The place of CEPs in Anvisa, Brazil

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ANVISA

Overview

- ANVISA: mission and scope
- API regulation at ANVISA
- ANVISA and EDQM: history
- ANVISA: Actions for a common future
- ANVISA and EDQM: Expected Benefits from the use of CEPs in Brazil
- ANVISA and EDQM: Future of the cooperation in ANVISA
**Mission:** To protect and promote health of the population, ensuring the quality and safety of goods and services subject to health surveillance and taking part in developing access to them, in a coordinated and integrated action within the Nacional Health System (SUS)

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**API regulation at ANVISA**

- **Finished drug product**
  - Marketing authorization
    - RDC nº 60/2014
  - Post approval changes
    - RDC nº 73/2016

- **API**
  - API marketing authorization (specific lists of 30 APIs)
    - RDC nº 57/2009
ANVISA’s objectives for API
International cooperation

- Find Solutions to increasing workload,
- Optimal use of resources,
- Increase access to health with quality and contribute to the development and innovation of the pharmaceutical sector
- Pursue a mutually beneficial cooperative relationship with EDQM

ANVISA and EDQM: history

2003: Brazil officially recognizes the European Pharmacopeia as official standard
2012: 1st Memorandum of understanding
2017: 2nd Memorandum of understanding

GMP inspections Reports
Negative actions taken on CEP
Quality assessment reports
Exchange of review practices
Increase of confidence building activities
Information Technology

1st MOU

2nd MOU

Workshops
Exchange of visits
Laboratory activities
ANVISA: Actions for a mutual future

- ANVISA is learning and getting acquainted with CEP procedures
- An expansion in the exchange of quality assessment reports, to help the review of the backlog in ANVISA is in course.
- The ANVISA regulations are not yet harmonized with CEP procedures, but some "events" indicate that the harmonization is a question of time:
  - ANVISA is member of the International Generic Drug Regulators Programme - IGDRP
  - ANVISA joins the ICH initiative, as a member, in November 2016
  - The Brazilian API regulation are currently under review.

CEP benefits, views of ANVISA

- Further evidence of the reliability of an API manufacturer through EDQM inspections
- Contribute to a better understanding of the API review process internationally
- Improve review efficiency at ANVISA
- Contribute to a harmonized approach in API regulatory activities
ANVISA and EDQM: Future

- Increase the process of confidence building

- ANVISA will take actions to encourage the use of APIs that hold a CEP:
  Ex: Pilot project, currently in discussion, with the intention of acceptance of the CEP as part of the marketing authorization of low risk medicines.

- FINAL GOAL: The acceptance of the CEP (chemical entities) as part of the procedure in medicines marketing authorizations, added of additional regional data, like stability studies in zone IVB.

OBRIGADA!
Děkuji!!
THANK YOU!
MERCI BEAUCOUP!
MUCHAS GRACIAS!
GRAZIE MILLE!