



The place of CEPs in Anvisa, Brazil

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ANVISA

The place of the Certification Procedure in the global regulatory environment 19-20 September 2017 Prague, Czech Republic



Overview

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- ❖ 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





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)



Drugs



Post-market surveillance



Food



Cosmetics



Sanitizing Products



Tobacco



Toxicology (pesticides)



Health services



Publicity control



Ports, airports and frontiers



International



Market regulation



Medical Devices



Blood and blood products

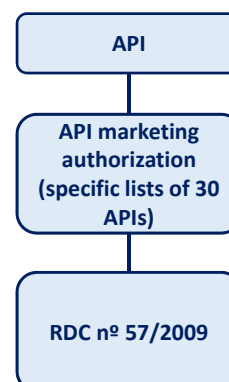
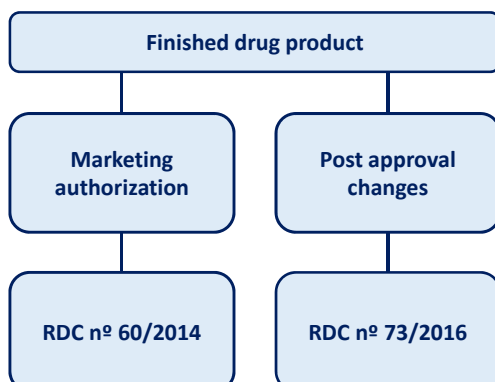


ANVISA

Agência Nacional de Vigilância Sanitária



API regulation at ANVISA



ANVISA

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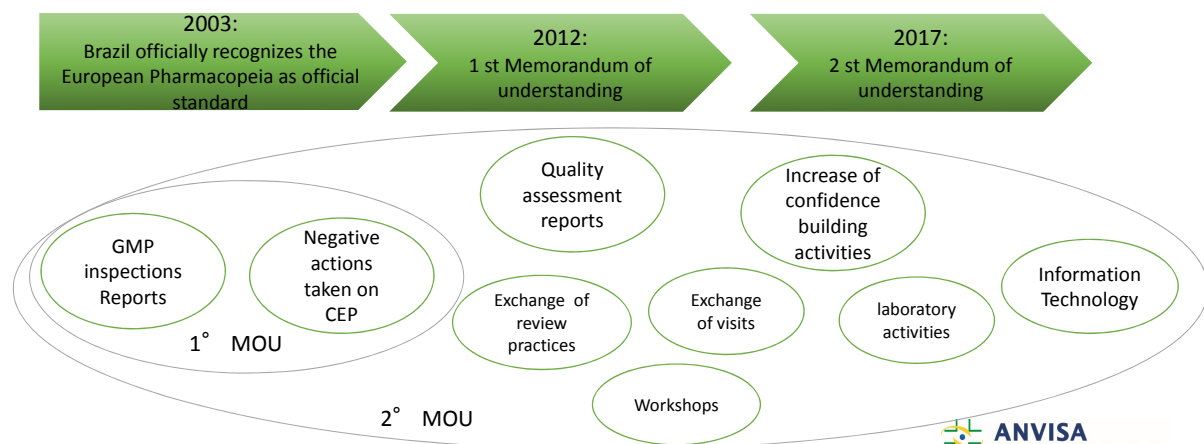


ANVISA's objectives for API International cooperation

- ❖ 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





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 taken 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.



Děkuji
Děkuji



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

Contato

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