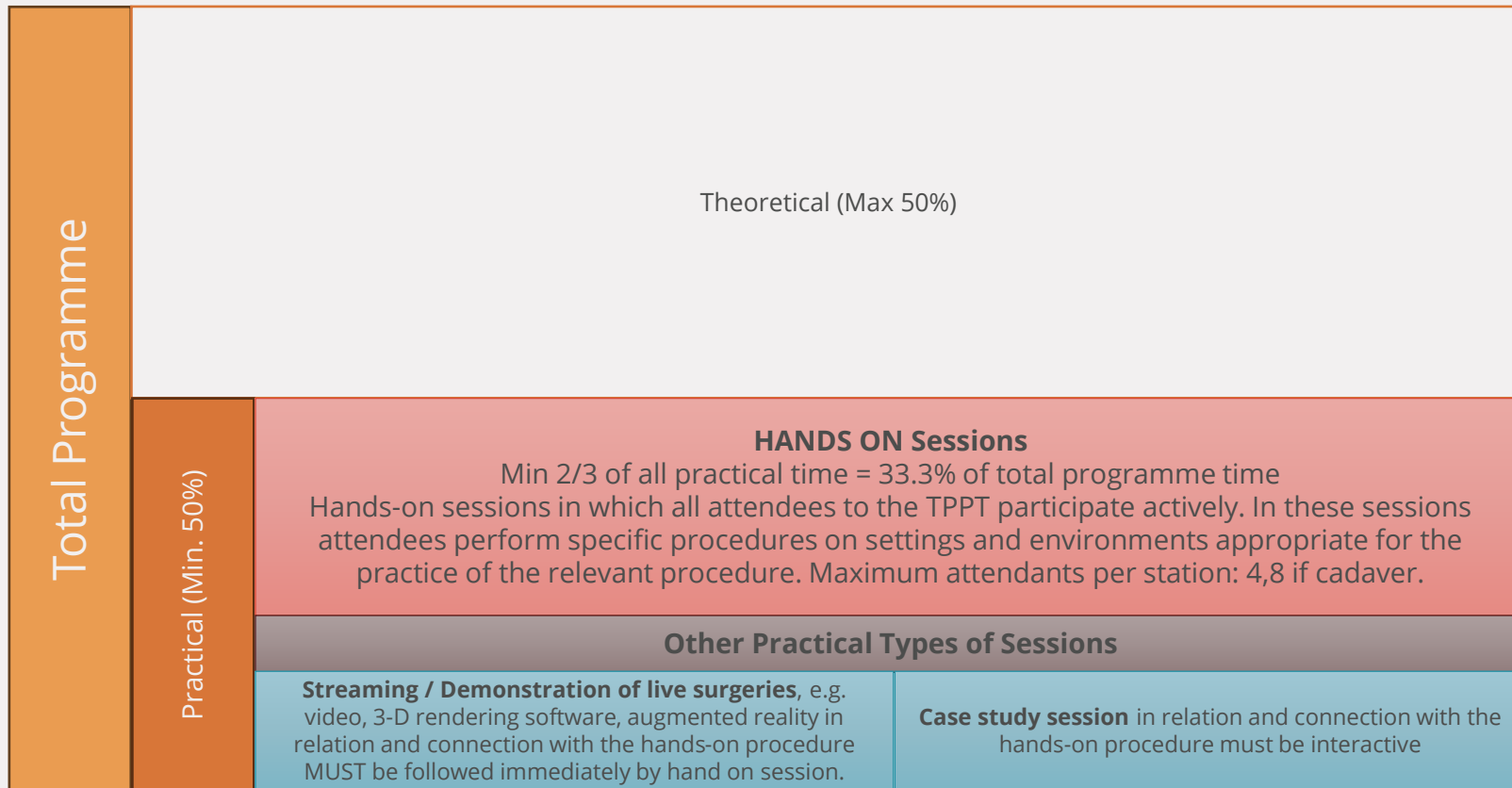
Member Companies may support Third-party Organised Procedure Training either via Educational Grants or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third-party Organised Procedure Training sessions, subject to the following criteria:

