Windshire Group, LLC

February 20th, 2023

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The Client – Global Cosmetic Company

Analytical Laboratory and Microbiological Testing

Becoming FDA registered and achieving ISO 22716:2007 certification

The Challenge: Repeat audit approximately one year after the cosmetic company gave the Analytical Laboratory a failing score. The laboratory did not effectively implement the changes that were reported in the 2021 audit non-conformances and during the repeat audit in 2022, repeat findings were identified as well as new issues.

The audit agenda for the repeat audit specified that the first task would be to review the corrective action taken for the nonconformance reports (NCRs). The audit agenda specified that the first task would be to review the corrective action taken for the nonconformance reports (NCRs) from the previous audit. The process to examine the actions was tedious and unorganized. Although willing to provide the information, the site participants did not appear prepared to systematically review the corrective actions. At the time of the June 2021 audit report, the site did not log a deviation or corrective and preventive action (CAPA) for each NCR and did not consolidate their actions into a reviewable record. Therefore, each subitem for each observation had to be discussed and then the objective evidence that supported their proposed CAPAs had to be verified from their procedures and records.

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Additionally, the official controlled documents are hard copy and were not in the audit room at the beginning of the audit and many of the relevant records were only in databases (unqualified). There was no one assisting the Senior Quality Manager in retrieving documents and records, so he had a dual role of answering questions and leaving the room to retrieve records.

The report documents observed NCRs in the areas of Facilities and Equipment, CAPA, Good Documentation Practices, and Documentation Control. In some cases, it may appear that the new NCRs are repeat issues, but where they are not listed as repeat observations, it appears that the corrective actions either revealed or generated new issues of compliance in those areas.

The audit was conducted in accordance with the Cosmetic Company's requirements and the relevant industry standards. The audit team recommended using the following methodology going forward to avoid future problems:

1. Review of the laboratory's policies and procedures, including the laboratory's Quality Manual and any other relevant documents on a regular basis;
2. Review of the laboratory's data and records, including any reports and results, laboratory logs, and calibration records on a regular basis, keeping up with industry standards;
3. Interview of personnel to assess their qualifications, updated training, and gaps in experience;
4. Monthly / quarterly at a minimum, internal observation / audit of the laboratories, including assessment of the laboratories current environment, equipment, and processes;
5. Evaluation of the laboratory's corrective action system;
6. Identification of any non-conformities and recommendations for corrective action; and
7. Submission of the audit report to the Cosmetic Company.

Outcome: The Cosmetic Company realized after the repeat audit that their quality system needed more management support and outside experts to advise them on how to most efficiently implement and operate their quality system.

Windshire Consulting Overview

We are a laboratory, CMC strategy, management, and tactical execution consulting firm exclusively serving the regulated life sciences industry. With offices in Boston, MA (US); Melbourne, Australia (APAC); and the UK (EU), our term Boston based with a global reach is true. Our clients include pre-clinical, emerging, established and mature global companies. Windshire and Labshire helps companies achieve important business objectives by bridging the gap between sound strategy and reliable execution. This enables the transition from scientific and technical excellence to business and commercial success. Our highly experienced consultants create strategic opportunities and execute to deliver results. They are all former executives, managers, and scientific, process development, manufacturing, supply chain, operational, quality, and regulatory practitioners from leading companies, with deep expertise in all areas, all therapeutics classes, and all stages of the product lifecycle.