

GMP, GCP & QUALITY CONTROL

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PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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Strengthening health regulation in the americas: The experience of N the national regulatory authorities of regional reference

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The regulation and quality assurance of health technologies is a crucial element in the development of national pharmaceutical policies and the national regulatory authorities are responsible for implementing these actions; of its development and level of maturity will depend on the quality, safety and effectiveness of the medical products that are made available to the populations. In the Americas region, since 2009, an evaluation and certification process has been developed that allows the designation of Regulatory Authorities of Regional Reference for medicines and biological products. To date, eight authorities have been certified and work together to achieve regulatory convergence through information exchange to streamline regulatory decision-making and regional cooperation to promote development of other authorities in the region, actions that have a direct impact on access to effective health technologies of guaranteed quality. The networking work has allowed the development of an important group of cooperation activities towards other NRAs in the region for the development and strengthening of their regulatory capacities, as well as a mutual recognition work that allows timely access to health technologies such as safety, quality and effectiveness guaranteed.

Biography

Lisette Perez Ojeda is a Professional in Pharmaceutical Sciences with 20 years of experience, 15 of them in the sector of Health Regulation of Medicines, focused mainly on the management of international cooperation from the National Regulatory Authorities, networking, project management, negotiation and implementation of agreements, the construction and monitoring of action plans, intellectual property and its linkage with access to medicines and other health technologies and the development and publication of scientific publications. She is also a Member of the Secretariat of the Regional Reference Regulatory Authorities.

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