Medical Device Professional Group

TERMS OF REFERENCE

Medical Device Professional Group (MDPG) Terms of Refence (ToR) document is the group's founding document and defines the working arrangements for the MDPG; provide information on the objectives of the group; provides for a decision making and unitary structure which conforms to best practice for MedTech Consultants and provisions of the Competition Act.

1. Role/Purpose

The purpose of the MDPG is to:

1.1. Provide an independent and objective expert opinion and guidance based on international best practice to the MedTech industry and Regulators with direct relevance to MedTech;

1.2. Keep up to date with local and international legislation, regulations and guidelines related to the MedTech industry;

1.3. To provide advocacy for and insights into the wider MedTech industry, especially Micro and SME organizations which lack internal capacity and knowhow;

1.4. To assist in communications between Regulatory Bodies and industry through

1.4.1. Interpretation;

1.4.2. Guidance;

1.4.3. Provision of objective accurate information; and

1.4.4. Advocacy.

1.5. Promoting ethical business practices and minimum standards for MedTech Consultants through a Code of Conduct;

1.6. Support and Promote Training and Accreditation including ethics, technical skills for MedTech Consultants; and

1.7. Provide Expert Opinion based on experience of the Group as evidenced by its Skills and Experience Inventory Document *(Still to be developed).*

2. Term

This ToR document is established as a founding document, approved by the founding members at a meeting on 26 February 2020 to which all known MedTech Consultants were invited, and is valid until the group dissipates or is replaced in terms of Clause 7 below.

3. Membership

Membership is open to any natural person, with professional occupation in the Medtech consulting, and upon commitment to these ToRs.

Membership forms and a list of members is published on www.mdpg.co.za

4. Roles and Responsibilities

4.1. Chairperson – Responsible for the overall functioning of the group, primary contact with external stakeholders and chairs all meetings;

4.2. Vice Chairperson – Will stand in for the Chairperson at meetings where the Chairperson is not available or in other circumstances in which the Chairperson is unable to fulfill their duties and obligations

4.3. Secretariat – Responsible for administration, minutes of meetings, distribution of information to the group and establishing and WebAdmin for www.MDPG.co.za

4.4. Members – Responsible for contributing towards the effectiveness and efficiency of the group and promoting its goals and objectives. Members are required to complete a membership form and subscribe to the Code of Conduct. Members are expected to attend all meetings, to be fully prepared and engaged at all meetings.

5. Meetings

5.1. At the first meeting of the MDPG a chairperson of the Group will be nominated and approved, who shall serve for a period of two years.

5.2. Frequency – meetings will be held at least twice a year or as required by

5.3. Quorum – 1/3 of its members in good standing

5.4. Notice – At least 10 business days ahead of the meeting at which time an agenda must be provided.

5.5. Attendance may be via electronic or telephonic means.

5.6. Decision Making –

5.6.1. is by consensus and members are bound by the decision made and positions agreed to.

5.6.2. Where consensus cannot be reached the chairperson may call for a vote for which a simple majority is required (besides to change the ToR, which required a 2/3 majority of members).

5.7. Only matters contained within the agenda may be discussed at a meeting.

6. Definitions

6.1. MedTech – Shall mean Medical Technology in its broadest application to includes any technology that can be used in a care setting, which covers disposables, capital equipment and surgical procedure innovations, through to implant technology, biomaterials and connected health IT, but exclude Medicines, Complimentary Medicines and foodstuffs.

6.2. MedTech Consulting / Consultant shall mean somebody who provides services to a MedTech Company in relation to MedTech products and services. This excludes business or strategy consulting and professional services of a general nature. It is however noted that MedTech Consultants may also provide services in these other areas, which shall not preclude them from membership of this group.

6.3. Member in Good Standing shall be taken to mean that the member meets all of the following requirements:

6.3.1. Subscribes to the goals, objectives and

6.3.2. Commits to the Code of Conduct of the Group

6.3.3. Has completed a membership form

6.3.4. Has not been found guilty of an offence in terms of any of the Regulatory Bodies involved with MedTech, such as Act 101

7. Amendment, Modification or Variation

These ToR may be amended, modified or varied in any manner by a 2/3 majority of its members in good standing.

Founding Member Signatures:

[redacted]
Simone Rudolph-Shortt (Apr 16, 2020)

felistas (Apr 16, 2020)

Maureen Dennehy (Apr 16, 2020)

Mark Brand BrandTech Healthcare (Apr 30, 2020)

Dr Mark Bodley (May 4, 2020)