Press release

# PQE as main coordinator of pharma industry coalition for a position paper on Audit Trails Review

*Berlin, 27th June 2018* - It will be Christian Scheidl of Novartis who will present at the 3rd PDA Europe Annual Meeting the new position paper signed by PQE and other five pharma industries as Arevipharma, Boehringer Ingelheim, Novartis, Rentschler and Sanofi.

Regulated Companies are expected to comply with regulatory requirements applicable to the GxP relevant Computerized Systems and to the data they generate. Main purpose of these requirements is having confidence in the quality and the integrity of the data generated and being able to reconstruct activities.

Among these requirements, the ones related to the Audit Trail and its review represent a particularly difficult challenge due to the high severity of possible failures to comply with them and due to a number of technical and practical problems the regulated companies have to deal with to be compliant.

For a large number of software applications, an effective compliance to the regulatory requirements for Audit Trail and its review is currently jeopardized by the poor maturity of Audit Trail functionality. Most recurrent problems range from user-unfriendliness, time-consuming interrogation and limited possibility to query and filter the Audit Trail data, to incompleteness of information recorded and lack of adequate protection of the Audi Trail contents.

This Position Paper should be considered as a means of understanding the requirements of the Author on Audit Trail for GxP relevant Computerized Systems and its review.
The requirements defined in this document should be used as an input for the suppliers of software applications delivered to the Life-Science industry, in order to develop software solutions provided with fully compliant and automated Audit Trails and with suitable tools for a timely and effective review of the Audit Trail.

The implementation of the requirements defined in this document is expected to facilitate the retrieval of a full Audit Trail information and allow a more efficient and effective review of it. It should ultimately result in a general improvement of the current level of compliance of the Regulated Companies to the provisions



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and regulatory expectations set forth by the Agencies in regard to computer-generated Audit Trails and Audit Trail review.

This Position Paper was produced by a task team led by Christian Scheidl (Novartis) within the Industry Coalition; PQE has been represented by Roberto Bertini, Operations Director and by Ulrike Malordy, Managing Director PQE Germany, as the only service provider partner of the coalition.

“We accepted the team's ideas - Bertini says - and then we wrote the document on the basis of some best practices we had already consolidated, sharing it with the other partners. Our Position Paper is a call to action, an input that we would like to be collected by several software companies in order to solve the gap with the law requirements. In any case – Bertini continues – this is a great opportunity for PQE to be part of an important coalition, being, among pharma companies, the only consultant firm: a goal that demonstrates surely our growth in the pharma market and not only.”

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