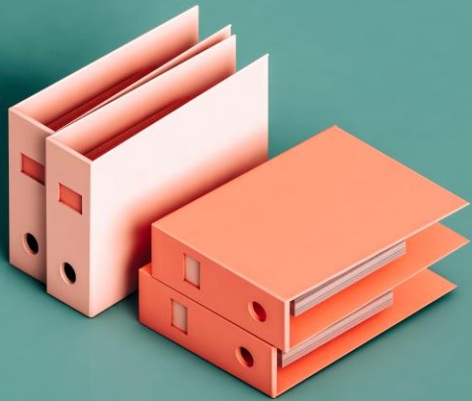
- Member companies may support HCP delegates but not speakers, the latter being independent.
- Member Companies may therefore pay travel, hospitality, and the registration fee.
- Should the participants' practical, hands-on portion of a Third-party Organised Procedure Training be cancelled or made virtual, the Event itself would no longer qualify as a Third-party Organised Procedure Training. As such, Member Companies would only be able to support such an Event via an educational grant and registration fee/access to the recording to such an event. Under no circumstances may travel expenses be paid in such a situation.

## Further Criteria for support

- Programme – hands on practical training (medical skills transfer relevant to a procedure rather than a specific product) involving more than one provider/manufacturer / sponsor. See next slide for the programme breakdown
- Venue – Typically a clinical environment as opposed to a classroom setting
- Stand-alone event – not part of a third-part organized event/conference

# Third-party Organised Procedure Training





## Some of the major changes Chapter 3: Company events

# General principles

May invite HCPs to:

- **NEW:** Company organised educational events
- Product and procedure training
- Sales, promotional, product launch and other business meetings
- **NEW:** Satellite Symposia (Company Events taking place in the context of Third-Party Organised Educational Events)

**Note:** these must still comply with Chapter 1

# Company organised educational events

- Objective: genuine and bona fide medical education, and the enhancement of professional skills
- Content: current scientific information of a nature and quality which is appropriate to attending HCPs
- There should not be any non-scientific or non- educational events or activities organized for the other part of the day
- Written agreements for faculty HCP honoraria at fair market value

# Product and procedure training

- Member companies should make product and procedure training available to relevant HCPs
- Ensure that personnel conducting the product and procedure training have the appropriate expertise to conduct such training

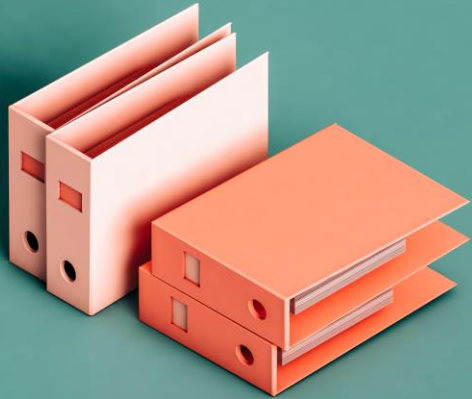
# Company Events taking place in the context of Third-Party Organised Educational Events

- Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating in Company Events which take place during, around, or at the same time and in the same approximate location as a Third-party Organised Event.
- Member Company may only pay the contractual compensation and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the Healthcare Professional's attendance at the Third-party Organised Educational Event, such as registration costs, hospitality, additional travel, or accommodation.

# Sales, promotional, product launch and other business meetings

- Such meetings should, as a general rule, occur at or close to the HCPs place of business.
- The objective of a sales, promotional or other business meeting is to affect the sale and/or promotion of a company's medical technologies and/or related services. These meetings may include discussions of product features, benefits and use and/or commercial terms of supply.
- Companies should generally not pay for travel and accommodation and these meetings should occur close to the HCP place of business. Exceptions might be for a national launch or where demonstrations of non-portable equipment are necessary.





