



SINDUSFARMA

**III Seminar
Brazil-Japan
Pharmaceutical
Products and Medical
Devices Regulations**

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PHARMACOPOEIAL COOPERATION & OTHER SUBJECTS

BRAZILIAN PHARMACEUTICAL INDUSTRY PROPOSAL



AGENDA

REASONS FOR A PHARMACOPICIAL
COOPERATION

IN PROGRESS EXAMPLES

COOPERATION AGREEMENT - SINDUSFARMA

CONCLUSIONS

Reasons for a pharmacopoeial cooperation

- Worldwide & dynamic global operations: there is a strong necessity to harmonize requirements = requirements equalization (at a minimum).
- ≠ Specifications mean ≠ methods could mean ≠ products?
- The same product can be different in different countries.
- Resources savings: medicines should reach very quickly any region where it is necessary to be available.
- Counterfeiting: APIs and FPP.
- Quick identification of any quality deviation/problem.
- Costs could be reduced? Tests exceeding specifications?
- Governments need to reduce the prices paid by medicines for your Health System = policy of public health.

Examples in progress

- Brazil- Argentina strengthening agreement.
- ANVISA – USP cooperation agreement.
- Mercosul Pharmacopoea.
- Others.

These examples of cooperation are the starting of an integration and we need to support them, be on the side of the pharmaceutical industry or governments side or representative entities side.

Sindusfarma - Cooperation Agreement

- Sindusfarma has a Cooperation Agreement with US Pharmacopoeia, with some specific objectives:
 - Workshops organization
 - Meetings
 - Mutual support for the interest topics
- Common Benefits
 - To insert Brazilian professionals in contact with USP experts.
 - Interchange knowledge.
 - To know specific USP chapters.
- The same model could be applied between Sindusfarma and JP in order to establish a similar agreement.

CONCLUSIONS

Convergence is a word used instead of harmonisation.

Harmonisation is difficult: each case, one specificity.

BUT,

For a wide range of pharmaceutical products is possible the convergence or even a harmonisation.

Is possible to take advantages:

- Costs for public health could be less

- Counterfeiting & deviations

- Process simplification

Hard work, but efforts forward this action are possible.



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