QAtor Enters into Agreement to Provide Change and Deviation Management Solution to ALK-Belló

September 13, 2010, Copenhagen- Denmark | ALK-Abelló A/S, the world's leading company within specific allergy treatment, has after an extensive evaluation of Quality, Risk and Compliance solutions followed by an on-site pilot April thru July 2010 selected QAtor's solution for electronically handling changes and deviations, QAchange™. The final contract was signed August 25. The integrated and flexible solution is to be used by their quality assurance and production units and will be implemented in 2H 2010 at the ALK global headquarters in Hoersholm, Denmark, followed by and enterprise-rollout to regional offices worldwide. The solution includes:

- CAPA (*Corrective Action and Preventive Action*)
- Complaints and Feedback
- Role-Based Work Flow Management
- Document Control, including Deadline Management and Escalation procedures
- Control of Non-Conformances
- Management of Electronic Reviews and Approval Process
- Flexible reporting and searching, including review reporting for management

One of the major triggers for ALK has been, that QAchange™ covers most throughout functional and operational areas of GxP and validation, as well as providing management with the visibility, control and business intelligence required to continuously optimize performance. Furthermore, the solution is delivered FDA-GMP pre-validated leading to fast implementation ready-to-use, strong arguments which were convincingly documented during the initial pilot.

As part of the agreement, other QAtor compliance solutions sharing the same database as QAchange™ have been pre-negotiated and are expected to complement the instantly implemented change and deviation management solution. This in order to optimize the use of electronic data and knowledge management throughout the organization and thus ensuring the continuing transformation from paper-based processes to digital and automated respectively in a multi-site cooperation.

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ABOUT QATOR AND QACHANGE™

QAchange™ (use link for detailed product fact sheet) automates the change control and deviation process via an intelligent Web-based interface. It supplies fully automated handling of the workflow for any given deviation or change control case, and through customizable templates that relates roles to specific tasks. Any template workflow defined by customer SOPs can be implemented in the systems templates, all made easy accessible where needed via the Web-interface.

QAtor is acknowledged as a technology-leader in Quality, Risk and Compliance solutions for the Life Science industry. This heavily regulated industry benefits from a fully Web-based, validated compliance management framework managing quality processes, regulatory and industry-mandated compliance and corporate governance initiatives. Solutions include standard templates and protocols, electronic signature functionality, configuration management, change control processes, and security features in order to reduce Total Cost of Quality. QAtor is headquartered in Copenhagen, Denmark, and can be reached at www.QAtor.com (use link to seamless access to company web site).

MEDIA

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