DCVMN Regulatory Affairs WG 2022
Key Learnings & Activities

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DCVMN Commitment to Regulatory Affairs

• RAWG seeks to identify and address regulatory challenges for the vaccine life cycle, and potential opportunities for increased efficiency of regulatory processes worldwide by:
  • Tracking for the RAWG goals for the ongoing year.
  • Holding bi-monthly meetings and facilitating members discussion.
  • Determine topic suggestions for presentation and position papers.
  • Examination of hot button issues (if any) with open mindset/perspective.
  • Organize workshops and trainings to address industry priority topics with those needed to initiate change.
DCVMN Regulatory Affairs WG
Areas of Focus 2022

• WHO Collaborative Registration Procedure
• DCVMN – CEPI Collaboration
• Industry (DCVMN-IFPMA) joint interaction with ICMRA
• Ongoing Assignments in 2022
WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

- Promote the use of CRP allowing for greater global access to products and reduce regulatory registration hurdles.
- Workshop held with WHO management, to discuss registration challenges and industry engagement identified in DCVMN CRP survey (Aug 10th – Sep 2nd 2022)
- Roadmap to improve operational procedures of CRP implementation for 2023 established.
  - Participation in six WHO CRP regional advocacy workshops.
  - WHO to hold workshops with NRAs and members on 5-year plan to change SRA to WLA.
  - Public health impact vaccine/s will be identified and a CRP pilot program will be applied by mid 2023.
DCVMN – CEPI Collaboration

• DCVMN collaboration with CEPI provides win-win situation for both DCVMN and CEPI.
• DCVMN will have access to CEPI backed projects and manufacturing information on vaccines against emerging threats.
• Few key collaboration topics are:
  ▪ Tech-transfer process and clinical trials in developing countries
  ▪ Foster Reliance concept
  ▪ Focus DCVMN-CEPI efforts for Pandemic Preparedness & Response.
DCVMN-IFPMA joint interaction with ICMRA

• Discussion with ICMRA included:
  ▪ Industry Associations’ proposal
  ▪ Reliance for PACs and hybrid GMP inspections
  ▪ Labelling flexibility
  ▪ Manufacturing and distribution related matters

• Participation for Asia Regulatory Conference
  ▪ Risk based approach for PACs

• Participated for development and finalization of Joint Reflection Paper on “Pharmaceutical Quality Knowledge Management Capability to Support Regulator and Manufacturer Agility”
ONGOING RAWG ASSIGNMENTS

• Post Approval Changes training materials revision & re-training module creation
  ▪ Workshop addressing changes to PACs and new module on regional PACs requirements

• Registration dossier development - Clinical and Preclinical Trial Data Moodle training
  ▪ A course proposed to inform and train the DCVMN members regarding presentation of Preclinical and Clinical Study Data in the registration dossier.

• Training on CRP to DCVMN manufacturers
  ▪ Identify the various manufacturing related challenges and its way forward.
Regulatory Affairs WG Key Learnings

• Internal RAWG collaboration has helped to share experience to focus on key topics and to highlight the areas of change.

• Cooperation between various DCVMN working groups has highlighted topics that require regulatory input.

• External regulatory organizations/authorities value DCVM and DCVMN input to advocate and support adoption of new regulatory frameworks.
Thank You