

Rogue Particle Identification



Business Overview

Novartis was created in 1996 through the merger of Ciba-Geigy and Sandoz. Novartis is a world leader in the research and development of products to protect and improve health and well-being. The company has core businesses in pharmaceuticals, vaccines, consumer health, generics, eye care and animal health. Novartis' cCork plant is predominantly a manufacturing plant specializing in the manufacture of and employees 450 people.

Challenges

Despite the best efforts of manufacturers to produce to the highest standards, there are a number of ways in which pharmaceuticals and food products may become contaminated by foreign bodies. Such contamination may at best be unwelcome, or at worst potentially life threatening for users of pharmaceutical products such as injectables. From a production point of view, the discovery of a contaminant may render the entire batch unusable, resulting in wasted production time, production costs and raw materials.

At Novartis an unknown material found in the Solvent Recovery Plant. The material was thought to be a by-product of caustic neutralisation. As a result the solvent recovery plant was closed until the unknown chemical was identified and source of contamination was found. Consequently production of API was stalled.

Timeline

Within 2 hours of receiving a phone call from the process engineer in charge of the solvent recovery plant, one of our fully trained engineers was on-site to collect the sample of the unknown material.

An assessment of the site was also made in attempt to learn as much about the process and possible sources of the contamination.

A full report was issued to Novartis within 24 hours of receiving initial phone call. The data was also presented to Novartis staff at a weekly progress report meetings.

Benefits

- Rapid Turn around time
- Reduced Down time
- Improved Process Design
- Local Knowledge
- 40 years experience
- Immediate response
- Quality guaranteed

"We got a very professional response and with the company being so close to the site the turn around time was excellent

-Niall Noonan Engineering Manager Novartis

Glantreo Solution

Deep scientific knowledge and experience combined with state of the art chemical analysis equipment allow Glantreo identify foreign body material quickly and accurately.

In this particular case by combining

- A deep materials science knowledge and 40 years experience of our scientists
- The ability of SEM/EDX (scanning electron microscopy/energy dispersive x-ray) to identify all known chemical elements in a single scan
- The ability of the XRD (x-ray diffraction) to identify the exact chemical phase of the unknown material. As a result, the source of the contaminant was also identified.

Novartis Corporate Profile

Headquarters:

Basel, Switzerland

Revenues:

\$9.9 billion (2007)

Employees:

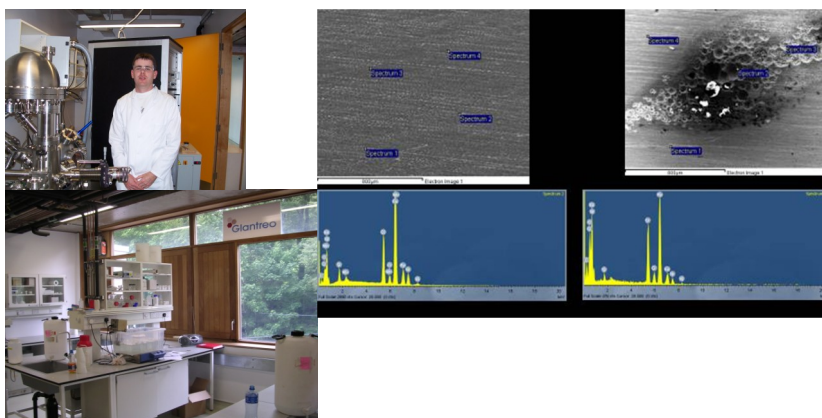
98,000

Industry:

Biopharmaceuticals / Pharmaceuticals/
Animal Medicines

Products:

Diovan, Glivec, Zometa, Femara



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About Glantreo

Glantreo's vision is the exploitation of its Material Science capabilities and knowledge in three distinct business units. The business units comprise of (1) the licensing of technologies from Irish Academic Institutions to Industrial Partners, (2) the continued growth of the consultancy / analysis business to Pharmaceutical, Medical Devices and Biotech companies in Ireland, and finally (3) the development, manufacture and supply of pilot scale materials to select clients in high growth markets.