Personalized Medical Devices (PMD) Working Group
March 2021 Update

Tracey Duffy
Therapeutic Goods Administration - Australia
# Working group members

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Representatives</th>
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<tbody>
<tr>
<td>Argentina</td>
<td>Marcela Rizzo</td>
<td>Japan</td>
<td>Yoshiyumi Nagai&lt;br&gt;Kanako Sasaki&lt;br&gt;Yoshimasa Yokoyama</td>
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<tr>
<td>Australia</td>
<td>Tracey Duffy (Chair)&lt;br&gt;Rebecca Bateson&lt;br&gt;Uphar Chamoli&lt;br&gt;Madeleine Neill</td>
<td>Portugal</td>
<td>Mariana Isabel Vaz Afonso Pires Madureira</td>
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<tr>
<td>Brazil</td>
<td>Priscilla Consiglierio de Rezende Martins&lt;br&gt;Maria Angela da Paz&lt;br&gt;Marcia Cristina de Moraes Reis Ribeiro</td>
<td>Russia</td>
<td>Konstantin Ivanov</td>
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<td>Canada</td>
<td>Andrea Katynski</td>
<td>Saudi Arabia</td>
<td>Abdullatif S. Al Watban</td>
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<td>China</td>
<td>Yue Min&lt;br&gt;Shuo Pan</td>
<td>Singapore</td>
<td>Shuling Peng</td>
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<td>European Commission</td>
<td>Nada Alkhayat</td>
<td>South Korea</td>
<td>Jang-yong Choi&lt;br&gt;Seon-mi Lee&lt;br&gt;Sang-jin Park</td>
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<tr>
<td>Germany</td>
<td>Matthias Neumann</td>
<td>USA</td>
<td>Matthew A. Di Prima</td>
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Benefits of additional guidance for PMD

• Addresses an emerging trend for increased use of personalized treatments in healthcare
• Enhances sharing and use of relevant information and scientific expertise among stakeholders
• Supports harmonization for safety, performance and manufacturing of these products
• Provides a basis for consistent and transparent requirements across multiple jurisdictions
• Aligns with IMDRF strategic priorities
PMD working group publications

Definitions for PMD (N49)

Published in October 2018

• Custom-made medical device
• Patient-matched medical device*
• Adaptable medical device

* Designed and produced within a specified design envelope
PMD working group publications

Regulatory Pathways for PMD (N58)

Published in March 2020

• Regulatory requirements for different categories of PMD
• Medical Device Production System
• Considerations for point-of-care manufacturing of PMD
PMD working group publications

• **N49, N58** introduced new definitions and concepts relating to the production of personalized medical devices

• PMD Working Group proposed developing a new technical document building on the previous publications

• Technical document to propose requirements for validation of production processes that are unique to PMD

• MC approved drafting of the new technical document (New Work Item Extension) on 25 September 2020
New Work Item Extension (NWIE)

PMD – Production Validation

Scope of work

<table>
<thead>
<tr>
<th>Technical considerations for validation aspects of a specified design envelope</th>
<th>Technical considerations for validation aspects of a Medical Device Production System</th>
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<tbody>
<tr>
<td>• Intended use(s) and range of user needs</td>
<td>• Quality management system requirements</td>
</tr>
<tr>
<td>• Geometrical, material, performance, operational variants</td>
<td>• Risk management plans</td>
</tr>
<tr>
<td>• Worst-case scenario design validation testing</td>
<td>• Usability assessments</td>
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<td>• Clinical evaluation, etc.</td>
<td>• Requirements for labelling and instructions for use, etc.</td>
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PMD - Production Validation

• First meeting (held 15 December 2020) via teleconference
  – Discussed the scope of work
  – Identified a number of countries already have useful documents that can inform this NWIE

• Members have shared relevant documents to inform the Working Draft

• Working Draft to be discussed at the next Working Group meeting in March 2021
Forward plan

Key dates:

- Working Group currently developing the Working Draft
- Aiming to submit the final Working Draft to the MC in January 2022 for review*
- Three months (March-May 2022) public consultation on the Proposed Document
- Potentially Final Document due to the MC for consideration before September 2022 meeting#

* Following MC approval, the Working Draft will advance to the Proposed Document stage
# Following resolution of comments received during the public consultation, the Proposed Document will advance to become the Final Document
Forward plan

Key dates:

• Targeted circulation of Working Draft among Working Group members (October – November 2021)
• Final Working Draft forwarded to the MC (January 2022)
• Public consultation of the Proposed Document (March – May 2022)
• Submission of Final Document to MC (July – August 2022) for consideration at the September 2022 meeting
Thank you