GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
Center for Devices and Radiological Health
US Food and Drug Administration
Title: Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialists

Scope:

- Define knowledge, skills, and attributes for personnel carrying out pre-market review/assessment of technical documentation/design dossiers of "high-risk" medical devices.
- Define criteria for various degrees of competence and training needs based on roles.
GOALS

• Providing a common set of training and competency requirements can assure that certain aspects of the pre-market review process become more consistent across various Regulatory Authority partners thus allowing for greater opportunities to rely on other Regulatory Authority partners work.

• Innovative medical devices can reach the patients faster and more efficiently when Regulatory Authorities can partner and rely on consistent work performed by other Regulatory Authorities.

• Reduction of regulatory redundancies around the globe has positive effects of bringing safe medical devices to the patients around the world.
ALIGNMENT WITH IMDRF STRATEGIC PRIORITY

“Improve the Effectiveness and Efficiency of Pre-Market Review”

• This work item aligns with the strategic priority and will be a first step towards improving the pre-market review process by addressing the competencies and training requirements for pre-market reviewers.
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<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Organization and Position</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Dr. Elizabeth McGrath</td>
<td>TGA - Director Conformity Assessment, Medical Devices Branch</td>
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<td>Camila Gonçalves Moreira</td>
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<td>Canada</td>
<td>Caroline Vanneste</td>
<td>Health Canada - Manager, Good Review Practices Group</td>
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<td>China</td>
<td>Yuxi Yang</td>
<td>CFDA - Reviewer, Division IV, Center for Medical Device Evaluation</td>
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<td>Shiqing Zhang</td>
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<td>EU</td>
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<td>Japan</td>
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<td>Russia</td>
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<td>Roszdravnadzor - Counsellor of the department of state registration of medical devices</td>
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<td>Melissa Torres (Chair)</td>
<td>US FDA – Acting Associate Director, International Affairs</td>
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<tr>
<td>WHO</td>
<td>Robyn Meurant</td>
<td>WHO - Prequalification Team – Diagnostics Assessment</td>
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WORKING DRAFT DOCUMENT

• Use of IMDRF/MDSAP WG/N4FINAL:2013 as basis.
• Proposed document content includes:
  – Commitment to Impartiality and Confidentiality
  – Entry Level Requirements
  – Training Requirements
  – Experience Requirements
  – Competence Evaluation
  – Reaffirmation of Code of Conduct
  – Records of Pre-requisites, Competence Evaluation and Monitoring
  – Remediation
RELEVANT DOCUMENTS

- IMDRF/MDSAP WG/N4FINAL:2013
- Commission Implementing Regulation (EU) N° 920/2013
- Commission Recommendation 2013/473/EU
- Annex VI of the new EU regulation on medical devices
- US FDA Reviewer Certification Program
- Other IMDRF Members Reviewer competence or training specifications
**IMDRF**

*International Medical Device Regulators Forum*

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**Timeline**

- **Work Group Formation**
  - Dec 2015

- **Face to Face Meeting**
  - Sydney, Australia
  - April 2016

- **Proposed Document Public Consultation**
  - July/August 2016

- **Submit Final Draft to MC for Review**
  - Jan 2017

- **Proposed Working Draft Document Submitted to MC for June teleconference**

- **Face to Face Meeting to Resolve Comments and Prepare Final Draft**
  - Fall 2016

- **Routine working group teleconferences**
CURRENT STATUS

- Working group formed
- Working group draft document created
- Comments received from working group on initial draft
- Routine teleconferences
- Working group gathering resources from each of their respective Regulatory Authority to ensure harmonization of requirements
THANK YOU