Press Release

PQE Group and the Russian State Institute for Drugs and Good Practices (SID&GP), together for Data Integrity Guidance

Reggello, 5th September 2018 - PQE Group is proud to announce that the draft of the new **Russian Guide for Industrial Data Integrity** has been published on the website of GILS - Russian State Institute of Drugs and Good Practices .

After the collaboration with **COFEPRIS**, the Mexican Regulatory Authority, for the creation of the data integrity chapter of the NOM 059 (the GMP Rule in Mexico) PQE Group is now supporting GILS and THE MINISTRY OF INDUSTRY AND TRADE OF THE RUSSIAN FEDERATION in setting all the GMP Data Integrity Requirements.

PQE Group **CEO Gilda D'Incerti** presented the past week the new Data Integrity Guidelines at the **3rd Annual GMP Conference in Kazan**, the event organized by the Ministry of Industry and Trade of the Russian Federation and Federal State Institution «State Institute of Drugs and Good Practices».
Together with the **Operations Director & Partner Roberto Bertini** they explained to all local industry and all interested stakeholders the new rules edited for **GILS in collaboration with SID&GP and the Ministry of Industry and Trade of the Russian Federation.**

Certified Tick-IT and PDA Auditor, Gilda D'Incerti is nowadays a worldwide recognized Expert on Data Integrity providing war room support and strategic consultancy for clients in order to comply with the FDA and other regulatory bodies during critical inspections.

TOPIC:
The globalization of the supply chain of pharmaceutical products leads to a steady increase in the complexity of the process, when a product can pass through several intermediaries before it can reach a patient. Such an environment implies the probability of penetration into the supply chain of counterfeit, falsified, substandard or improperly manufactured medicines, as forgers constantly improve the process of manufacturing counterfeit products that look identical to the original; most counterfeit drugs have little or no therapeutic value, and can cause serious health problems, since active substances in counterfeits are often absent, their dosage is reduced, their content is distorted or extended beyond the expiry date.

To minimize the risks associated with such problems, many state regulatory and control bodies have established specific rules aimed at ensuring the authenticity of pharmaceutical products and, in most cases, tracking drug products throughout the chain of sales. In general, these rules provide for the duty of the

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owner of the registration certificate to introduce a set of computer systems for the registration, authentication, preservation and exchange of reliable reporting on commercial products before it is released to the market.

“The landscape in the sphere of regulation is changing – **Francesco Amorosi, Business Development VP, tells** - and all companies involved in the production of drugs and medical products must adapt to these changes.
For PQE, as a provider of global solutions, is possible to support these companies in their efforts to participate in this internationalization process. I believe that this trend will be positive for us. For the same reason, we have opened many branches around the world, including in Russia, this year.”

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