Quality Systems Check-Up

Effective and efficient Quality Systems and Quality Controls are critical organizational components at any Life Sciences Company. They are especially important when planning to enter the developmental stage. However, Start Up companies often underestimate Quality Systems' functions and features, and consequently may lose time advancing innovative products towards the market.

Companies further developed (i.e., products already on the market) are sometimes prone to delays gaining regulatory approval of existing or novel products in different geographical and global markets when their quality systems have gaps or lack features.

New Guide offers an introductory overview of potential quality control risks. After becoming familiar with your company's general Quality System status (and production plans), an expert quality systems advisor will indicate Quality Management areas where you should pay particular attention to. This 'snap shot' of existing Quality System and Quality Control processes identifies any current risk areas, which may include addressing such questions as:

- Is the current Quality Management System adequate for its purpose?
- Does the Quality Management System address relevant ISO, national and technical standards?
- Are established Quality Control Processes functional?
- Does the Management System has an effective Regulatory Approval Process?
- Are national and international regulatory requirements correctly followed?
- Are sufficient resources (e.g. infrastructure, instruments, production facilities, personnel) provided and organized to ensure product safety & performance?
- Do personnel receive adequate training to conduct their tasks?
- Does the Quality Management System possess a CAPA system (Corrective Action & Preventive Action)? Is this CAPA system adequate for its tasks?

If your company has these or related questions in mind with regards to manufacturing first-time products, or already has an established quality system but would like to explore whether there may be room for improvements, a New Guide Quality Systems Check-Up can help.

Check-Up Process

The check-up process involves a couple steps to conduct an efficient, individualized review:

- A basic, preliminary questionnaire, customized for Pharma, Med Tech, or In-Vitro Diagnostic companies, is sent to management before a one-day visit.
- A one-day visit.

Deliverables
Management receives a short report reviewing the company's current situation, including a future risk assessment (contingent on receiving sufficient information about development plans). All information is held strictly confidential.

If there are risks requiring action beyond enacting standard control measures, New Guide would either recommend individuals or firms to resolve the issues, or the type of experts necessary.

Fees
A flat affordable fee covers the Quality Systems Check-up, one-day visit, and report. Travel and hotel expenses are extra. The fee and expenses would be discussed and mutually agreed by the advisor and management.