OPPORTUNITIES OF INTERNATIONAL REGULATORY COOPERATION

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Overview

1. ANVISA
2. REGULATORY DEVELOPMENT
3. ANVISA’S PERSPECTIVES ON ONGOING COLLABORATIVE INITIATIVES
4. ANVISA’S ROLE IN REGULATORY COOPERATION
ANVISA

- Founded in 1999 (Law 9782/1999)
REGULATORY DEVELOPMENT

• International references
  • (WHO, ICH, PAHO, Mercosur...)

• Regulatory agencies
  • (EMA, FDA, Health Canada, TGA)

• Dialogue with civil society
  • (Academia, Citizens, Manufactures and Other Government Stakeholders)

REGULATORY DEVELOPMENT

• National characteristics and needs

• Brazil’s legal framework
  • Mandatory x Recommendation

• Convergence x Harmonization
  • Recently approved – Marketing authorization and post approval changes;
  • Under revision – Stability and Validation;
ANVISA’S PERSPECTIVES ON ONGOING COLLABORATIVE INITIATIVES

• Chance do enhance ANVISA’s capabilities;

• Comparison of regulatory systems;
  • Development of competencies;

• Equivalence on regulatory practices;
  • Workshare;

ANVISA’S PERSPECTIVES ON ONGOING COLLABORATIVE INITIATIVES

• Think in a national and global way.
  • Better use of limited resources;
  • Reduce barriers to innovation;
  • Promote access to new markets;
ANVISA’S ROLE IN REGULATORY COOPERATION

• Building confidence
  • Understanding the assessment of each partner;
  • Exchange knowledge and information;

• IGDRP
  • Pilot;
  • API assessment.
ANVISA’S ROLE IN REGULATORY COOPERATION

• Regional Leadership
• Cooperation projects:
  • Argentina
  • Burkina Faso
  • Cape Verde
  • Colombia
  • Dominican Republic
  • Ecuador
  • El Salvador
  • Mozambique
  • Paraguay
  • Peru
  • Uruguay
  • Venezuela
  • Farmacovigilance
  • Farmacoeconomia
  • GMP Inspections
  • Intelectual Property
  • Marketing authorization
  • Pharmacopea
  • Toxicology

Thank You!

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