

PDA Italy Chapter Meets Italian Medicines Agency

PDA headquarters is not the only part of the Association driving the connection with regulators. On May 8, 2012, the PDA Italy Chapter had the pleasant opportunity to present its activities to the new General Director of the Agenzia Italiana del Farmaco (AIFA, the Italian Medicines Agency). Professor **Luca Pani** met with Chapter leaders at the AIFA headquarters in Rome.

Italy Chapter President **Dr. Walter De Matteo**, Past President **Dr. Stefano Macciò**, CTP, and Chapter Steering Committee member and PDA Director **Dr. Gabriele Gori** met with Dr. Pani and other employees and inspectors of different AIFA offices.

The meeting began at about 14.30 with an introduction by Dr. Macciò and a discussion of PDA and the Italy Chapter by Dr. De Matteo. The latter presentation covered the Vision and Mission of PDA and highlighted various technical publications issued by PDA.

The PDA Italy Chapter, founded in 2000, aims to apply the goals and mission of PDA, though tailored to meet the specific needs of members in Italy,

without losing sight of the international standards. The objective of the Italian Chapter is to establish an avenue of dialogue between AIFA and industry, in order to facilitate understanding of the applicability of the regulations.

Dr. Gori said this initiative will allow both industry and the Agency to access and share a heritage of great scientific and technical knowledge—the result of activities and collaboration between PDA and many scientific and regulatory institutions around the world. Together, the PDA Italy Chapter and AIFA can adapt and develop this information according to specific needs of the Italian market and open a way to further the contribution of Italian experts to the advancement of pharmaceutical science.

Dr. Pani showed much interest in the training/information activities carried out by the PDA Italy Chapter. He recommended that these initiatives be implemented in Rome, thereby minimizing the costs of travel of inspectors. He then outlined the new rules and limitations for requesting participation of inspectors from the Italian health agency

to events organized by professional associations. For these purposes, the PDA Italy Chapter proposed to AIFA the active participation of AIFA representatives in planning conferences and workshops, in PDA task forces and other activities.

Dr. Pani confirmed the interest in a partnership between PDA and AIFA, provided the following criteria are met:

- PDA will ask the Agency's formal consent whenever the Italian Agency is referenced in PDA Chapter material
- The Agency shall have the right to veto any document or PDA Italy Chapter activities involving the Agency which is not considered appropriate by the Agency itself.
- AIFA personnel who will collaborate from time to time with the Association will be chosen by the Agency.

The PDA Italy Chapter offered three free annual PDA memberships for AIFA personnel, to be selected by Prof. Pani and communicated by AIFA: This will allow them to receive free Technical Reports and Association documents.

The meeting ended with mutual satisfaction of both parties.

PDA Who's Who

Luca Pani, General Director, AIFA

Walter De Matteo, IBSA

Stefano Macciò, CTP

Gabriele Gori, Novartis Vaccines & Diagnostics 

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