

Case Study – Regulatory Compliance Project

Major regulatory compliance project

- CLIENT** A major pharmaceutical company based in Europe.
- PROJECT** A large compliance project.
- OBJECTIVE** Review all European-registered licenses and bring into compliance with current manufacturing site practices.
- SOLUTION** Pharmalink provided a dedicated team of regulatory affairs specialists to work on the project for 3 years.

One of the key advantages that Pharmalink was able to bring to the project was the ability to adjust the number of consultants working on the project to fit the client's needs and hit every deadline whilst always maintaining the level of quality.



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Project Details

- Consultants reviewed registered details against manufacturing site documents, highlighting compliance issues.
- Consultants worked with site QA departments in preparing remediation plans for each license.
- Over 600 licenses were reviewed and each phase of the project was delivered to the client's timelines.
- Pharmalink's staff exceeded the client's expectations on each phase of the defined project, resulting in the client engaging Pharmalink to prepare all of the Variations and submit to all EU agencies in order to bring the product licenses into compliance.

