

Terms of Reference

NAFEMS Medical Devices & Life Sciences Technical Working Group

1 TECHNICAL AREA COVERED BY THE GROUP

The NAFEMS Medical Devices and Life Sciences (MDLSWG) promotes the development, understanding, and practical application of in silico simulation techniques in the medical and healthcare sectors, while ensuring that these tools meet the rigorous standards required for clinical and regulatory use.

The scope of the MDLSWG covers

- Biomedical modelling and simulation, such as ergonomics, tissue engineering, epidemiology, physiology.
- Development of medical devices for applications such as diagnostics, treatment and prevention.
- Pharma and biopharma - systems and computational biology, pharmacokinetics & pharmacodynamics, drug development, drug delivery, drug manufacture.
- Regulatory affairs such as assessment frameworks, verification, validation & uncertainty quantification, standardisation and post market surveillance.

2 AIMS

The group aims to:

- Facilitate Collaboration. We will create a platform for open dialogue and the exchange of ideas among professionals from academia, industry, and software development.
- Promote Best Practices. By drawing on the collective expertise of our members, we aim to develop guidelines, standards, and best practices.
- Develop a Competency Framework. Building a framework of competencies that is required for an engineering simulation professional to be successful in the domain of Medical Devices and Life Sciences.

3 STRUCTURE

The Technical Working Group (TWG) is composed of experts who contribute their time and knowledge on a voluntary basis. TWG members are responsible for identifying the outputs, directing and contributing to the activities of the TWG.

The outputs of the TWG are commissioned by current TWG members. TWG outputs may be developed by TWG members or external experts. Where an output is produced by an external

expert, the TWG is responsible for ensuring that the output is technically accurate and relevant to the NAFEMS membership.

At the discretion of the TWG, focus groups may be formed to address a specific application area/numerical method.

4 BYLAWS

4.1 TWG MEMBERS

Members of the TWG are listed on meeting minutes as present, contributing or sent apologies.

If a member of the TWG does not contribute for more than 9 months, they will be warned that their membership of the TWG may be terminated. An individual's TWG membership may be terminated after 12 months of non-contribution, at the discretion of the Chair.

New TWG members are required to be a representative of an organisation that holds a current NAFEMS membership.

At the discretion of the TWG Chair, participation in a TWG meeting may be represented by one of two or three individuals from the member organization to reduce the workload on individuals.

The number of TWG members should ideally range from between 10-20.

The membership of a TWG is listed on the NAFEMS website.

4.2 JOINING THE TWG

Potential new TWG members are required to submit a curriculum vitae (or equivalent) to the NAFEMS Technical Working Group Manager (TWGM) indicating their knowledge and experience in the area covered by the TWG. The TWG may ask the potential new member to explain why they want to join the TWG and what they can contribute. The information provided will be reviewed by the TWG and if approved, the person will be invited to attend meetings and participate in the group's activities. It is expected that TWG members will hold a senior technical position and have significant technical expertise.

4.3 MEETING LOGISTICS

Minutes will be taken for all TWG meetings and actions will be identified. The minutes should be circulated within a month (ideally less) of a meeting date. The TWGM will produce the meeting minutes unless another meeting attendee is selected by the Chair.

The primary method of meeting will be via a web-based platform to enable international involvement in the group. The TWG is encouraged to take advantage of major NAFEMS or industry events to meet in person. Where a physical meeting is scheduled attempts should be made to provide a web-based connection to the meeting to allow participation of those who are not able to attend the meeting in person.

The TWG is required to meet at least 6 times a year.

4.4 LEADERSHIP ROLES

The positions of Chair and Vice-Chair are open for review every three years on the anniversary of the initial appointment. There is no requirement for the role to be rotated. Only current members of the TWG may vote or be nominated as Chair. The responsibilities of the TWG Chair and Vice Chair are defined in Section 8.

The Chair of the TWG should ideally be an industrial user of modelling, analysis and simulation technology.

4.5 DECISION MAKING

Where a vote is required it will be carried out via email to the Chair or, if the position of Chair is being voted on, to the TWGM.

Only current members of the TWG are allowed to vote. Each organisation that has a representative in the TWG will have one vote. If an organisation has more than one person participating in the TWG, the vote will be shared between the participants.

If required, the casting vote will be held by the Chair.

4.6 COMMUNICATION

TWG communication should be carried out using the group email address. It is the responsibility of the NAFEMS TWGM to ensure that the TWG distribution list is current. Personal distribution lists are discouraged as they require constant updates.

5 MEASURES OF SUCCESS

The success of the TWG is measured in terms of:

- Outputs include but are not limited to:
 - Publications
 - Developing/maintaining an area of the NAFEMS PSE Framework
 - Webinars
 - “How to..” Guides
 - Training Courses
- Activity & Engagement including but not limited to:
 - Number of TWG meetings
 - Number of attendees per meeting
 - % of TWG group members who attended zero meetings in the last 12 months
 - Number of individual leaving the TWG
 - Number of new expression of interest in joining the TWG

6 RESOURCE REQUIREMENTS

The group is administered by the NAFEMS Technical Working Group Manager (TWGM).

Logistical support for the TWG, consisting of providing a web-based meeting platform, scheduling meetings and web-hosting of TWG output is provided by NAFEMS.

Funding is available from NAFEMS to support the development of TWG outputs. This funding can take the form of contracts for authors, contracts for the individuals tasked with reviewing. Applications for funding should be made to the NAFEMS Technical Officer.

7 DURATION

The TWG will continue in perpetuity until terminated by the NAFEMS CEO.

8 ROLES & RESPONSIBILITIES

TWG Members are responsible for:

- identifying the outputs and directing the activities of the TWG
- ensuring that TWG output is technically accurate and relevant to the NAFEMS membership
- regularly contributing to TWG activities. Contributions can include:
 - attending and actively participating in TWG meetings;
 - participating in topic discussions and activities between meetings, whether individually or as part of a focus team;
 - sending relevant comments or reports on agenda items to the Chair in good time for the meeting;
 - volunteering for and carrying out actions arising from the meetings including developing outputs, reviewing TWG resources, authoring invitations to tender etc.

TWG Chair is responsible for:

- providing leadership to the TWG
- acting as the focal point of the TWG
- ensuring that TWG meetings are run effectively.

TWG Vice Chair is responsible for:

- providing leadership to the TWG
- chairing the TWG in the absence of the Chair.
- supporting the TWG Chair.

NAFEMS Technical Working Group Manager is a NAFEMS staff member responsible for:

- acting as the primary point of contact between the TWG and NAFEMS
- TWG meeting logistics
- Processing new member requests
- Producing the minutes for TWG meetings

NAFEMS Technical Officer is a NAFEMS staff member responsible for:

- acting as the NAFEMS point of contact for TWG funding
- acting as the NAFEMS point of contact for approving TWG output

NAFEMS CEO has the authority to terminate or request a change of scope for the TWG

9 APPROVAL

T R Morris
CEO, NAFEMS

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