PERU 🇵🇪
Regulatory requirements
CMC & Clinical
Pharmaceutical & Biotech

Agenda

Day 1 : Regulatory landscape | CMC requirements

- Peru's regulatory framework, current technical regulations and their modifications. (DS 016-2011 SA)
- Data protection (DS N.° 002-2009-SA)
- Regulatory process: From submission to approval
- Drug clasification
- Dossier content
  - Legal documents
  - CMC
  - Clinical information
  - Labeling
  - Country specific requiermets
- Stability guideline R.M N° 111-2022/MINSA - DIGEMID
- GMP guideline for overseas companies
- Cases discussion
- **Q&A**

Day 2 : Regulatory pathways: Rare desease | Oncology | Bioequivalence

- Bioequivalence requirements (DS N° 024-2018-SA)
- Mandatory molecules
- Voluntary Bioequivalence submissions / Local forms
- Oncogoly & Rare desease registration pathway (Law N° 31738)
- Renewal process (Requirements / Timelines / Fee)
- Post approval changes
- Major variations
- Minor variations
- Minor variations with inmediate implementation
- Stock depletetion process.
- Approvals timeline & How to perform a regulatory intelligence in Perú
- Cases disicussion
- **Q&A**

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Day 3 : Biotech | Biosimilar | CMC | Clinical Information

- Biotech regulation (DS N° 011-2023-SA)
- Dossier content for Biological products
- Legal documents
- CMC
- Clinical information
- Labeling
- Country specific requiermets
- Biosimilar regulation
- Cases discussion
- **Q&A**

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