## Some of the major changes Chapter 4: Virtual and hybrid events








# Virtual and hybrid events

Meals to HCPs during virtual events are prohibited unless the event is held at a hub and more than 3 HCPs are in attendance. In such instances:

- only meal delivery is permitted and providing cash or cash equivalents (e.g., restaurant or meal delivery service vouchers or gift cards) are prohibited.
- invited HCPs must confirm their attendance before the event and member companies must track attendance to ensure that only appropriate recipients of the Virtual training/education program are receiving the meals.

In respect of a Continuing Medical Education (CME), no commercial promotion of the product may be allowed during the CME accredited presentation portions of the event. Commercial promotion is allowed during non-CME slots, for example, lunch or comfort breaks earmarked for advertising purposes.

# Reminder of important dates

-  8 November 2023 Forum: Educational grant
-  17 November 2023 Forum: Charitable donations, intermediaries & the enforcement process
-  1 February 2024 Code Version 8 comes into effect
-  1 February 2024 Code certification period opens (existing members)
-  TBC February 2024 Forum: Your questions answered
-  31 July 2024 Code certification period closed (existing members)
-  31 August 2024 Deadline for Annual Declarations



# Questions and comments

**SAMED**   
advancing patient care through MedTech

# Thank you for joining us.

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Email additional questions to: [communication@samed.org.za](mailto:communication@samed.org.za)



MEMBER FORUM

## Regulatory Forum: Bridging the ISO 13485 Gap

7 November 2023, 09:00 - 10:00, Virtual

ISO 13485 is a mandatory licence requirement from the South African Health Products Regulatory Authority (SAHPRA). Exemption on this requirement was granted for a three-year period until 16 January 2025. Time is running out to achieve accreditation. Join us on this session on the benefits of accreditation as we bridge the ISO 13485 gap.

[REGISTER NOW](#)



MEMBER FORUM

## Market Access Forum: Private Hospitals and POPIA & Public Sector Debt tracking

8 November 2023, 09:00 - 10:00, Virtual

Join us as we understand the impact of private hospital group's POPIA policies on medtech companies and launch the SAMED Public Sector Debt tracking platform to enable SAMED to advocate for payment of outstanding invoices at public health facilities.

[Register now](#)



MEMBER FORUM

FORUM 3 OF 4 ON THE CODE UPDATES

## Medical Device Code Forum: Supporting and Delivering Compliant Events and HCP interactions

8 November 2023, 14:00 - 16:00, Virtual

Medical technology companies are often approached to support the continued professional development of healthcare professionals in their field. Join us as we cover updates around indirect educational grants and HCP support.

[REGISTER NOW](#)



MEMBER FORUM

## Transformation Forum: Tracking Sectoral Targets

17 November 2023, 09:00 - 11:00, Virtual

Join us as we unpack what sectoral targets will mean for your company and why it will be of vital importance that you maintain accurate records (tracking) of employment data to ensure compliance with legislature.

[REGISTER NOW](#)



MEMBER FORUM

## Transformation Forum: SAMED-YES Alumni Platform Launch

21 November 2023, 10:00 - 11:30, Virtual

SAMED and the Yotuh Employment Service (YES) formed a partnership to capacitate medtech one youth at a time. To facilitate further opportunities for the youth that complete a 12 month programme, we now launch the Alumni Programme. Join us for this exciting opportunity to skip the recruitment fees and gain access to YES youth alumni.

[REGISTER NOW](#)



MEMBER FORUM

FORUM 4 OF 4 ON THE CODE UPDATES

## Medical Device Code Forum: Donations, intermediaries and enforcement

22 November 2023, 09:00 - 11:00, Virtual

In this forum we take a look a charitable donations, third part intermediaries and the enforcement process as we conclude the series covering the updated Medical Device Code of Ethical Market and Business Practice.

[REGISTER NOW](#)