



Latin American Association of
Regulatory Affairs Professionals

- SYMPOSIUM -
**REGULATORY
INTELLIGENCE**

LATAM

Medicines and Medical Devices Regulatory Environment:
Threats, Challenges and Opportunities

Coming soon

Mexico City

TOGETHER REDUCING THE KNOWLEDGE GAP

SYMPOSIUM ON REGULATORY INTELLIGENCE

LATAM MEDICINES AND MEDICAL DEVICES REGULATORY ENVIRONMENT: THREATS, CHALLENGES AND OPPORTUNITIES

Day one:

LATAM Regulatory Environment: what we know today about expected commitment to comply with international and regional standards

SCHEDULE	DISCUSSION TOPIC
09:00 - 10:00 h	Regulatory system capacity and strengths: Current situation and opportunities for regulation of medicines and medical devices.
10:00 - 11:00 h	International harmonisation, convergence and reliance: Current situation and opportunities regulation of medicines and medical devices.
11:00 - 12:00 h	Mexican regulatory system: previous alignment and expected commitment for medicines and medical devices.

LATAM Regulatory Environment: potential threat and unknown risks for the pharmaceutical industry and or applicants

12:00 - 13:00 h	Change in regulatory policy: Government proposal and known or expected timelines.
13:00 - 14:00 h	<ol style="list-style-type: none"> 1. Change in regulatory policy: Government actions 2. Change in regulatory policy: potential positive and negative impact for: pharmaceutical industry, applicants, public and patients.

LATAM Regulatory Environment: how to mitigate risks and build opportunities

14:00 - 15:00 h	Government and regulatory institutional changes: How this can impact the current medicines access and public and patients.
15:00 - 16:00 h	Government and regulatory institutional changes: How this can impact the pharmaceutical business model in Mexico.

LATAM Regulatory Environment: discussions with focus group

16:00 - 17:00 h	Point of view of: Industry decision makers, Regulatory professionals, Applicants, Health professionals and Public and patients.
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LATAM Regulatory Environment: conclusions and recommendations

17:00 - 18:00 h	How to overcome or and mitigate risks: Industry decision makers, Regulatory professionals, Health professionals and Public and patients.
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