

Compliance audit for pharmaceutical development company

Challenge

Company F is a small drug discovery company, developing and testing new candidate medicines. It also toll manufactures active pharmaceutical ingredients (APIs) for other companies to use in investigational and licensed medicinal products.

The company contacted REACHReady after a university taking small research samples for laboratory testing asked for safety data sheets (SDS) for the candidate APIs. They previously considered such materials exempt from REACH and CLP and queried the request with us.

Solution

REACHReady visited the company as part of our Consultancy service. Our expert started the day with a short presentation on REACH and CLP. The presentation explained the relevant scope, including the exemption from REACH registration for APIs, and the exemption from safety data sheet obligations only once a medicinal product is in the finished state, as intended by the final user. The consequent REACH and CLP duties on the company were discussed.

During the visit, our expert carried out a compliance audit involving a site inspection and interviews with the R&D, Production and Regulatory Affairs teams. Key findings included confirmation that:

- REACH registration would not be necessary, as Company F's substances were either exempt APIs or were manufactured below 1 tonne per year;
- CLP notification and correct labelling would be required for research samples and intermediates sent off-site for laboratory analysis;
- SDS must be provided for hazardous chemicals supplied to third parties;
- Technical grade and candidate APIs which are not in the finished state for the patient must be labelled correctly;
- Chemicals imported from non-EEA suppliers need CLP notification, re-labelling and SDS.

Results

Having identified a number of key compliance issues, REACHReady helped the company define an action plan to achieve compliance. Following the visit, our expert submitted a concise audit report to senior managers which highlighted the company's outstanding obligations.

Further information

REACHReady's Consultancy service offers the opportunity to discuss your company's business confidentially and in-depth. Our technical experts can audit your REACH and CLP activities and help you identify an action plan to achieve and maintain compliance. Following an initial free telephone consultation, the pricing for consultancy is based on a standard day-rate of £1,300 plus VAT and any associated expenses. We aim to provide a value-for-money service of the highest quality and the flexibility to fit your budget.

For more information please call +44 (0) 20 7901 1444 or email enquiries@reachready.co.uk