ENVIRONMENTAL CONSULTING CASE STUDY

COMAH Support at Irish Pharmaceutical Facility

CHALLENGE

A pharmaceutical manufacturing facility planned to expand its existing laboratory site and needed to determine whether this would constitute a 'significant modification' under COMAH.

SOLUTION

AWN was engaged to conduct a Significant Modifications Assessment following the Health and Safety Authority's (HSA) guidance.

RESULT

The assessment concluded that the laboratory expansion did not introduce any major accident scenarios or increase risks and so was not classified as significant under COMAH.

INTRODUCTION

AWN Consulting Ltd, a Trinity Consultants team, specialises in providing expert services in Significant Modifications Assessment and risk modelling for facilities subject to major accident hazard regulations. Their approach helps operators of COMAH sites systematically evaluate proposed changes to installations or processes, ensuring compliance with regulatory requirements while managing safety risks effectively. By applying robust methodologies aligned with Health and Safety Authority (HSA) guidance, AWN supports clients in identifying whether modifications could significantly impact on-site or off-site risk, enabling informed decision-making and appropriate risk management. For this project our client needed to confirm that their expansion plans were compliant with HSA guidance.

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CHALLENGE

A pharmaceutical manufacturing facility in Ireland, classified as a Lower Tier COMAH site, planned to expand its existing laboratory space. The challenge was to determine whether this modification would constitute a 'significant modification' under the Chemicals Act 2015 (COMAH Regulations 2015), potentially increasing the risk of major accidents involving hazardous substances. Given the regulatory requirements, the facility needed to assess if the expansion could lead to greater risks to personnel or the environment, which might necessitate referrals to authorities and additional safety measures.

SOLUTION

AWN was engaged to conduct a Significant Modifications Assessment following the Health and Safety Authority's (HSA) guidance. The methodology involved a two-stage process: an initial preliminary analysis followed by a detailed analysis if required. The preliminary analysis evaluated potential increases in risk or consequence from fire, explosion, or toxic release scenarios by assessing hazard endpoints such as thermal radiation, overpressure, and toxic fatality thresholds. This approach allowed for a focused review of whether the proposed laboratory expansion, which involved only small quantities of hazardous chemicals and no increase in staff numbers, posed any significant new risks.

RESULT

The assessment concluded that the laboratory expansion did not introduce any major accident scenarios or increase risks to personnel or the environment. Since there was no rise in workforce numbers and only minor quantities of hazardous substances were involved, the modification was not classified as significant under the COMAH Regulations. As a result, no further detailed risk assessments or additional technical safety measures were necessary. The facility complied with regulatory obligations by maintaining documentation on-site for inspection, ensuring continued safe operation while enabling the planned expansion.

ABOUT TRINITY CONSULTANTS

Trinity Consultants, a leading global environmental consulting firm, provides services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Founded in 1974, Trinity has the technical expertise, industry depth, and capabilities to help clients achieve their goals across the natural and built environments.

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