Announcement July 2014

Medfiles strengthens its business with services in food and nutrition

Oy Medfiles Ltd, a full-service Finnish contract research organization (CRO), complements its current clinical research and regulatory affairs services for pharmaceutical and medical device companies with research and registration services for food and nutrition products.

Medfiles has employed two new experts in food and nutrition: Mari Lyyra, Regulatory Affairs Expert, starts on 15 July 2014, and Essi Sarkkinen, Senior Regulatory Affairs Expert, on 11 August 2014. They both come from Oy Foodfiles Ltd which will end its operation this month.

New services in food and nutrition and so-called borderline products strengthen Medfiles' position significantly in the interface of medicinal products and food products. We can now offer food, pharma and medical device companies even more comprehensive services related to legislation and registration of food products (including food supplements, food ingredients, food products for special nutritional purposes and food additives) as well as other kind of consultation. All our new services are listed at the end of this announcement.

We also provide services related to clinical trials (GCP, medicinal products, medical devices, functional foods, including health benefits of their ingredients) and laboratory analytics (e.g. vitamin and trace element analysis) in our GMP certified laboratories. Our other services include health economics, pharmacovigilance, regulatory affairs for medicinal products, and CE marking for medical devices.

We are looking forward to hearing from you!

Oy Medfiles Ltd

Tuija Keinonen
CEO

Please contact us for additional information:

Oy Medfiles Ltd
Tuija Keinonen
CEO, PhD (Pharm)
+358 20 7446 802, +358 50 555 1541
tuija.keinonen@medfiles.fi

Oy Medfiles Ltd
Essi Sarkkinen
Senior Regulatory Affairs Expert, PhD
+358 44 700 1201
essi.sarkkinen@medfiles.fi

Our services in food and nutrition:

- Food supplement notifications
- Health claim dossiers
- Evaluation of nutrition and health claims
- Novel food applications and notification dossiers
- Notifications for foodstuffs for particular nutritional uses (PARNUT)
- Package labelling checks and translations
- Issues related to food improvement agents, such as food additives, enzymes, aromas and flavourings
- Evaluation of product documentation (specifications, study reports, analysis documents, gap analysis, etc.)
- Information retrieval (incl. food, nutrition, analytics)
- Literature reviews and summaries
- R&D support
- Clinical research and regulatory plans and strategies
- Legality check for food compositions
- Liaising with the authorities, including European Commission, EFSA, national competent authorities (ministries and agencies)
- Consultation in above-mentioned subjects

Oy Medfiles Ltd (established in 1987) is the biggest contract research organization (CRO) in Finland. We offer comprehensive services in pharmaceutical development and analytics, clinical studies on medicinal products and devices, regulatory affairs, health economics, and pharmacovigilance. Our clients include pharmaceutical and other life science companies, and now also food and nutrition companies thanks to our new expert services.

Our high-quality services, wide range of domestic and foreign clients and partner networks create a firm basis to extend our current service portfolio and to develop novel services and new business models – for the needs of our clients. Our driving values in all business are Flexibility, Fairness and Freshness.

Additional information:

www.medfiles.eu