A framework for collaboration between a lead organisation (Cardiff University) of the Microneedle Array Patch Regulatory Working Group (MAP-RWG) and partners/collaborators

Table of Contents

1. Introduction/ Overview

The (Microneedle Array Patch Regulatory Working Group) MAP-RWG was formed as part of the Centre of Excellence for MAP technology, an initiative to accelerate the development of MAPs as a technology platform for high-priority needs (vaccines and essential medicines) in low- and middle-income countries. As part of this Centre of Excellence, PATH has partnered with Cardiff University (CU) to co-Chair a group that includes representatives with MAP expertise in both the commercial and academic sectors, vaccine development experts and representatives from national regulatory authorities, international pharmacopoeia and the WHO pre-qualification of medicines programme.

Mission: The MAP-RWG aims to inform, guide and define the regulatory science of the MAP dosage form. It is hoped that this will help facilitate clinical translation of safe and effective MAP products.

Scope of work / Remit: The work of the MAP-RWG focusses on the key contemporary CMC-related regulatory issues for MAPs, which are identified by consultation with MAP-RWG members and key stakeholders.

Activities: Four parallel work streams have been established by the MAP-RWG. The aims of these are to:
(1) establish a definition for the MAP dosage form
(2) identify and understand MAP critical quality attributes (CQAs)
(3) develop standardised validated test methods to evaluate the quality of finished MAP products and/or the development of pre-clinical prototypes
(4) inform the microbiological requirements for MAP products.

Timely dissemination and consultation with a range of stakeholders will take place through appropriate publications (preferably Open Access) and the dedicated MAP-RWG website (www.microneedleregulatory.org).

Philosophy: The goal of the MAP-RWG is to provide sustainable benefits related to the regulatory science of MAPs for all stakeholders, including product developers, regulatory authorities, public health bodies and end-users. This can only be facilitated by collaborative working (to ensure informed and harmonised development of activities) and a commitment to international accessibility.

2. Rationale – Why do we need a framework?

The MAP-RWG aims to inform and guide the Regulatory Science of the MAP dosage form. A portfolio of projects is likely to develop under the remit / guidance of the MAP-RWG. This will include activities in the laboratory (e.g. the development of standardised test methods for the dosage form) and outside the laboratory (e.g. the development of guidance for the dosage form).

These projects necessitate collaboration between MAP developers, regulatory bodies, test development specialists and other relevant stakeholders. Project contributors may be MAP-RWG members or other stakeholders. CU (co-chair of the MAP-RWG) will provide a primary convergence point to manage these interactions and collaborations, and in some cases will also directly contribute to and/or lead these projects. A formal collaborative framework is therefore needed to clear demarcate the boundaries of these partnerships, including how activities, information and materials are managed within any project/activity that takes place under the remit of the MAP-RWG. Where possible, project partners and collaborators will be identified, to ensure transparency.

This document explains how CU (under the remit of the MAP-RWG) will work with partners from commercial, academic, government, and other organisations to ensure mutual benefits for project partners and the wider MAP community/stakeholders. This guidance document provides a transparent framework and philosophy for collaboration, on which legally binding MTAs and NDAs will be developed between partners to facilitate collaboration.

3. Aim

This framework provides a transparent mechanism for interactions between CU and partners when conducting work under the remit of the MAP-RWG. These interactions will include, but are not limited to, dialogue, knowledge exchange and the transfer of materials.

The aim of the MAP-RWG is to inform, guide and define the regulatory science of the MAP dosage form. Current activities include: (i) the development and validation of standardised test methods to assess MAP specific critical quality attributes, (ii) publication of expert opinions and recommendations that informs the Regulatory Science related to MAPs and (iii) engagement with MAP stakeholders through mechanisms such as the RWG website (www.microneedleregulatory.org). These activities are currently led by CU.

