## Natural Fish Oils Now available as API

(Active Pharmaceutical Ingredient)



**SINCE 1938** 

For a number of years there has been an increasing demand for pharmaceutical grade fish oils and today some markets require fish oils to be registered as pharmaceuticals.

In order to meet customers' needs LYSI adapted its processes to the requirements of standards on good manufacturing practice (GMP) for active pharmaceutical ingredients (API). This work concluded with GMP certification in 2007.

In September 2014, after passing an audit conducted by the Icelandic Medicines Agency, LYSI was registered in the European Inspections database as an approved API manufacturer. In May 2015, LYSI was approved by the British Medicines & Healthcare products Regulatory Agency (MHRA) as the manufacturer of APIs used in the production of two licenced medicinal products.

LYSI can now offer its customers several fish oil products as active pharmaceutical ingredients. With the expertise and experience gained from registration of API products, LYSI also offers its customers assistance in registering their own products.

Offering natural fish oils as active pharmaceutical ingredients has placed LYSI in a unique position in its market.



API grade oils at LYSI are based on corresponding monographs in the European Pharmacopoeia. As part of purchasing API grade fish oil from LYSI our customers will receive an Active Substance Master File required for registering medicinal products within the EU. Included are appropriate validations and stability data in accordance with ICH guidelines.

## Food grades

- Cod liver oil
- Omega-3 fish oil
- Cod oil
- o Tuna oil
- Shark liver oil
- O Salmon oil
- Omega-3 EE concentrates

## **API** grades

- Cod liver oil
- Omega-3 fish oil