Regulatory Convergence within the Global Educational Curriculum
A Novel Initiative

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Presentation Topics

- A global platform to introduce Latin America regulatory convergence initiatives, country/regional
- 2015 RAPS Regulatory Convergence Congress
- 2016 Latin America becoming globally engaged in the international regulatory space
  - Case study: competency building - developing a regional regulatory system - CARICOM.
  - Optimizing Regulatory Processes for low income
- Conclusion

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

A community of 25,000 professionals from 60 countries

Members work in:

- Industry
- Regulatory
- Government agencies
- Academic institutions
- Clinical organizations

Involved with:

- Drugs
- Biologics
- Medical devices
- Diagnostics
- Nutritionals
- Cosmetics
- Veterinary & other regulated healthcare products

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Cofepris Comisión Federal para la Protección contra Riesgos Sanitarios
Red PARF Red Panamericana para la Armonización de la Reglamentación Farmacéutica
Organización Panamericana de la Salud
Organización Mundial de la Salud Américas
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RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

Driving Regulatory Excellence™

Chapters and affiliates throughout North America, Europe, Asia and soon….in Latin America

Studies the changing role of the regulatory profession

Develops the standards for knowledge, competency and ethics

Leads as the profession's most trusted source for education and information

REGULATORY AFFAIRS CERTIFICATION RAC

The only accredited post-academic credential for regulatory professionals

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RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

- Since 2012 – RAPS active participation in the development of the Global Curriculum of Fundamental Regulator Competencies.

- Elaborated the framework for competency/ knowledge/skills building divided into a 4 level program

  I. Entry level
  II. Journey Level
  III. Management and Technical Expert
  IV. Executive Leadership

- Implementing Certificate programs, RAC Exams and FRAPS – honors for leadership in the regulatory profession

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Medical devices, IVDs, Biopharmaceuticals, Nutritional cosmetics, veterinary products

local, regional, global and harmonized perspectives

Global Competency Regulatory	Curriculum Framework		
IV. Executive Leadership	•Stakeholder outreach •Public/media relations •Health policy	•Talent management •Changing business and regulatory models	•Change management •Corporate organizational strategy and policy
III Management and Technical Expert	•Global regulatory strategy •Risk management/risk communication •Lifecycle management •Due diligence	•Regulatory policy and standards development •Harmonization and alignment	•Regulatory business integration •Management and finance •Supply chain management •Regulatory team management •Crisis management
II Journey Level	**RAC Exams** •Regulatory pathways and operations •Regulatory intelligence •Regulatory strategy (domestic, regional, global) •Pre clinical and clinical development (GLP's and GCP's) •Design, development and manufacturing	•Quality Systems •Pre approval interfacing •Registration content, development and management •Electronic submission and document management •Review process management and interactions (internally and externally) •Pre marketing compliance and maintenance	•Audits and inspections •Surveillance and vigilance •Supply chain management •Distribution •Marketing and Advertising •Labeling •Crisis management
I Entry Level	**Certificate Program** Product definition and lifecycle Regulatory pathway and operations Regulatory information management	Role of regulatory professional Pre clinical and clinical processes (GLP's and GCP's) Pre approval processes Quality systems overview Basic registration content	Document management Review processes and tracking Post marketing compliance and maintenance Basis of Marketing and advertising Labeling
Strategic Planning	**Preapproval**	**Approval**	**Postapproval**

Rising Leaders

Executive and Leadership Development

Information and Knowlege updates, Emerging Issues

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2015 RAPS Regulatory Convergence Congress Latin America Biopharmaceutical session tracks

2015 RAPS Regulatory Convergence

- Baltimore, Massachusetts, USA // October 24th - 28th, 2015

Main Congress Program

- 4 consecutive sessions
- 4 Latin American guest speakers per session (NRA, industry, non profit organizations)

2015 RAPS Regulatory Convergence Congress Latin America Biopharmaceutical session tracks

- **Session 1-2-3:Regulatory Harmonization in Latin America Political Regulatory Environment Convergence of Government and Industry. Regulatory Policy Implementation and Government in Latin America**

- **Key note speaker**: James Fitzgerald, PhD, MPSI, director of health systems and services, PAHO/WHO with panelists (health agency and industry) from Mexico, Argentina, Colombia and Brazil

- **Session 4 - Aligning the Biosimilar Latin America Regulatory Environment.**

- Expert speakers from Agency and industry shared knowledge on what companies are doing to define a truly global development strategy in the Latin American market.

2015 RAPS Regulatory Convergence Congress Key Note Speakers: PAHO, Argentina, Brazil, Mexico, Colombia, Puerto Rico

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2015 Regulatory Convergence
Outcome: 98% Successful Audience Rating !

2016 RAPS Regulatory Convergence Congress Latin America Biopharmaceutical session tracks

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- **Session 1 – Latin America Regulatory Convergence Perspectives & Challenges Moving forward**
  - **CARICOM and Caribbean Regulatory System - Case Study**. PANDRAH perspective: Charles Preston (PAHO)
  - **Optimizing Regulatory Processes for low income** (Speaker: Gates Foundation).
  - **Mexico – COFEPRIS** Using Regulation to better protect the population's health and transform the market in line with the International Harmonization Strategy.
- **Session 2. Pharmacovigilance – Best practices moving forward:** PV harmonization practices in Brazil in line with Global Regulations.
  - **Case Study: "Transformation and Regulatory Alignment of NRA in Central America- El Salvador".**
  - **Cuba: "New Horizons" – Regulatory Convergence, Research, Product Development and Market Access** - Cuban top regulatory authority discussed the country's regulatory environment and robust biotechnology industry

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2016 RAPS Regulatory Convergence Congress Latin America Biopharmaceutical session tracks

- **Session 3. Latin American Regulations and Market Access: Orphan Drugs, Rare Diseases and Low Incidence Cancer: Brazil, Cuba, El Salvador and the Latin American Region.**

- **Session 4. Zika: Challenges across the Americas to stop the spread to pandemic proportions and Multi-site Clinical Trials response**

2016 RAPS Regulatory Convergence Congress Puerto Rico Argentina, Cuba, El Salvador, Mexico, Brazil, PAHO, Gates Foundation

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2017 LATIN AMERICA – RAPS Chapter Driving Regulatory Excellence Together

- Regional LATAM RAPS chapter
- **Scope:** Deliver unparalleled education and networking opportunities with an emphasis on driving excellence for regulatory professionals, regulators and industry.
- Each chapter has the logistic and administrative support of the international RAPS headquarters in Washington, DC

Thank you! Muchas gracias!

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