

that the import of thionyl chloride was in accordance with government regulations. The inspectors and the staff then discussed the problems involved in the production of a Schedule 1 compound at the site.

#### Assessment of the inspection

- The success of the inspection was to a large extent due to the excellent cooperation of the staff of the company, both at head office and at the site. This is an internationally oriented pharmaceutical company used to inspections from national and international bodies. The facility had previously been inspected by the American Food and Drug Administration and by several Norwegian authorities concerned with environmental, fire and explosives controls, and being a pharmaceutical company of high integrity it is used to keeping detailed information both on the production process and products.

- A preliminary visit was not considered essential as long as we had experience of a similar pilot plant. The opening conference was regarded as necessary in order to discuss the limitations of the inspection, to work out a system of protection of confidential information, and to allow the facility to approve of the equipment belonging to the inspection team, with regard to the safety regulations at the plant.

- An inspection requires detailed information about the chemical process to be inspected. However, a complete analysis of all the products and reactants is not always necessary. The most important objective is to account for the mass flow of the restricted chemical compounds. The use of toxicity testing, as described in CD/961, may reveal presence of supertoxic and harmful compounds and such testing has the advantage that knowledge of the