4. Scope of interactions (types of collaboration)

Typical examples of collaborative activities between CU and partners will include:

- The exchange of materials (e.g. MAP prototypes) from partners to CU to help develop and / or validate activities that aim to develop standardised test methods for MAP technology.
- The exchange of materials (e.g. testing materials and apparatus) from CU to partners to help develop and / or validate activities that aim to develop standardised test methods for MAP technology.

- The two-way exchange of knowledge (e.g. protocols) between CU and partners to help develop and / or validate activities that aim to develop standardised test methods for MAP technology.

Note: Operation within this framework will require development of MTAs and NDAs between collaborating partners. These legally binding documents should be built on the philosophy of this framework.

5. Working principles

Collaboration

The management of internal (members of MAP-RWG) and external stakeholder interactions in this project is based on the principles of transparency, independence and integrity, accountability, appropriateness, broad representation, effective communication, and continuous improvement.

In accordance with the MAP-RWG mission and philosophy, any collaborative partnerships with CU in this project must be consistent with the following principles:

- Clear link to mission
- Recognition of the collaborator needs (clearly defined)
- Clear Definition of Roles, Responsibilities, and Expectations
- Transparent Collaboration
- Appropriate Selection of Collaborators
- Appropriate Management of Risk
- Dissemination of Results
- Awareness of Potential Conflicts of Interest
- Ensuring High Standards of Quality and Ethics

The function of this collaborative framework will rely on the following elements:

a. **Mapping of stakeholders with relevant expertise**

The mapping of stakeholders with an interest in regulatory activities enables targeted communication and facilitates interactions that are of mutual benefit. Organisations can register their interest and contact the Chairs of the MAP-RWG using a dedicated open access widely disseminated webpage (https://www.microneedleregulatory.org/contact-us.html).

ii. Evolution of collaborative expertise to keep pace with advances in MAP development and relevant Regulatory Science

To maintain an informed and contemporary regulatory ecosystem it is critical to ensure access to the best expertise across a broad range of scientific domains. Advances in research and development will be closely monitored to ensure access to the most appropriate expertise to support the activities of the MAP-RWG.

iii. Identifying opportunities to promote progress made in the Regulatory Science of MAPs

Progress made by the MAP-RWG will be disseminated through:

- contributions to international conference/meetings

- formal publications of the findings
- dissemination through the dedicated website (https://www.microneedleregulatory.org)

iv. Promoting and reinforcing dialogue through effective communication

Effective dialogue between MAP developers, regulators, test development specialists and other interested parties will underpin implementation of this framework. The role of chairs (CU and PATH) is to facilitate multi-stakeholder dialogue.

6. Implementation of the work

The framework will be implemented in co-operation with relevant stakeholders, ensuring mutual benefit is achieved. It will be reviewed and updated (with version control) as experience is gained. Open consultation and any activities that are not part of the MAP-RWG remit are not covered by this framework document.

7. Access to Innovation

The activities and outputs from projects that fall within the remit of the MAP-RWG aim to provide direct and indirect benefit to a range of stakeholders. The knowledge and information created during activities must therefore be effectively disseminated, and any resulting commercial products should be made accessible to all relevant stakeholders i.e., internationally available at an affordable price.

Partnerships and collaborations between academic, industry and public sector organisations will be fundamental to some of the projects that have been initiated under the guidance of the MAP-RWG and may involve the transfer of materials and 'know-how' to inform innovation. It is therefore important that intellectual property (IP) rights are transparent and are not a barrier to meaningful collaboration. This collaborative framework does not preclude commercial opportunities; in some cases, commercialisation will be an essential means to facilitate access. Any data that is created will be effectively managed and appropriately shared under an agreement between the named partners/collaborators.

This collaboration framework provides a flexible and pragmatic approach to the IP and data that is generated within projects that are with the remit of the MAP-RWG and encourages meaningful partnerships that stimulate innovations with wide applicability. The diversity of potential projects, outcomes and partners/collaborators means that relationships will be managed at the partner/collaborator/project level. However, these relationships must be built on a philosophy of international accessibility for key stakeholders.