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One-Stop Shop For Regulatory Service Providers: New Search Engine Launched

by Amanda Maxwell

As a manufacturer, how do you find out the specific notified bodies, authorized representatives and suppliers specific to your area? A new search engine makes this information accessible in one place.

Medtech companies in Europe now have access to a unique package, some of it free, to find the regulatory service providers they need.

Newly launched *Quality Engine* (QE) is a professional search engine for the various service providers in the healthcare, medical, IVD and combination devices sectors. For the moment, it is focused on a number of service providers which are relevant for the medtech sector. At its launch, the search engine is more focused on Europe. But it is open for members globally and the intention is to grow it more internationally.

It allows medtech manufacturers to make informed decisions about who they choose to support them and should help industry save time and ultimately make faster progress with launching their products. This is especially important now as the Medical Device Regulation and IVD Regulation application dates loom on 26 May 2020 and 26 May 2022, respectively.

Bassil Akra, CEO and co-owner of QUNIQUE consultancy, which launched the search engine, said one of its aims was to increase transparency in the sector in an objective way. (The service is intended to have a global coverage eventually.)

"It brings together in one place all the service providers in the industry. Service providers can display services and qualifications" to "attract clients," the consultancy says.

The service providers listed on QE include: authorized representatives; consultancy services; distributors; importers; notified bodies; person responsible for regulatory compliance; recruitment services; suppliers of components/materials; translation services; and sterilization



services.

Manufacturers can search for these for free, as can anyone else.

Why This Is Urgently Needed

There is currently no single place where it is possible to do a comprehensive search on what services are available. The sector wastes much time trawling through and following up possibilities that more general search engines may throw up.

The medtech industry is so fragmented between different technology types that it needs to be able to search very specifically.

This has this become particularly apparent during the COVID-19 crisis, when it was slow and difficult for new manufacturers to find and team up with the people they needed, Akra told *Medtech Insight*.

Expanding The Platform

The plan is to grow the service to include lawyers, for example, and relevant societies.

The service is also being translated into different languages, including Chinese. Most of the suppliers to EU IVD and medical device manufacturers are based in China, Akra said.

Notified Body Search Example

Even finding a notified body means hours of searching the European Commission's Nando website. But under the new venture, manufacturers and other users will be able to search for providers for free by inputting specific information on which they are searching.

A quick glance at the section on notified bodies shows how it is possible to first search for the regulation under whose scope a product falls, then submit the notified body codes (denoting each testing service offered), and interrogate whether, for example, the notified body can also audit to the international quality system standard, ISO 13485, or is part of the global Medical Device Single Audit Plan (MDSAP). This information could also be narrowed down by country, for example.

Importance For Suppliers

Angelina Hakim, founder and CEO of QUNIQUE said that the new search engine should also make suppliers more visible, something that is particularly important in the current said COVID-19 environment. Additionally, suppliers will be able to search for manufacturers who may be of interest to them.

