DCVMN Regulatory Affairs WG 2022
Key Learnings & Activities

DCVMN
Developing Countries Vaccine Manufacturers Network

Parag NAGARKAR, Serum Institute of India
Chair of the DCVMN Regulatory Affairs WG

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

DCVMN

Developing Countries Vaccine Manufacturers Network