



CASE STUDY: Quality Management System

| | | | |
|--|-----------------------------------|--|----------|
|  CLIENT SIZE | Large Canadian Pharma Company |  GEOGRAPHY | Global |
|  THERAPEUTIC AREA | Pharmaceutical and Medical Device |  TIME-LINE | 6 months |

CLIENT NEED

- ▶ Client's business model includes both virtual and traditional elements. Company procures products over 500SKUs, from a number of suppliers
- ▶ Client holds title of product for a period of time, a WDA was required to operate in compliance with legislation
- ▶ A consultancy company had been working on the project but due to the complexity of the supply chain and inexperience in GDP, the consultancy company was unable to deliver
- ▶ PharmaLex Ireland was requested to develop the Quality Management System for the client's supply chain and distribution office
- ▶ PharmaLex Ireland was requested to deliver within a very tight timeline

OUR SOLUTION

- ▶ The team developed a tailored plan outlining the scope of the project to meet the client's requirements
- ▶ A number of multidisciplinary face-to-face workshops took place to allow the development of a QMS to accurately reflect the client's activities
- ▶ Many challenges were encountered throughout the project due to the fact that there were numerous territories involved with a very complex supply chain

PHARMALEX VALUE TO CLIENT

- ▶ The client successfully obtained a WDA from the HRPD within the required time-lines with no observations relating to the QMS
- ▶ Highly-experienced team was able to deliver high quality in short amount of time
- ▶ No need to increase the client's internal resources during peak times of workload

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

MARKETING AUTHORIZATION
/ APPROVAL

PRODUCT
MAINTENANCE