Regulatory Affairs by ELC

Steps involved in managing regulatory queries for nitrosamine impurities

Step 1: Risk evaluation report

- Deadline for the notification: 26 March 2020
- The MAH should inform the agency when the risk evaluation is concluded.
- Risk evaluation documents do not need to be submitted but should be made available upon request.
- If a risk of presence of nitrosamines is identified as a result of the evaluation, the MAH should proceed to Step 2 i.e. confirmatory testing.

Step 2: Confirmatory testing

- The MAH should inform the competent authorities as soon as possible if tests confirm the presence of nitrosamine, irrespective of the amount detected.
- The immediate risk to patients should be assessed and appropriate action taken to avoid or minimise the exposure of patients to those impurities.

Step 3: Variation

- Deadline: within 3 years
- In case nitrosamines are identified in the product, a variation will be required.
- For ongoing procedure, risk assessment can be performed and notified during the process.
- If there are any possibilities of risk of nitrosamine impurities in the proposed product for ongoing registrations, same should be discussed with the agency with appropriate timelines for Step 2 and Step 3 as applicable.

ELC Group is a fully-fledged global regulatory partner, working with pharmaceutical stakeholders for over a decade. From the development stage through to the implementation of clinical trials, completion of product registration, and successful marketing of the product, ELC Group aligns itself as a strategic partner to help pharmaceutical companies achieve their goals.

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