

SIEF & Consortia Management



The formation of SIEFs and, in some cases, consortia has been driven by the need to share data for the purpose of REACH registration. Taking this process through to a successful conclusion clearly relies on technical and regulatory knowledge but it also calls for specific organizational, legal and financial expertise.

The REACH Centre offers a fully flexible SIEF/consortium management package incorporating all the key elements required to support organizations undertaking the registration process. The package can be adopted in its entirety or viewed as a catalogue of services that can be selected individually or in combination as needs dictate. The service is underpinned by the technical, regulatory, managerial and legal expertise of the company's consultants and affiliates.

The REACH Centre recognizes the fact that the registration process involves several distinct areas of activity. Its SIEF/consortium management framework has therefore been structured to provide support accordingly.

- **High level administrative support:** SIEF/ consortium management, consortium agreements, establishing formal consortium structure, coordinating financial activities, SIEF Facilitation, Third Party and Lead Registrant roles, establishing substance identity and sameness, coordinating data compensation process and arranging annual audits
- **Data gathering and review:** Gathering, validating and valuing existing data, gap analysis, searching and retrieving data from alternative sources, QSARs and read-across
- **Acquisition of missing data:** Devising test strategies, costs and schedules, preparing proposals for new testing, test coordination, validation of new data, study summaries and robust study summaries
- **Generation of the registration dossier and associated documents:** Downstream user information, Exposure Scenarios, identification of Risk Management Measures, Classification and Labelling, Hazard Assessments (including PBT and vPvB), derivation of DNELs and PNECs, performance of CSAs and assembly of CSRs, preparation of SDS, dossier preparation and submission
- **Post-registration monitoring:** Management of regulatory status, late registrants, dossier updates

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